NATIONAL PUBLIC HEALTH LABORATORY
MINISTRY OF HEALTH MALAYSIA

BRAVING THE COVID-19 PANDEMIC:

The NPHL Journey

NATIONAL PUBLIC HEALTH LABORATORY
MINISTRY OF HEALTH MALAYSIA

BRAVING THE COVID-19 PANDEMIC:

The NPHL Journey

National Library of Malaysia Cataloguing-in-Publication Data

ISBN 978-967-13278-3-8

Braving the COVID-19 Pandemic: The NPHL Journey

The greatest care has been taken in compiling this book. The information presented has been prepared using sources believed by the writers to be reliable and accurate. However, National Public Health Laboratory (NPHL) and the writers make no warranty or assume any legal liability or responsibility for the accuracy or completeness of any information presented. Moreover, the NPHL and the writers accept no responsibility for the decisions made by the readers.

Published by:
National Public Health Laboratory
Lot 1853, Kampung Melayu
47000 Sungai Buloh, Selangor.
Tel Number: +603-61261200
Fax Number: +603-61571036 / 03-61402249
Website: https://mkak.moh.gov.my/

DISCLAIMER
The details, views, interpretations, implications, conclusions, and recommendations expressed in this book are those of the contributors alone and do not necessarily represent the views or policies of the Ministry of Health Malaysia.

TABLE OF CONTENTS

TABLE OF CONTENTS

SPECIAL DEDICATION

This book is dedicated to

all staff of the National Public Health Laboratory (*Makmal Kesihatan Awam Kebangsaan*), Ministry of Health Malaysia for the endless dedication and hard work managing the COVID-19 Pandemic. May the moments be engraved in our memories and motivate us to keep giving our best ...!!!

Keep Moving!!!

Keep Fighting!!

#LabWarrior!!!

FOREWORD BY NPHL DIRECTOR

Since its establishment in 1999, the National Public Health Laboratory (NPHL) has continuously been strengthened and expanded to fulfill its responsibility as the country reference laboratory.

The capacity and capability of NPHL have been enhanced for the preparation to handle outbreaks of any emerging and re-emerging diseases and novel diseases. Thus, the discovery of Malaysia's COVID-19 first case by NPHL on the night of 24th January 2020 signifies that NPHL has the capability to detect any new pathogens. As the number of samples escalating, NPHL continues to enhance its role in responding to the outbreak. NPHL has led in several approaches and aspects to increase the nationwide laboratory capacity and capability in testing the SARS-CoV-2 virus without compromising the quality and standards that need to be maintained. Realizing that a reliable and timely laboratory result is one of the important key elements in this pandemic, NPHL has upgraded our current Laboratory Information System -SIMKA to fulfill this requirement.

As time progressed, the testing modalities for the SARS-CoV-2 virus also expanded and evolved. NPHL has further innovated our PCR testing method by using the samples pooling method; advancing into the Whole Genome Sequencing (WGS) test and developing and validating the testing method by using the wastewater samples as the supplementary surveillance of COVID-19. This surveillance was among several other COVID-19 surveillance that NPHL continuously conducted and monitored. NPHL is also one of the key institutions that led the training on the management of high-risk samples.

From the first wave of COVID-19 in early 2020 to the transition to the endemic phase in 2022, NPHL has been responding to the outbreak accordingly. Along the way, NPHL has gone all out to make great strides to overcome obstacles and challenges, and these show the commitment of every individual in NPHL. Hence, this book summarizes the journey of NPHL in braving this COVID-19 pandemic and as a symbol of an appreciation for the endless contribution of all NPHL personnel. ***They are indeed the true heroes and warriors of the country in managing the COVID-19 Pandemic.***

Dr Fatanah Ismail
Director NPHL

SPECIAL APPRECIATION
FORMER DIRECTOR OF NPHL

NPHL would like to express our gratitude and appreciation to the former Director of NPHL, Dr. Hani binti Mat Husain, and Dr Noorliza binti Mohamad Noordin who have led NPHL during this COVID-19 pandemic.

Dr. Hani Mat Hussin who was NPHL director from 24th January 2018 till 18th July 2021, has successfully spearheaded NPHL during our crucial time. As a national public health reference laboratory, the capacities and capabilities of NPHL have been developed in preparation for any emerging and re-emerging outbreak. NPHL's capability was proven by the discovery of Malaysia's first case of COVID-19 in January 2020. She was the main driving force in ensuring that SIMKA was expanded to meet the country's needs that required reliable and timely COVID-19 testing results. As Director of NPHL, she has been leading the national laboratory network to ensure that Malaysia's testing capacity was enhanced to meet the demand of the country. Under her leadership, the NPHL evaluation service has been developed, and currently, NPHL has become one of the country's main COVID-19 kit evaluation centers. The contribution she made during her tenure as Director of NPHL is undeniable and her leadership in leading NPHL is greatly appreciated.

SPECIAL APPRECIATION
FORMER DIRECTOR OF NPHL

Dr. Noorliza Mohamad Noordin has taken over as director of NPHL from 19 July until 16 March 2022. She continues the legacy of the previous director by ensuring that NPHL continues to strive as the country's main and reference laboratory during this pandemic. Under her leadership, NPHL's testing capabilities were enhanced with Whole Genomic Sequence (WGS) testing. She was also directly involved in the development of the National COVID-19 Testing Strategy (NTS) as well as leading NPHL in the parliamentary sessions screening activities. Although her tenure at the helm of NPHL was short, her contribution was greatly appreciated and we deeply thank her for it.

EDITORIAL BOARD

Advisor:

Dr Fatanah binti Ismail

Editorial Board Member

Dr Norfazillah binti Ab Manan

Dr Esah binti Md Ali

Pn Wan Noraini binti Wan Yusoff

Pn Siti Noraini binti Md Isa

Dr Santhi A/P Subramaniam

Graphic Team:

Cik Hazly binti Mohamed

Pn Hardiana binti Halipah

Pn Norhidayah binti Sahid

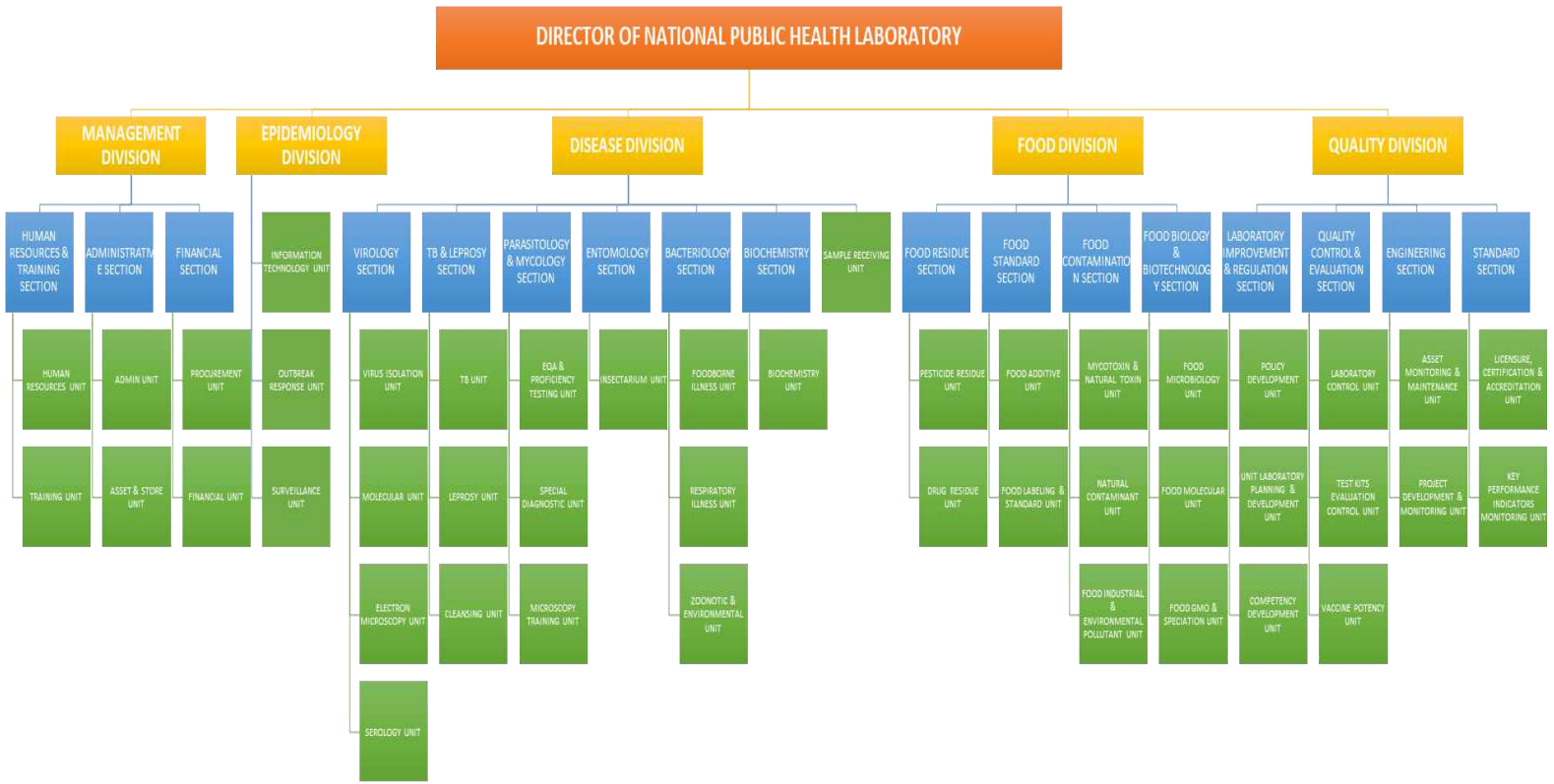
Pn Yuganes A/P M. Chandran

Pn Nurhuda Sakinah binti Abd Karim

LIST OF CONTRIBUTORS

Dr Maria Suleiman
Dr Norfazillah binti Ab Manan
Dr Esah Md Ali
Dr Wan Amani binti Wan Abdul Azim
Dr Nor Zahrin binti Hasran
Dr Donal Huda binti Nasril
Dr Mimi Rodzaimah binti Abd Karim
Dr Santhi A/P Subramaniam
Dr Joshita Hephzibah A/P Jothimanickam
Pn Yu Kie A/P Chem
Pn Wan Noraini binti Wan Yussof
En Selvanesan A/L Sengol
Cik Zirwatul Adilah binti Aziz
En Amrish Shah bin Osman
Pn Salfaryna binti Alzahari
Pn Noriah binti Mohd Yusof
En Khairul Azan bin Hashim
Pn Noor Aishah binti Mohd Dawi
Pn Nurul Aina Murni binti Che Azid
Pn R. Pusparani A/P Ramasamy
Pn Siti Noraini binti Md Isa
Pn Suhaili binti Suhaimi
Pn Kiroshika Pillai A/P Veel Pilay
Pn Ushananthiny A/P Ravi
Pn Hannah Phoon Yik Phing
Pn Wan Nur Afiza binti Wan Mohd Arifin
En Kamal Hisham bin Kamarul Zaman
Pn Rehan Shuhada binti Abu Bakar
En Mohd Hamidi bin Mohd Rani
Pn Siti Fairuz binti Mar Ramli
Cik Nur Sofia binti Muchlas
Cik Nurul Huda Hazwane binti Rohani
Pn Nur Shafinas binti Uyeup

ORGANIZATIONAL CHART NATIONAL PUBLIC HEALTH LABORATORY



LIST OF ABBREVIATION

ABBREVIATION		EXPLANATION
ADU	:	Air Disaster Unit
AKEPT	:	Higher Education Leadership Academy
AMS	:	ASEAN Member States
AOCC	:	Airport Operations Control Centre
API	:	Application Programming Interface
APSED	:	Emergency Diseases and Public Health Emergencies
ASEAN	:	Association of Southeast Asian Nations
ATM	:	*Angkatan Tentera Malaysia*
BCP	:	Business Continuity Plan
BKP	:	Disease Control Division
BSL 3	:	Biosafety Laboratory Level 3
CCP	:	Crisis Communication Plan
CDC	:	Centres for Disease Control and Prevention
CME	:	Continuous Medical Education
COHORT	:	Cohesion, Operational Readiness and Training
COVID-19	:	Coronavirus Disease 2019
CPE	:	Carbapenemase Producing Enterobacterales
CPRC	:	Crisis Preparedness and Response Centre
CPRC	:	National Crisis Preparedness and Response Centre
CRC	:	Clinical Research Centre
CSR	:	Corporate Social Responsibility
CT-VALUE	:	Cycle Threshold Value
DHO	:	District Health Office
DRP	:	Emergency Response Plan
DTS	:	Deep Throat Saliva
EHA	:	Ecohealth Alliance
EIA	:	Environmental Impact Assessment
ELISA	:	Enzyme-Linked Immunosorbent Assay
EQA	:	External Quality Assessment
ERP	:	Emergency Response Plan

ABBREVIATION		EXPLANATION
ERT, DRT & CCT	:	Emergency Response Team (ERT), Disaster Recover Team (DRT) & The Crisis Communication Team (CCT)
ESBL	:	Detection of Extended Spectrum Beta Lactamase
GHSA	:	Global Health Security Agenda
GISAID	:	Global Initiative on Sharing Avian Influenza Data
GISRS	:	Global Influenza Surveillance and Response System
GIZ	:	German Corporation for International Cooperation
GMO	:	Genetically Modified Organism
GP	:	General Practitioners
GPP	:	Global Partnership Program
HATTM	:	*Hospital Angkatan Tentera Tuanku Mizan*
HCW	:	Healthcare Workers
HFMD	:	Hand Foot Mouth Disease
HPLC	:	High-Performance Liquid Chromatography
IBBC	:	Institution of Biosafety and Biosecurity
ICTV	:	The International Committee on Taxonomy of Viruses
ICU	:	Intensive Care Unit
IHR	:	International Health Regulation
ILC	:	Inter Laboratory Comparison
ILI	:	Influenza-Like Illness
IMR	:	Institute for Medical Research
IMU	:	International Medical University
ISNS	:	Information Security Management Systems
IT	:	Information Technology
JE	:	Japanese Encephalitis
JEE	:	Joint External Evaluation
JKAM	:	Food Analysis Committee
JKKTAM	:	Food Analysis Technical Working Group
JPKM COVID-19	:	The Special Laboratory Team Committee For COVID-19
KATS	:	Ministry of Land, Water, Natural Resources
KKT	:	Technical Working Group Meeting

ABBREVIATION		EXPLANATION
KLIA	:	Kuala Lumpur International Airport
KPAS	:	*Unit Keselamatan dan Kesihatan Pekerjaan*
LAMP	:	Loop-Mediated Isothermal Amplification
LIS	:	Laboratory Information System
LTAC	:	National Laboratory Technical Advisory Committee
LTAT	:	Laboratory Turn Around Time
MAEPS	:	Malaysia Agro Exposition Park Serdang
MAHB	:	Malaysia Airports Holdings Berhad
MAMPU	:	Malaysian Administrative Modernisation and Management Planning Unit
MARDI	:	Malaysian Agricultural Research and Development Institute
MCO	:	Movement Control Order
MDA	:	Malaysian Medical Device Authority
MEP	:	Measles Elimination Program
MESTECC	:	Ministry of Energy, Science, Technology, Environment & Climate Change
MGI	:	Malaysian Genome Institute
MINDEF	:	Ministry of Defence
MKAK	:	*Makmal Kesihatan Awam Kebangsaan*
MKKM	:	*Makmal Keselamatan dan Kualiti Makanan*
MLST	:	Multi Locus Sequence Typing
MOA	:	Ministry of Agriculture & Industry
MOE	:	Ministry of Education
MOH	:	Ministry of Health
MOHE	:	Ministry of Higher Education
MOSTI	:	Ministry of Science, Technology, And Innovation
MTMKA OR TWG	:	Technical Working Group Meeting
MYSED	:	Malaysian Strategy for Emerging Diseases
MYSEJAHTERA QR	:	My Sejahtera Quick Response Code
MYSTEP	:	Short-Term Employments Programme
NADMA	:	National Disaster Management Agency
NAHRIM	:	National Water Research Institute of Malaysia
NGO	:	Non-Governmental Organizations

ABBREVIATION		EXPLANATION
NGS	:	Second-Generation Sequencing
NP	:	Nasopharyngeal
NPHL	:	National Public Health Laboratory
NTS	:	National COVID-19 Testing Strategy
OMS	:	Outbreak Management System
OP	:	Oropharyngeal
OSH	:	Occupational Safety and Health
PCR	:	Polymerase Chain Reaction
PEG	:	Polyethylene Glycol
PERKESO	:	*Pertubuhan Keselamatan Sosial*
PHEIC	:	Public Health Emergency of International Concern
PHF	:	Public Health Facilities
PHL	:	Public Health Laboratory
PHLIS	:	Public Health Laboratory Information System
PHLJB	:	Regional PHL Johor Bahru
PHRL	:	Public Health Regional Laboratory
PHSMS	:	Public Health Social Measures
PKD	:	*Pejabat Kesihatan Daerah*
POE	:	Point of Entry
PPE	:	Personal Protective Equipment
QPCR	:	Real Time PCR
RMCO	:	Restriction Movement Order
RMK	:	Sixth Malaysia Plan
RNA	:	Ribonucleic Acid
RRT	:	Rapid Response Team
RTK TEST	:	Real Time Kinematic
RTK-AB	:	Rapid Antibody Test
RTK-AG	:	Rapid Test Kit Antigen
RT-PCR	:	Reverse Transcriptase Polymerase Chain Reactions
SARI	:	Severe Acute Respiratory Illness
SARS	:	Severe Acute Respiratory Syndrome
SHD	:	State Health Department
SIMKA	:	*Sistem Informasi Makmal Kesihatan Awam*
SME	:	Subject Matter Expert
SOP	:	Standard Operating Procedure

ABBREVIATION		EXPLANATION
TOR	:	Term of Reference
TOT	:	Training of Trainer
UM	:	University of Malaya
UMMC	:	University Malaya Medical Centre
UPS	:	*Unit Penerimaan Sampel*
VIL	:	Virus Isolation Laboratory
VOC	:	Variant of Concern
VOI	:	Variant of Interest
VRI	:	Veterinary Research Institute
VTM	:	Viral Transport Medium
WGS	:	Whole Genome Sequencing
WHO	:	World Health Organization
WPRO	:	Western Pacific Region

CHAPTER 1
INTRODUCTION

WRITERS

CHAPTER	NAME
1.1	Dr Esah binti Md Ali
1.2	Dr Norfazillah binti Ab Manan

1.1 National Public Health Laboratory

Strong laboratory capability is one of the prerequisites for a resilient public health system preparedness and response. In many instances, laboratory testing is the only way to confirm the diagnosis allowing rapid and early detection of the causative agent in patient management, outbreaks investigation, disease surveillance, control, and preventative, health emergencies and public health crises. This crucial role played by the laboratory has had a huge impact and contributed significantly to the overall management of the recent COVID-19 Pandemic in Malaysia.

Looking back at the milestones, before the establishment of the Public Health Laboratory (PHL) in Malaysia, the Institute for Medical Research (IMR), Kuala Lumpur delivered laboratory analysis for public health. In view of the urgent need to re-align IMR for a high-end research program which is its core function, the development of PHL was proposed in the 1960s by Professor Dato' Dr. Ungku Omar Ahmad, the 16th director of the IMR (Figure 1.1.1.) The main idea was to develop a laboratory that was specifically designed to support the Public Health needs of the country.

Figure 1.1.1: Professor Dato' (Dr.) Ungku Omar Bin Ahmad was born in Johor Bahru on 18th January 1931. He was the 16th Director of IMR from 1965- 1969 and was acknowledged for his excellent services by the institutes in strengthening research programs, standardization of laboratory work, establishing a post-graduate program in IMR and other agencies.

After the departure of Professor Dato' Dr. Ungku Omar Ahmad in 1969, the effort was continued by the former Director General of Health, Ministry of Health Malaysia (MOH); Tan Sri Abu Bakar Suleiman in 1992. The proposal was approved under the Sixth Malaysia Plan (RMK 6; 1990-1995). Subsequently, a PHL was built in Sungai Buloh, Selangor, which was later mandated as National Public Health Laboratory (NPHL). The development of NPHL was financed by the World Bank with an allocation of RM 27.7 million. It was completed in 1999 and officiated in 2003 by Dato' Dr. Chua Jui Meng, former health minister of Malaysia.

Concurrently, four (4) regional PHLs were proposed to improve the accessibility of PHL services. These include Regional PHL Johor Bahru which was designated for the Southern Region, Regional PHL Ipoh for the Northern Region, Regional PHL Kota Bharu, Kelantan for the Eastern Region, and Regional PHL Kota Kinabalu for the Borneo region of Malaysia. The NPHL and all Regional PHLs formed Public Health Laboratory Network providing public health laboratory support for the whole country (Figure 1.1.2).

In addition, a new Public Health Laboratory project was approved in 2019 by the Economic Planning Unit, Department of Prime Minister to be developed in Kuching, Sarawak under Twelve Malaysia Plan. (RMK12). Moving towards a more coordinated approach to disease control and preventative activities, NPHL has been placed directly under the purview of the Disease Control Division (BKP), Public Health Program, MOH Malaysia. Although the management and operational aspects of Regional PHLs have been placed under the respective State Health Departments, the technical development of Regional PHLs is maintained under the responsibility of NPHL. At the national level, NPHL is one of the country reference laboratories providing high-end laboratory testing. (Figure 1.1.3), (Figure 1.1.4)

In the early phase of the operation, the NPHL was focused on Food Safety Monitoring, Enforcement of the Food Act 1983 (Act 281), Biochemistry (congenital hypothyroidism screening), and laboratory services for Tropical Diseases. Being mandated as a reference laboratory for the country, the capability and capacity of NPHL are continuously being improved. (Figure 1.1.5)

Figure 1.1.2: Public Health Laboratory Network and Coverage Area.

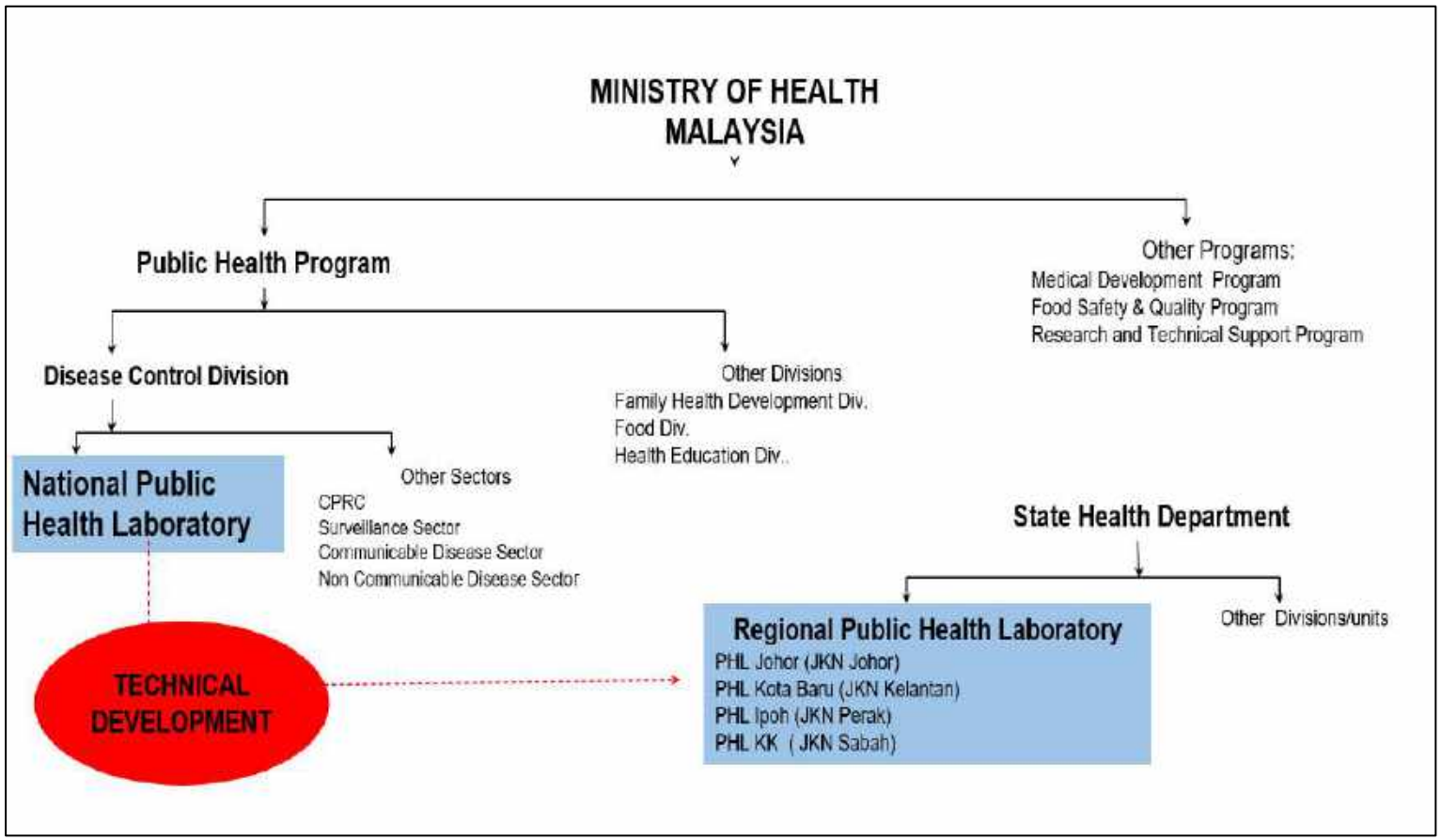


Figure 1.1.3: The organizational linkages between the Public Health Laboratory and the Stakeholders

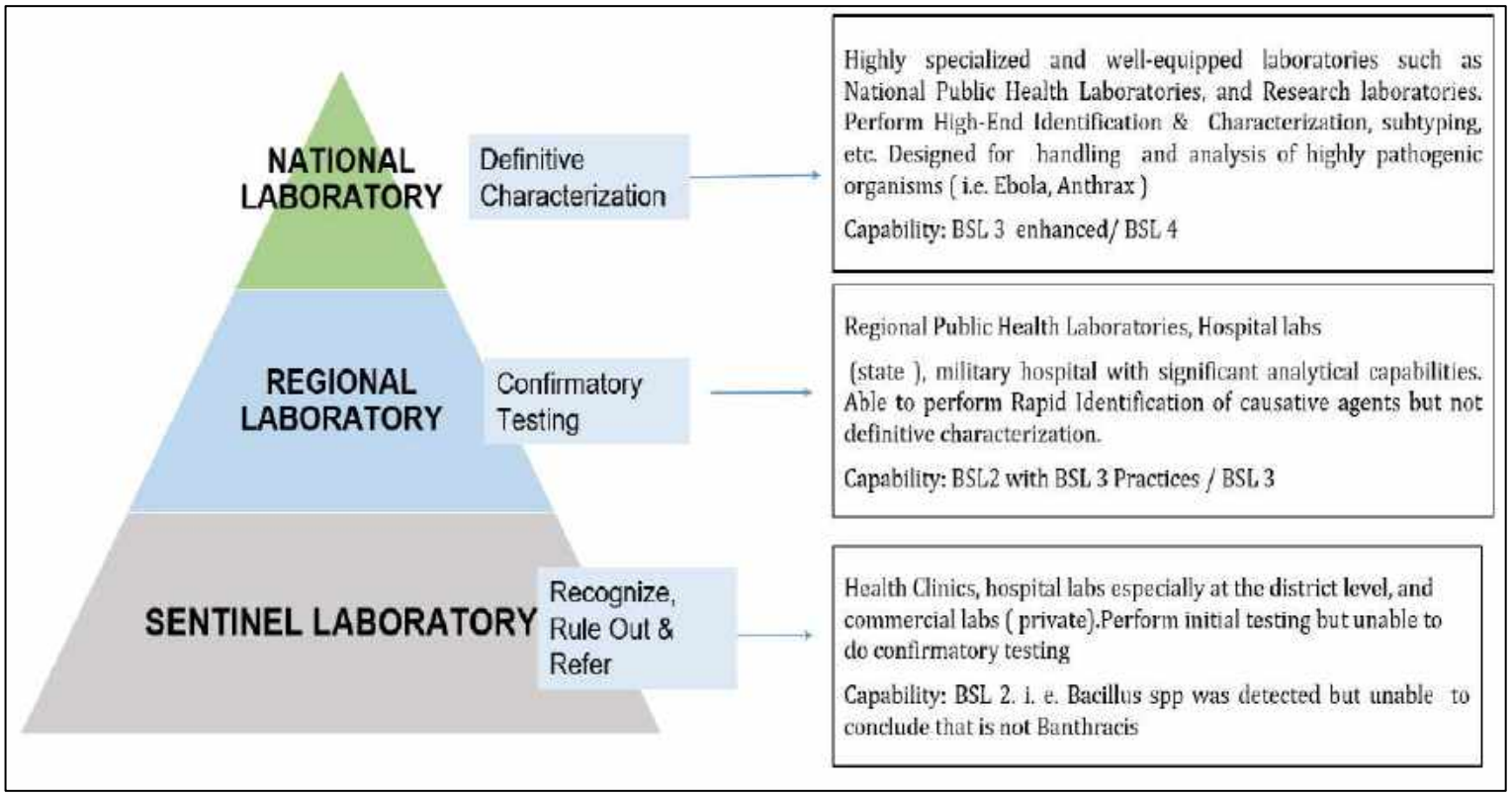


Figure 1.1.4: Public Health Laboratories Response Network Involving Nationwide Laboratories Services Across Ministerial.

- Reference Lab for TB & Leprosy (2003)
- Reference lab for Influenza (2004)
- Reference Lab for Mycotoxin Analysis (2005)
- Reference Lab for Chikungunya (2008)
- Official Laboratory for Monitoring of Fishery Products for Export to European Countries & United States of America (2008)
- Reference Lab for Dengue (2009)
- Official Laboratory for Monitoring of Fishery Products for Export to Russia (2010)

Figure 1.1.5: Role of NPHL as a National Reference Laboratory.

The development of specialized facilities such as high containment Biosafety Level 3 (BSL3) laboratory, Electron Microscope suites, and vaccine potency laboratory have enabled NPHL to further expand the scope of services offered. In addition, an ongoing project of the Public Health Reference Laboratory, National Centre for Disease Control at Bandar Enstek, Negeri Sembilan will further strengthen the country's public health preparedness and response. This facility is scheduled to be completed in 2025. (Figure 1.1.6).

In addition, the in-house production of Viral Transport Media (VTM) for SARS-CoV-2 by NPHL during the recent pandemic has helped other laboratories and testing centers involved in SARS-CoV-2 testing overcome the shortage of VTM's supply primarily during the first two waves of the pandemic. New services that were developed by NPHL such as Diagnostic Test Kits/ Assays Evaluation have improved the accessibility and availability of diagnostic test kits needed throughout the pandemic. Concurrently, collaboration in scientific research, technology transfer on molecular-based testing, laboratory services for communicable (emerging & re-emerging) diseases, non-communicable diseases, entomology services, environmental health, vaccine potency, laboratory control & standard as well as private wing services are among the important areas to be expanded.

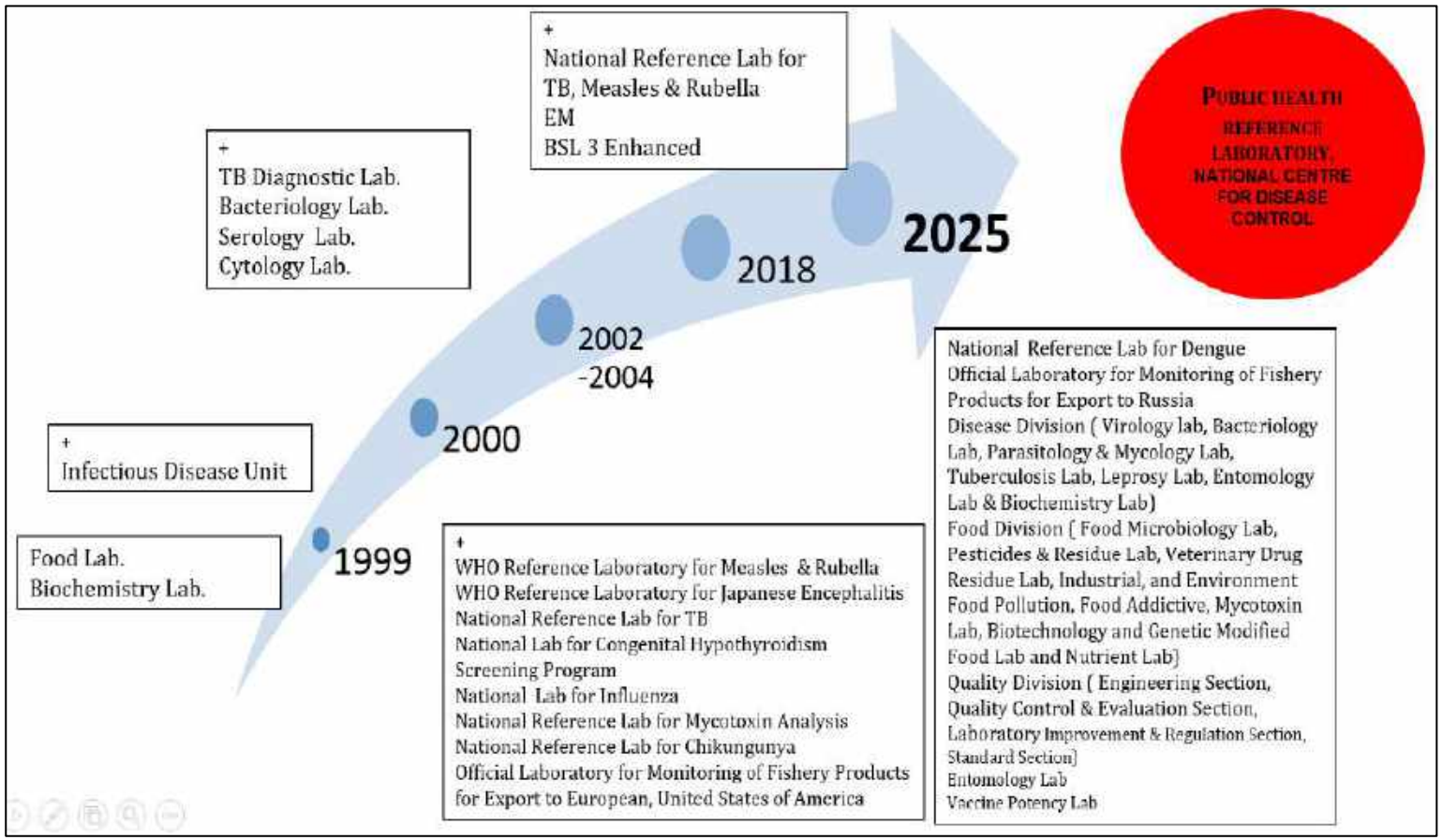


Figure 1.1.6: NPHL Expansion of Services.

In relation to human resource strength, NPHL has a diverse workforce. Over the years, the number of trained Public Health Specialists, laboratory personnel in Microbiology, Biochemistry, Food Technology as well as Entomology has increased. Its capabilities were further expanded with the appointment of Pathologists, Medical Officers, Engineer, and Statisticians as part of the team. In line with the all-hazard approach, NPHL is now technically capable to conduct more specialized testing covering a wide variety of clinical, non-clinical, food, and environmental samples including laboratory investigation of potential agents of terrorism.

As part of laboratory quality improvement, NPHL has successfully accredited with ISO 15189:2014 Medical laboratories Requirements for quality and competence, ISO/IEC 17025:2017 Testing and calibration laboratories, ISO 17043:2010 Proficiency Testing Provider and certified with ISO 9001:2015 Laboratory Quality Management System. In addition, NPHL has also been recognized as World Health Organisation (WHO) National Measles and Rubella Laboratory and WHO National Japanese Encephalitis Laboratory in 2004 and 2012 respectively. (Figure 1.1.7).

Moving towards a more sustainable approach, innovative measures have been incorporated into public health laboratory services delivery. In-house development of a Laboratory Information System (LIS) or *Sistem Informasi Makmal Kesihatan Awam* (SIMKA) covering end to end process of laboratory works is an added value to NPHL and the country as a whole. SIMKA has been mandated as an official system for the COVID-19 Pandemic and has contributed significantly to the overall pandemic management.

Given the experiences and involvement in managing outbreaks as well as public health crises, NPHL has and will continuously grow, adapt, and develop to be more resilient, robust, and responsive to the country's public health needs. This book; Braving the Pandemic COVID-19: The NPHL Journey is published to celebrate and document our journey in managing one of the most significant pandemics of this century.

ISO 15189:2014 Medical laboratories — Requirements for quality and competence

ISO/IEC 17025:2017 Testing and calibration laboratories

ISO 17043:2010 Proficiency Testing Provider

World Health Organisation (WHO) certification

ISO 9001:2015 Laboratory Quality Management System certification

Figure 1.1.7: Accreditation and Certifications That Have Been Awarded to NPHL.

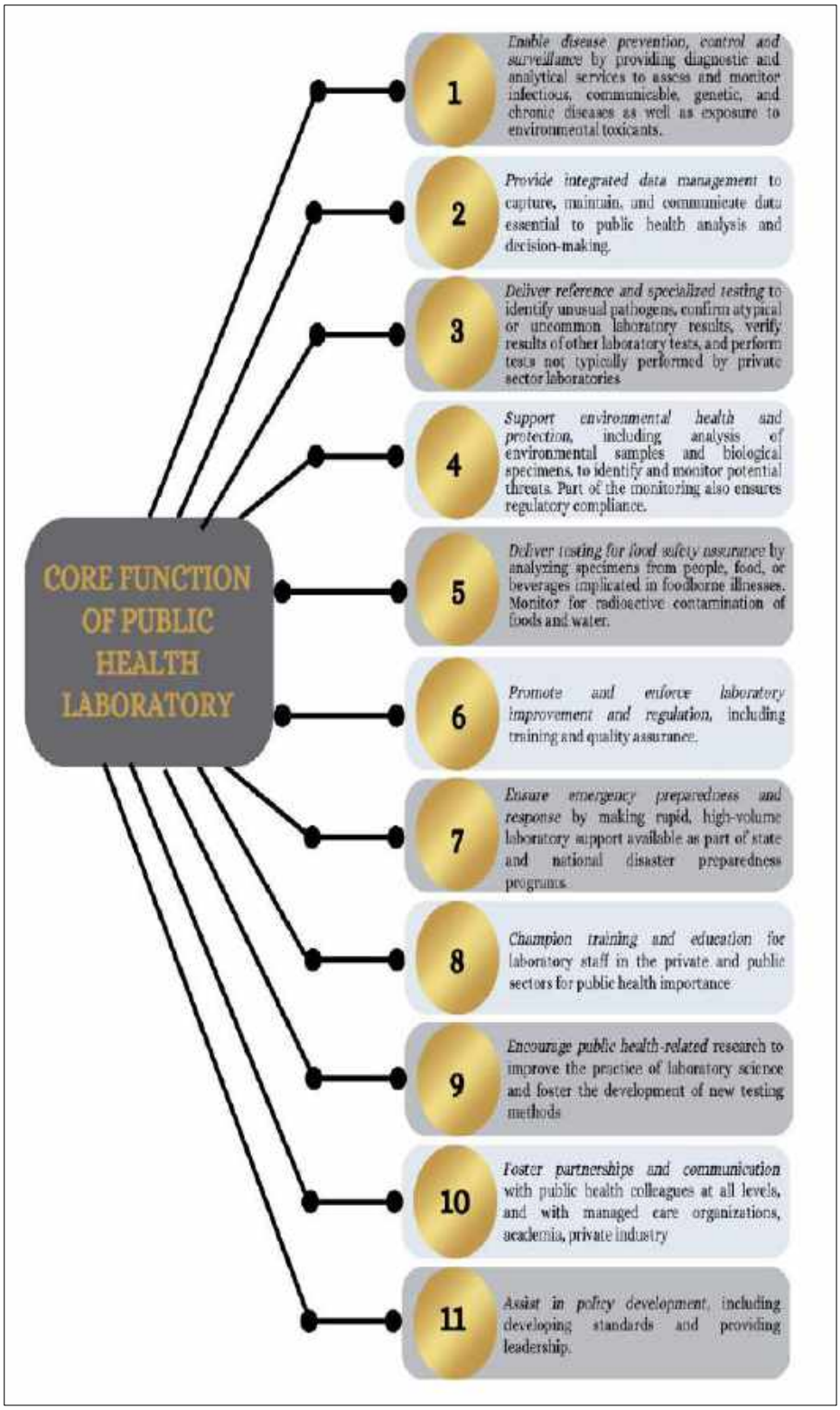


Figure 1.1.8: Core Functions of Public Health Laboratory.

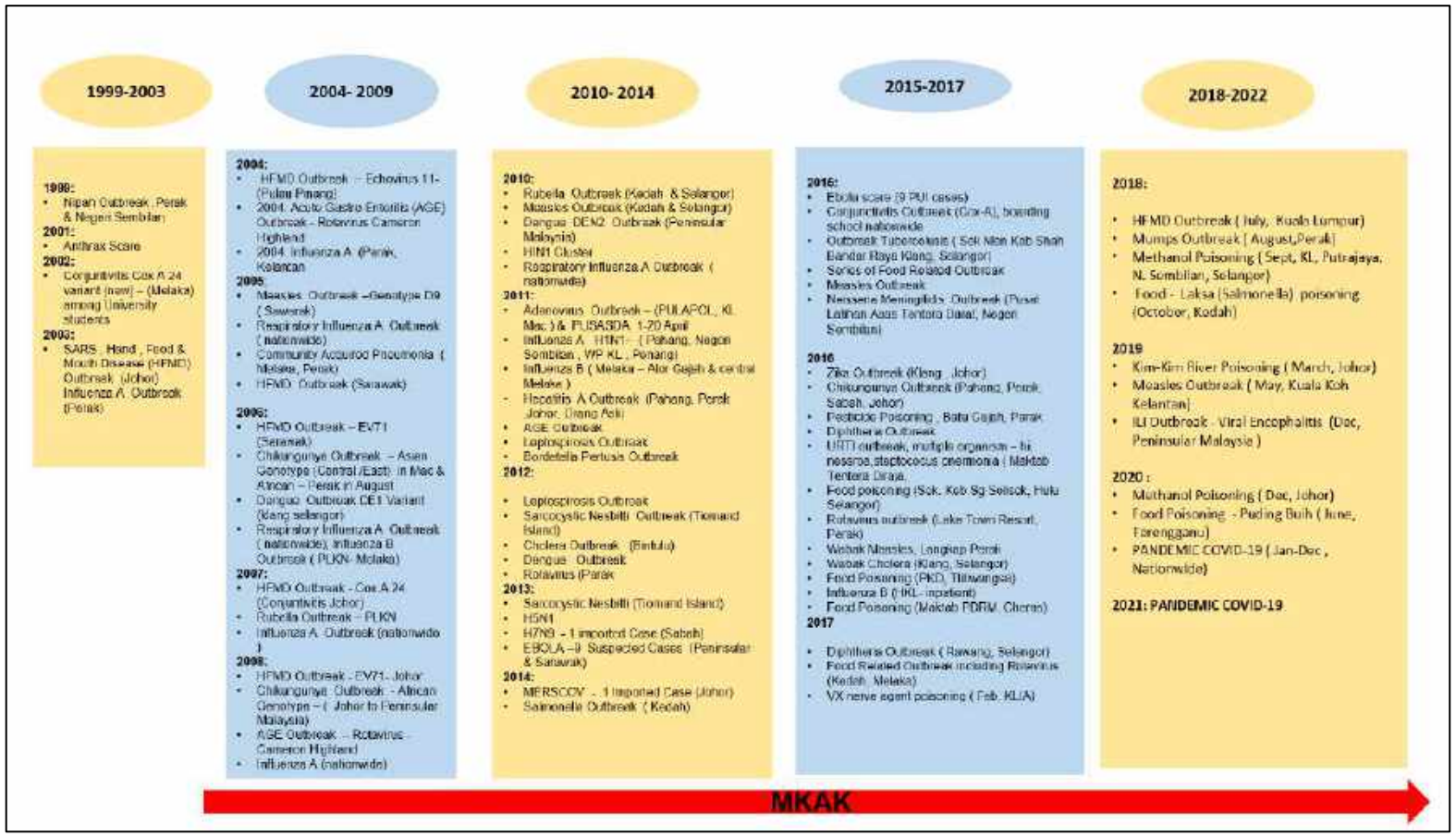


Figure 1.1.9: Timeline Disease Outbreak and NPHL Involvement.

List of References:

1. https://www.imr.gov.my/index.php/en/corporate-info/past-director
2. https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5114a1.h

COVID-19 PANDEMIC MEMORABILIA

Photo showing delivery of COVID-19 samples to NPHL during 1st wave of the pandemic.

1.2 SARS-CoV-2 Virus, COVID-19 Pandemic & NPHL Involvement

In December 2019, a cluster of an unknown acute respiratory tract infection was reported in Wuhan City, Hubei Province, China which is believed to be originated from the Hunan South China Seafood Market with the first onset starting on 8th December 2019(1). The number of cases has increased to 27 cases and on 31st December 2019, World Health Organization (WHO) was notified. On 9th January 2020, Chinese scientists isolated the unknown viral sample from an infected person and sequenced its genome using the next gene sequencing tool, and identified it as a novel coronavirus, temporally named 2019-nCoV, as the cause of these cases. They reported that the virus had 96.3% genetic similarity with a Yunnan bat coronavirus RaTG13 and 70% homology with severe acute respiratory syndrome coronavirus and by 12th January 2020, the sequence of the virus was shared with the rest of the world (2).

The first case outside China was detected on 13th January 2020 in Thailand from a Chinese traveller and human-to-human transmission of the virus was confirmed on 20th January 2020. The virus spread rapidly to other countries and later was classified as a public health emergency of international concern (PHEIC) on 30th January 2020 by WHO. On 11th February, the virus was later renamed Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) by the International Committee on Taxonomy of Viruses (ICTV), and WHO officially named the outbreak as Coronavirus Disease 2019 (COVID-19) (3). As the infection rapidly spread all over the world, on March 11th, it was declared a pandemic by WHO and become the fifth documented pandemic since the 1918 flu pandemic. Malaysia's first COVID-19 case was detected on January 24th 2020 midnight and was officially announced on 25th January 2020 as shown in the timeline of the pandemic COVID-19 in Figure 1.2.1 below.

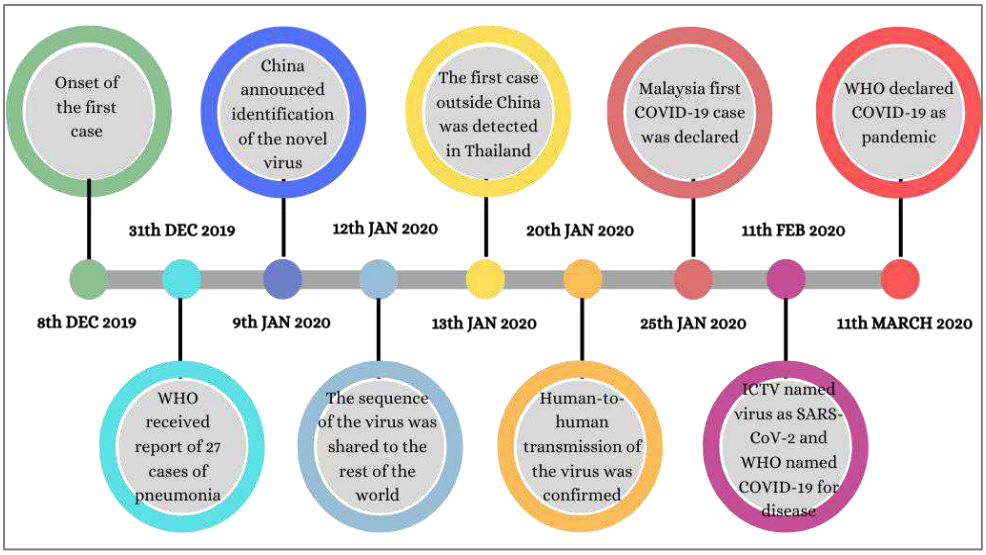


Figure 1.2.1: Malaysia's first COVID-19 case in the timeline of the key events of the COVID-19 pandemic.

As a national reference public health laboratory, NPHL has continuously been ready and prepared to handle outbreaks of any emerging and re-emerging diseases and novel diseases. NPHL core capacity and capability were strengthened using the framework of Malaysia Strategy for Emergency Diseases and Public Health Emergencies (MySED) II Workplan 2017-2021 which was adapted from Asia Pacific Strategy for Emergency Diseases and Public Health Emergencies (APSED) III 2017. During the Joint External Evaluation (JEE) in October 2019, NPHL as the national laboratory focal point demonstrated laboratory achievement in fulfilling the International Health Regulation (IHR) 2005 requirement.

Several activities and plans were already in place prior to the pandemic COVID-19. These include strengthening the laboratory-based surveillance system by improving the laboratory capacity and increasing the number of sentinel sites. Simulation exercises were conducted to pre-equip NPHL and other agencies in handling an outbreak. Laboratory protocol and contingency plan has been established such as Laboratory Test Protocol and Validation for novel/un-typable pathogen, Contingency Plan for stockpiling,

Laboratory Biosecurity & Biosafety Protocol, Business Contingency Plan, and Transfer Agreement Policy in Biological Material and Data Sharing. NPHL has established laboratory networking at the national and international level and is equipped with the Laboratory Information System. NPHL staff were trained in a specific area of expertise to make sure the laboratory has enough capability and capacity to fulfil its function.

Malaysia's first COVID-19 case was detected by NPHL and officially announced on 25th January 2020 and it traced back to three Chinese nationals who previously had close contact with an infected person in Singapore (4). Shortly after that, the first Malaysian was confirmed with COVID-19 on 4th February 2020, marking the first wave of infection in the country that lasted for about 3 weeks. On 12th March 2020, Malaysia reported its first sporadic case of COVID-19, where the infected neither travelled to an affected area nor had contact with an infected person (5). The COVID-19 cases has been escalating since then with several peak in the past two years as shown in Figure 1.2.2 below.

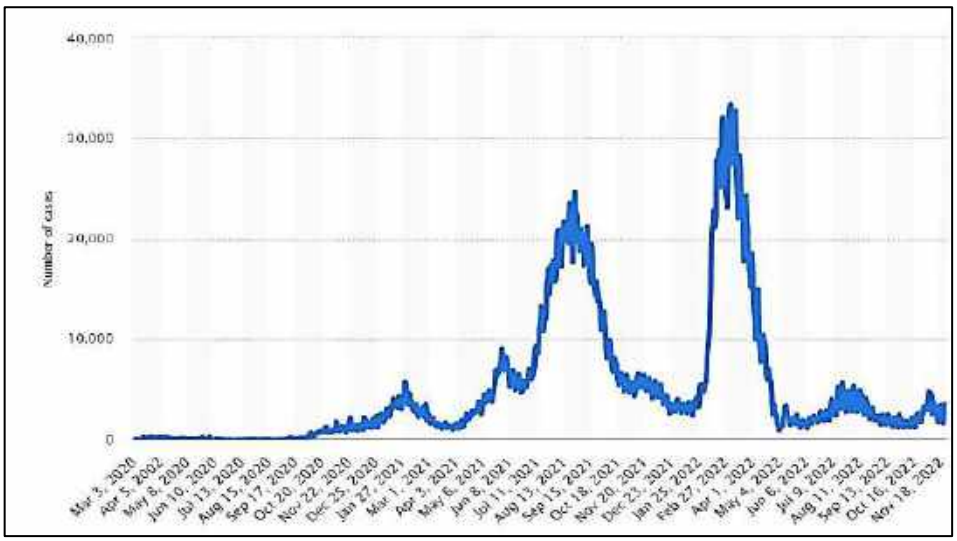


Figure 1.2.2: Number of COVID-19 cases from March 2020 to November 2022 (6).

As COVID-19 cases were spreading nationwide, and the number of samples was escalating. In response to the pandemic COVID-19, NPHL

has been involved in the management of COVID-19 samples and sharing the standardized testing protocol with other laboratories. NPHL plays a major role in scaling up the laboratories' services thru internal and external surge capacity response which includes interagency training, establishing a network with other laboratories, strengthening the public-private partnership, ensuring the quality of the testing laboratories as well as expansion of MOH laboratories. The laboratory surveillance system was enhanced by adding more sentinel sites and programs. NPHL is also involved in the procurement of laboratories resources for other laboratories and programs, acts as the laboratory technical advisory; production of biological material for testing purposes; innovation and adds specialized diagnostics; offering evaluation kit services; enhancement of SIMKA, and involved in several Rapid Response Team (RRT) activities.

As the nation moves towards living with the virus, NPHL had contributed to the development of the National COVID-19 Testing Strategy (NTS) which acts as a guideline for the relevant stakeholders in opening their sectors. NPHL also have expanded the surveillance program by introducing COVID-19 wastewater surveillance as supplementary surveillance of COVID-19.

Throughout the pandemic, NPHL faced many challenges. These include the expectation to keep up with rapid changes of technological advancement in laboratory testing, handling the resources as well as managing the nationwide laboratory's data. It is all not all blood and tears, but the pandemic COVID-19 has also given NPHL the opportunity to shine. NPHL in-house *Sistem Informasi Makmal Kesihatan Awam* (SIMKA), hosting the Whole Genome Sequencing (WGS) Training in collaboration with an Association of Southeast Asian Nations (ASEAN) and organizing the Sampling and Transportation Course for The High-Risk Specimen were among the success stories of NPHL for the past two years.

Two years had passed, but the pandemic still persist. The role of NPHL still continues but it has expanded accordingly. The NPHL's

involvement in the pandemic COVID-19 is summarized in Figure 1.2.3 below and this book further elaborates on the NPHL journey in braving the COVID-19 pandemic.

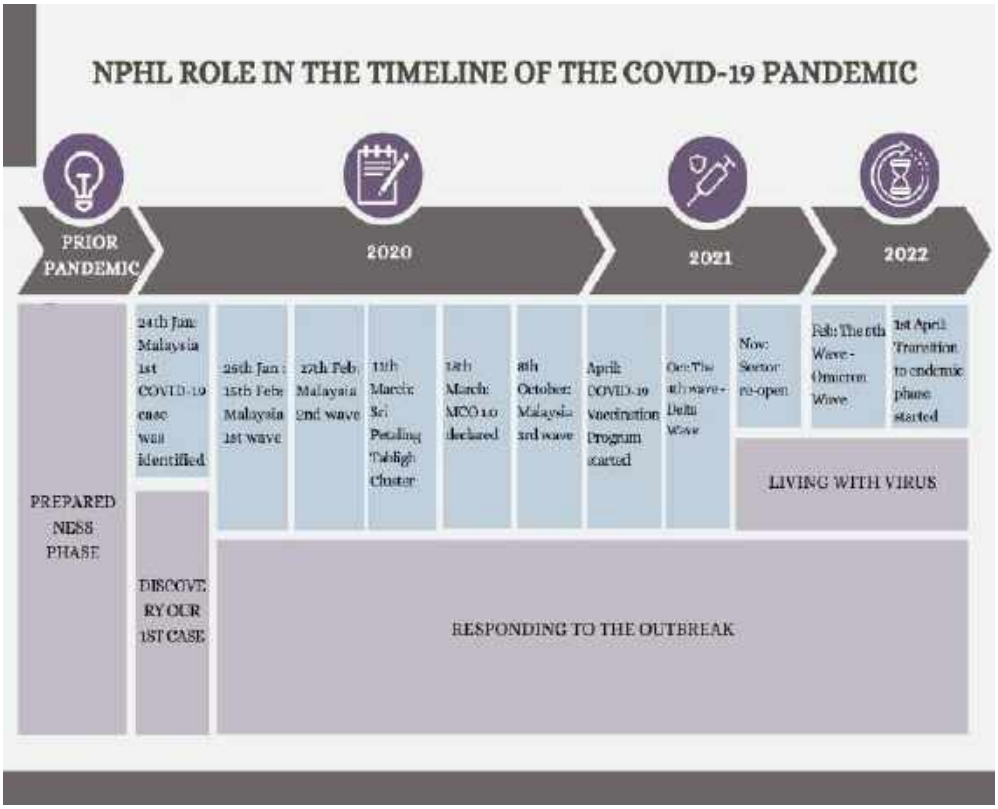


Figure 1.2.3: Involvement of NPHL in the pandemic COVID-19.

List of References:

1. Guo Y, Cao Q, Hong Z, et al. The origin, transmission, and clinical therapies on coronavirus disease 2019 (COVID-19) outbreak – An update on the status. Mil Med Res 2019;7(1): 11.
2. Singhal T. A review of coronavirus disease-2019 (COVID-19). Indian J Pediatr 2020;87(4): 281−6.ArticlePubMedPMCPDF
3. Hu, Ben, et al. "Characteristics of SARS-CoV-2 and COVID-19." Nature Reviews Microbiology 19.3 (2021): 141-154.
4. Hashim JH, Adman MA, Hashim Z, Mohd Radi MF, Kwan SC. COVID-19 Epidemic in Malaysia: Epidemic Progression, Challenges, and Response. Front Public Health. 2021 May 7;9:560592. doi: 10.3389/fpubh.2021.560592. PMID: 34026696; PMCID: PMC8138565.
5. Elengoe, Asita. "COVID-19 outbreak in Malaysia." *Osong Public Health and Research Perspectives* 11.3 (2020): 93-100.
6. Number of daily confirmed cases of the novel coronavirus infection COVID-19 in Malaysia as of November 24, 2022, Statista Research Department, https://www.statista.com/statistics/1110785/malaysia-covid-19-daily-cases/

CHAPTER 2
LABORATORY PREPAREDNESS PRIOR TO THE PANDEMIC

WRITERS

CHAPTER	NAME
2.1	Dr. Santhi A/P Subramaniam, Dr. Esah Md.Ali, Pn Wan Noraini binti Wan Yussof
2.2	Dr Maria Suleiman, Dr. Norfazillah binti Ab Manan, Dr Esah binti Md Ali, Pn Wan Noraini binti Wan Yussof
2.3	Pn Yu Kie A/P Chem, En Selvanesan A/L Sengol, Pn Wan Noraini binti Wan Yussof
2.4	Dr Esah binti Md Ali, Pn Noriah binti Mohd Yusof, Cik Nurul Huda Hazwane binti Rohani, Pn Nur Shafinas binti Uyeup
2.5	Dr. Nor Zahrin binti Hasran, Dr Esah binti Md Ali
2.6	Pn Yu Kie A/P Chem, En Selvanesan A/L Sengol, Pn Wan Noraini binti Wan Yussof
2.7	Dr Esah binti Md Ali, Pn Salfaryna binti Alzahari
2.8	Dr. Nor Zahrin binti Hasran, Dr Esah binti Md Ali, Pn Salfaryna binti Alzahari, Cik Nurul Huda Hazwane binti Rohani
2.9	En Amrish Shah bin Osman, Pn Wan Nur Afiza Wan Mohd Arifin, Pn Hannah Phoon Yik Phing
2.10	Dr. Esah binti Md Ali, Pn Siti Noraini binti Md Isa

2.1 Laboratory-Based Surveillance System

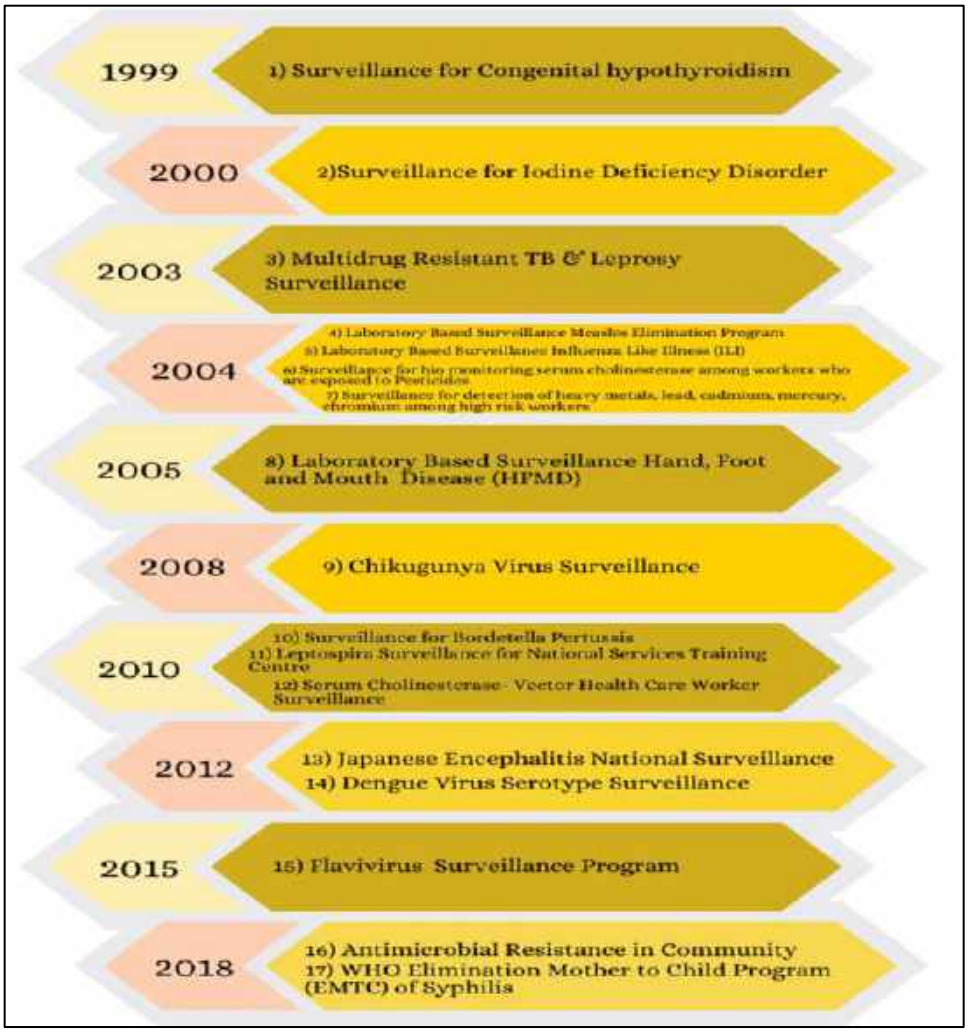
Surveillance program plays a crucial part in any disease prevention and control measures. It is defined as an ongoing, systematic collection, analysis, interpretation, and dissemination of health-related data essential to the planning, implementation, and evaluation of public health practices (WHO). Surveillance is needed to serve as an early warning system, understand the epidemiology of a condition to set priorities, and guide public health policy and strategies.

Accurate laboratory-based information is a critical component of disease surveillance. In view of this, Laboratory-Based Surveillance was officially implemented by the MOH Malaysia in August 2002 to complement the mandatory notifiable disease surveillance system under the Prevention and Control of Infectious Disease Act 1988 (Act 342) as shown in Figure 2.1.1. The surveillance which monitors the infectious disease agent or pathogen-specific has also been expanded to include information on the following and not limited to antibiotic resistance, biotype/serotype, genotype, antigenic shifts as well as changes in epidemic strains for predicting outbreak and potential crisis as an early warning system.

Figure 2.1.1: Laboratory-Based Surveillance Flow Chart, Ministry of Health Malaysia

NPHL has conducted various types of Laboratory-based surveillance systems of infectious as well as non-infectious diseases as part of the disease monitoring program and public health crisis preparedness (Table 2.1.1 and Table 2.1.2)). Virology and Bacteriology laboratory-based surveillance were the main surveillance activities conducted by Disease Division, NPHL. Virology was mostly involved in active laboratory-based surveillance which requires the sentinel sites to send samples on weekly basis to NPHL/PHL.

Table 2.1.1: List of Laboratory-Based Surveillance Programs by Disease Division, NPHL



These involve samples or suspected samples of Measles, Rubella, Hand-Foot and Mouth Diseases, Flavi-virus, Influenza-like illnesses, and others. Most of bacteriology laboratory-based surveillance are passive surveillance, as the clients (hospital, institutions) can send the isolates/positive cultures such as *Salmonella sp*., *Leptospira sp*., and *Haemophilus influenza*e for further sub-typing at NPHL/PHL.

Table 2.1.2: List of Laboratory-Based Surveillance Programs by Food Division, NPHL

YEAR	SURVEILLANCE PROGRAM	STATUS/ PROGRAM OWNER/ COLLABORATIVE PARTNERS
2009-current	Monitoring Programme of Captured Fish & Fishery Products for Exports to EU	Ongoing (Bahagian Keselamatan & Kualiti Makanan)
2009	Monitoring Programme of Shrimp for Export to the USA	Short Term
2011	Surveillance on Phtalate (DEHP) Content in Imported Food Produced from Korea and Hong Kong	Short Term
2012	Surveillance on Total Arsenic and Inorganic Arsenic Content in Local & Imported Rice	Short Term
2013	Surveillance on Determination of Colours on Soft Drink in Local Market	Short Term
2013- 2014	Surveillance on Heavy Metals & Microbiological Contaminantion in Seaweed Produced in Sabah	Short Term
2014	Surveillance on Contamination of *Salmonella Enteritidis* in Chicken Eggs from Local Market	Short Term
2014	Monitoring Programme of Captured Fish & Fishery Products for Exports to Russia	Short Term
2014-current	Surveillance on Contamination of *Brucella spp* in Fresh Goat's Milk at the Point of Sales	On going
2014-current	Monitoring of Presence of Antimicrobial Resistant Microorganisms in Fresh Fish & Meat from the Local Market	On going
2014	Surveillance on Determination of Colours in Soft Drink & Confectionery in Local Market	Short Term

Prior to the COVID-19 pandemic, a laboratory-based surveillance system was already in place. Influenza-like illness (ILI) surveillance was started in September 2003 following an influenza outbreak involving a few boarding schools in the same year. The surveillance system was further enhanced in December 2003, following an avian flu outbreak in the South-East Asia region. Under this surveillance program, clinical ILI data were collected from government health clinics with the involvement of 590 / 868 clinics (68%). Data on the number/consultation rate of ILI cases by age group were collected and analyzed (1). The report has demonstrated that ILI incidence has spread out over the country. In response to this, the Influenza Virus Surveillance program was expanded and strengthened for forewarning of outbreaks and early detection of emerging novel influenza viruses as shown in Figure 2.1.2. National Public Health Laboratory (NPHL) started receiving clinical samples from ILI outbreaks besides IMR and UMMC in 2008.

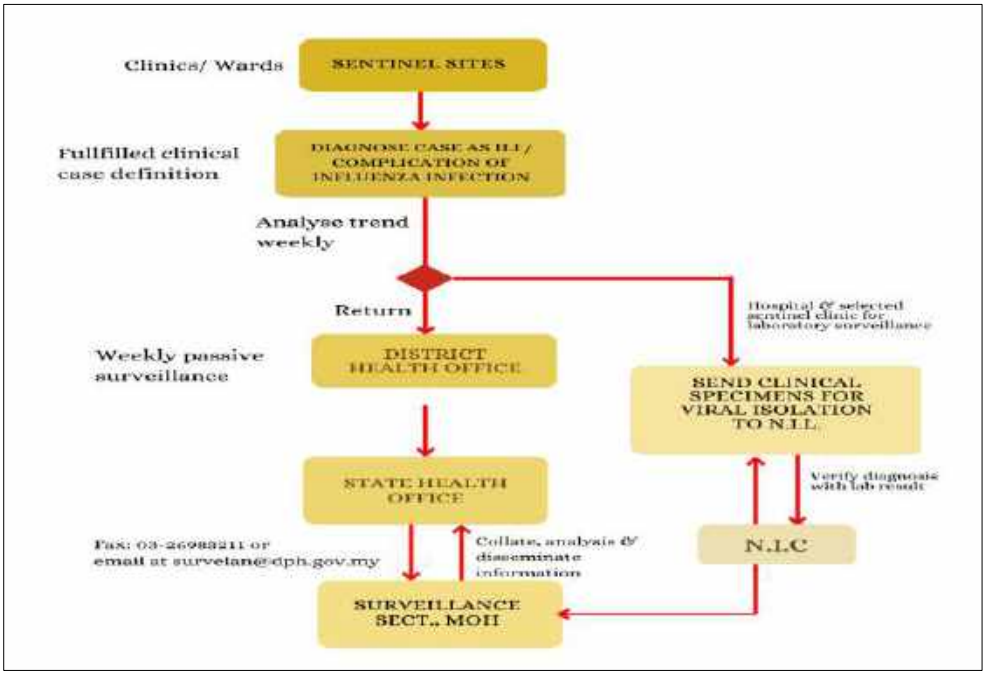


Figure 2.1.2: Flow of data related to influenza surveillance

In 2015 the sentinel site of ILI surveillance has been increased to thirteen (13) health clinics (2) (Figure 2.1.3). With the existing ILI surveillance sentinel clinic, MOH was able to monitor the trend of respiratory illness in the community.

Figure 2.1.3: Location of the sentinel clinic under ILI Surveillance program (since 2015)

During the early phase of the outbreak (February 2020), Malaysia used ILI sentinel surveillance to detect and monitor the local transmission of the SARS-CoV-2 virus in the community. Nine (9) sentinel primary healthcare facilities nationwide were selected by the MOH in this phase as part of ILI sentinel surveillance.

In addition, a set of criteria was developed by the MOH for these sentinel clinics. The case definition for Influenza-like Illness (ILI) is a clinical diagnosis of possible influenza or other respiratory viral infection causing a set of common symptoms in connection with the sudden onset of respiratory infection with at least one of these symptoms, shortness of breath, cough or sore throat with or without fever. Those patients who visited the selected sentinel clinics and fit into the case definition will be preceded with a PCR test. Both nasopharyngeal (NP) and oropharyngeal (OP) swabs will be taken and sent to regional public health laboratories for testing. Each sentinel clinic is required to send 15 samples per week. The readiness of laboratory-based surveillance system has facilitated early case detection and overall pandemic management.

List of References

1. Infectious Disease Outbreak, Ministry of Health Malaysia, 1st Edition, June 2003
2. Malaysia Influenza Surveillance Protocol, Surveillance Sector, Disease Control Division, Ministry of Health Malaysia, November 2015

2.2 Simulation Exercise

A simulation exercise is a fully simulated, interactive exercise that tests the capability of an organization to respond to a simulated emergency, disaster, or crisis situation. This exercise can help to develop, assess and test functional capabilities of emergency systems, procedures, and mechanisms which able to respond to outbreaks or public health emergencies. NPHL has been involved in several simulation exercises and played the role of the national laboratory focal point. Simulation exercises are normally held as field exercises or as tabletop exercises and include a scenario that is as close to reality as possible.

Throughout recent years, the exercise was more focused on the pandemic simulation exercise. The pandemic simulation exercise was designed to assess how much work is needed to bolster the disaster response systems, especially in areas where public and private partnerships will be necessary to respond during a pandemic. By joining this such exercise, NPHL has been given an opportunity to develop capabilities, stress-test plans, evaluate coordination and communication, and preview real-time response capabilities.

One of the simulation exercises is the IHR Crystal Exercise which is a yearly simulation exercise event organized by the Western Pacific Region Office (WPRO) of the World Health Organization (WHO) in which NPHL has actively participated. NPHL join other WPRO region countries as one participant in this exercise. It is a functional exercise conducted virtually through video conferencing and other communication tools to test the communication of IHR focal points in terms of public health reporting, verification, notification, information sharing, and risk assessment. The theme of the exercise varies each year but focuses on managing and responding to an outbreak. By participating in the exercise, NPHL is able to look at the gaps, capacities, capabilities, and networking with other laboratory partners within the country, ASEAN, and WHO (Figure 2.2.1).

Figure 2.2.1 The involvement of NPHL in the IHR Crystal Exercise.

In relation to this, an officer from National Public Health Laboratory and one (1) from Disease Control Division attended training as Facilitators for Simulation Exercise (SIMEX) at WHO Western Pacific Region Office in 2019. (Figure 2.2.2)

Figure 2.2.2: Representatives of NPHL and Disease Control Division attended the After-Action Review (AAR) and Facilitator Courses for Simulation Exercise (SIMEX).

2.3 Laboratory Test Protocol & Validation

Since 2013, the Virology Section of the National Public Health Laboratory (NPHL) had the PREDICT Protocol available for outbreaks investigation of new or unknown viral infectious diseases (Figure 2.3.1). This Polymerase Chain Reaction (PCR) protocol was shared by Eco Health Alliance (EHA), the organization based in New York as part of a collaboration project called PREDICT, with Conservation Medicine and the Ministry of Health Malaysia for zoonotic surveillance. It consists of consensus conventional PCR assays designed to identify up to 27 viral families/groups of known and new viruses. The assay was optimized and well validated with the PREDICT Universal Controls and was used to screen samples collected from *Orang Asli* communities and forest fringe animal facilities from 2016 to 2019. It will be used in the ongoing zoonotic surveillance when new samples were obtained. Additionally, prior to the COVID-19 pandemic, the protocol, primers, and reagents were well-maintained and ready for use in any potential outbreaks or undiagnosed cases by normative diagnosis.

On 04th January 2020, the Virology team of NPHL revisited the specific PREDICT Protocol (Watanabe et.al, 2010 and Quan et.al, 2010) as the first step in preparation to detect Pan Coronavirus (Figure 2.3.1). Following 22nd January 2020**,** NPHL received inactivated positive control from the University Malaya Medical Centre (UMMC) to use for further optimization of this assay. It was successfully identified as Pan Coronavirus with a product size of 434 bp and 328 bp for Watanabe and Quan et.al,2010, respectively. Subsequently, the RNA was used as a positive control for the assay (Figure 2.3.2). NPHL was the first laboratory to detect the SARS-CoV-2 imported cases on 24th January 2020. The same validated method was used as described in Quan et.al, 2010 to sequence part of the RdRp gene from three out of eight reported cases (Figure 2.3.3).

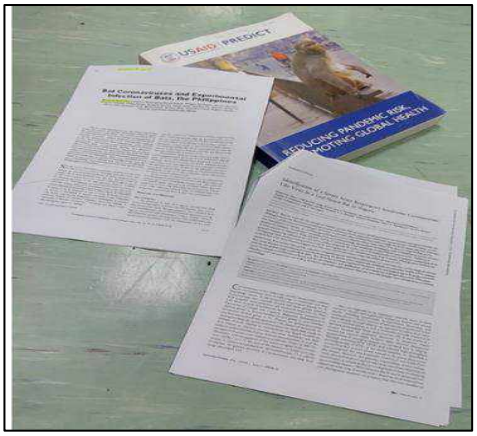


Figure 2.3.1: Reference protocol used in PREDICT Protocol for detection of Pan Coronavirus

Figure 2.3.2: The University Malaya Medical Centre (UMMC) shared RNA extracts as a positive control for optimized RT-PCR testing for SARS-CoV-2.

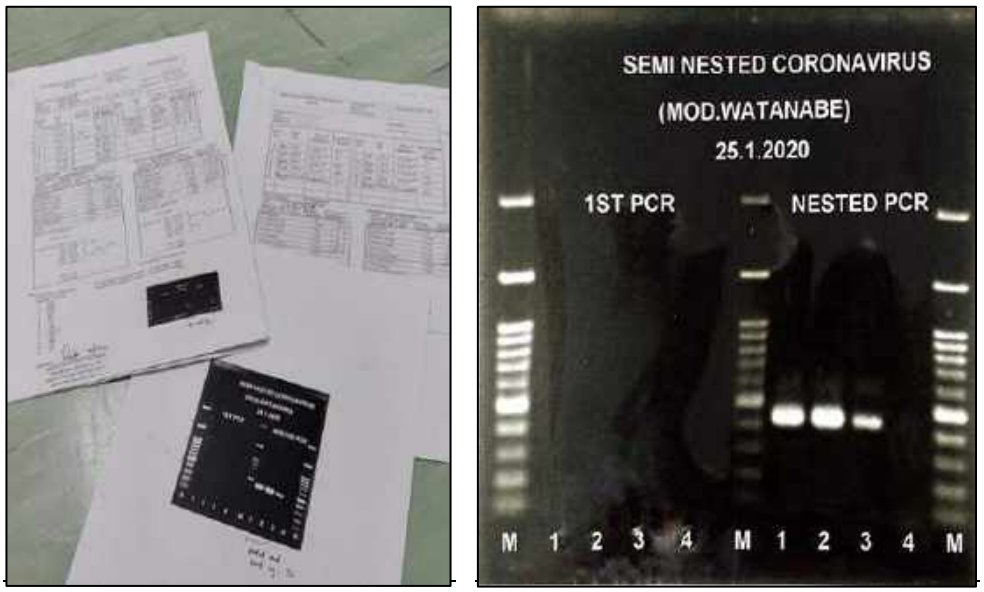


Figure 2.3.3: Gel electrophoresis for a target region of SARS-CoV-2

NPHL sequencing data confirmed the presence of SARS-CoV-2 and was consistent with the Real-time RT-PCR findings as described by World Health Organization, 2020; Corman et al., 2020 which has been optimized and validated with the same inactivated positive control (Figure 2.3.4). Subsequently, the WHO protocol has become the standard protocol used in the laboratory. As time passes, more COVID-19 detection assays are available, and the choice of the assay depends on the user's preference. Importantly, each test needs to be validated and optimised using current laboratory equipment before being used.

Figure 2.3.4: Performed confirmatory test on RNA extracts for detection of SARS-CoV-2 by RT-PCR

2.4 Contingency Plan for Stockpiling

Stockpiles of critical materials are one of the main components of public health preparedness. In an emergency situation, sustainable stockpiling of important items such as vaccines, laboratory reagents and kits, Diagnostic or Rapid Test Kits (RTK), antibiotics, and decontamination solutions was required to avoid any shortages and unnecessary surplus of supplies. Over or undersupply of these items will directly affect the effectiveness of overall events/ crisis management including laboratory performances and may lead to wastage. This situation can be avoided or minimized with the implementation of a Contingency Plan for stockpiling in which a reasonable buffer stock was made available for emergency use.

NPHL has been always ready to prepare for any outbreak and surge of cases. The laboratory items and reagents were properly kept and the movement of items was monitored and recorded. The first-in-first-out practice was implemented and generally governed by product expiry date. The Administration Team of NPHL was given the responsibility to monitor closely the items and arrange for their distribution to other health facilities if needed. The status of stock use and the reserve was also tabled during Management Review Meeting (MRM) under the ISO standard of ISO 9001:2015 for close monitoring of store performance.

In addition, the administration team will regularly share updates on stockpiles with the Technical Laboratory Team to match current usage and demand. This is to ensure laboratory stockpiles including consumables and PPE are sufficient for current use as well as adequate enough to cope with the sudden surge of potential outbreaks. Apart from that, NPHL has also maintained good cooperation with the local suppliers that can always be ready to be contacted. The suppliers will offer the information on the stock availability of the items and NPHL will proceed with the procurement process if required. The Technical Laboratory Team together with the Financial Team of NPHL will be responsible for the procurement process if needed.

NPHL also has regular meetings with the other regional PHLs to update the current status of laboratory supplies including reagents, consumables, and PPE. NPHL leads the purchasing for most of the items and reagents. The central procurement approach was implemented and items were kept at NPHL and other designated facilities before being distributed to other health facilities when needed. Issues of under or over-supplied laboratory stockpiles were managed through the mobilization of items from the current laboratory network at national as well as international levels such as WHO and IAEA. All stockpiles received from Non-Government Agencies (NGO) will be preapproved by the Secretary General of MOH, Malaysia for clearance of acceptance.

COVID-19 PANDEMIC MEMORABILIA

Photo showing External Audit Standard ISO 9001:2015 by SIRIM was conducted in 2021 to ensure the quality aspect of service delivery is maintained throughout the COVID-19 pandemic. The scope of ISO certification was successfully expanded covering analysis of the clinical and non-clinical samples and laboratory support services.

2.5 Laboratory Networking

Laboratory networking is one of the essential components of surge capacity enhancement. As one of the reference laboratories for the country, NPHL is obligated to continuously strengthen the laboratory capacity and capability for public health requirements. The accessibility and availability of public health laboratory services were also improved with the development of new scopes and the establishment of new public health laboratory services in critical areas. Concurrently, strategic collaboration with other institutions/ laboratories was also formed.

In view of this, NPHL has established and been a part of several networks at the national as well as international levels. The networks have facilitated sharing of critical information including pathogen sequences and technical advisory, technology transfer, and strengthening cross-border public health monitoring and overall public health laboratory services delivery. Apart from providing integrated epidemiology and microbiological surveillance of public health importance, the networks also play a critical role in supporting laboratory investigations and assessment of cross-border public health-related issues. In addition, the network has directly strengthened interlaboratory cooperation at the national and international levels and served several functions as listed in Table 2.5.1 below.

Table 2.5.1: The Expected Functions of The Laboratory Network

At the national level, NPHL, IMR, regional Public Health Laboratories, state hospital laboratories, and laboratories at primary health clinics formed a laboratory network to address the country's overall public health needs. Other agencies involved in these laboratory networks are universities, other ministries, private entities and Non-Governmental Organizations (NGOs) (Table 2.5.2).

Table 2.5.2: List of NPHL networks at the national level

AREA	LABORATORY NETWORK
Food Analysis Committee (JKAM) and Technical Working Group (KKT) - Mycotoxins, Additives and Contaminants, Microbiology, GMO, Pesticides, Drug Residue, Proficiency Testing and Marine Toxins	- Department of Chemistry - Chair of committee MKAK, other MKSa and MKKM as active members. - Other agencies - Dept. of Veterinary, Dept. of Fisheries, Universities, MARDI etc.
Food Analysis Technical Working Group (JKKTAM) - Mycotoxins and Marine Toxins, Food Microbiology, Biotechnology, Pesticide, Drug residue, Food Contact Materials, Industrial & Environmental Food Contaminants, Allergen & Natural Contaminants, Food Additives & Food Standards & Nutritional Labelling.	Food Safety & Quality Dept.- Coordinator MKAK, other MKAs and MKKM as active members
National Laboratory Steering Committee & National Laboratory Technical Committee Health Laboratory Sub-Committee: Quality Assurance (QA) Health Laboratory Sub-Committee: Laboratory Surveillance Health Laboratory Sub-Committee: Biosafety & Biosecurity	- Ministry of Agriculture & Industry (MoA) - Ministry of Energy, Science, Technology, Environment & Climate Change (MESTECC) - Ministry of Defence (MinDef) - Ministry of Education (MoE) - Ministry of Land, Water, Natural Resources (KATS) - Private Laboratories
Communicable Diseases- Virology, Bacteriology, TB, Leprosy, Parasitology	IMR, Universities, Private Hospitals, State Hospitals, Chemistry Dept., Dept. Of Veterinary, Dept. of Fisheries, Universities, MARDI, etc.
Non Communicable Diseases- Biochemistry (Iodine, Methanol), Entomology	IMR, State Hospitals, Chemistry Dept., Universities

Internationally, NPHL formed a network with the World Health Organization, WHO regional members for the Western Pacific Region, the World Health Organisation (WHO), the ASEAN Member States, and the Public Health Laboratory Network. In addition, NPHL has also participated in the Global Health Security Agenda (GHSA) which is a global initiative under US Centres for Disease Control and Prevention (CDC) for strengthening the nation's capability in combating infectious diseases.

Under the ASEAN platform, NPHL was the lead country for the ASEAN+3 Laboratory Network. The laboratory network under this platform has been integrated as one of the focus areas under the ASEAN Cluster 2 initiatives: Focus Area 10: Strengthening Laboratory Capacity, in which the NPHL is the national focal laboratory representing Malaysia under this initiative. This network aims to strengthen the national laboratory capacity of ASEAN Member States in the mitigation of biosafety and biosecurity threats through regional capacity-building activities, policy advocacy, and the exchange of information and expertise among ASEAN Member States.

Figure 2.5.1: Food Laboratory Networking of NPHL

Table 2.5.2 below shows NPHL's Networking at the International Level.

Table 2.5.2: List of NPHL's Networking at the International Level

No	Area of Work	Network
1	Measles Elimination Program (MEP): Measles & Rubella	WPRO, WHO
2	Asean- Canada Global Partnership Program (GPP) on Dengue and Flavivirus Asean Health Cluster 2 Initiatives- Strengthening Laboratory Capacity	ASEAN member state
3	Tobacco Control Program	WHO Tobacco Laboratory Network TobLabNet
4	PREDICT: Study of Zoonotic Infection Among Person Exposed to Wild Animals and Zoonotic Diseases Surveillance Program in Malaysia	Eco Health Alliance, New York
5	Assessing the Feasibility and Impact of Introducing a Measles Rapid Diagnostic Test into the National Surveillance Program in Malaysia	WHO, US CDC, PHE
6	IDENTIFY: Strengthening EQA of TB laboratories in Malaysia	Queensland Mycobacterium Reference laboratory, Australia

Figure 2.5.2 (a), (b), (c), and (d) showed the several international networking programs in which NPHL has been involved.

Figure 2.5.2 (a): NPHL participation in Public Health Laboratory Informatics Workshop by Association of Public Health Laboratories (APHL) Network

Figure 2.5.2 (b)

Figure 2.5.2 (c)

Figure 2.5.2 (b) and (c): NPHL Participation in Disease Elimination Program

Figure 2.5.2 (d): NPHL participation in Global Health Security Agenda & APHL Networking

COVID-19 PANDEMIC MEMORABILIA

Figures showing NPHL Participation in WHO World Health Assembly during the Pandemic , Delivering Key Notes on Enhancement Laboratory Biosafety & Poliomyelitis

2.6 Technical Acumen & Expertise

One of the NPHL functions is to provide laboratory services for surveillance monitoring, outbreak investigation, and high-end specialized diagnostics testing. As such, NPHL is required to offer laboratory tests that are updated, reliable, fast, and cost-saving. In order to do this, officers were trained to review or modify current or develop new tests as part of capacity and capability building for NPHL. Being tasked as a Capacity Building Centre for Public Health Laboratory Services, the NPHL officers and relevant staff were trained in areas such as Virology, Bacteriology, Mycobacteriology, Parasitology, Biochemistry, and Epidemiology Statistical Analysis. Specialized training was also provided in these areas to other laboratory services under the Ministry of Health (MOH) Malaysia, universities, and private laboratories. The training offered by NPHL was conducted based on a scheduled basis governed by requirements as well as budget allocations. Example of training are shown in Figure 2.6.1 (a), (b), and (c) below, and Table 2.6.1 show a list of training attended by NPHL in the year 2022.

Figure 2.6.1 (a): Microscopic Training for Detection of Mycobacterium leprae

Figure 2.6.1 (b): Training on Laboratory Detection of Mycobacterium tuberculosis

Figure 2.6.1 (c): Hands-On Training on Microscopic Detection of Mycobacterium tuberculosis

As a reference laboratory, NPHL staffs were well trained to handle specialized tests, and develop new test methods in molecular, serology, culture techniques, chemistry for clinical and non-clinical samples such as environmental, food, and chemical samples. Officers and laboratory personnel have attended various training either locally or overseas to enhance their skills in a laboratory test of interest and other relevant technical areas required to support public health functions. Echo training was conducted at NPHL by the selected trained officers as part of the internal institution's capacity enhancement. In line with this, NPHL has liaised with technical expertise and Subject Matter Expert (SMEs) from national as well as international agencies such as WHO Country Office, Malaysia, and WHO Western Pacific Region (WPRO) for current status or updates on pathogen detection and identification. This has enabled NPHL to be prepared accordingly if any crisis or new outbreak appears.

Table 2.6.1: List of Training Attended by NPHL In Year 2022

NO	LIST OF TRAINING / CONFERENCE. MEETING (YEAR 2022)	LOCATION
1	2nd Military Civilian Health Security Summit & Global Health Security Conference.	Singapore
2	World Health Organisation (WHO) Meeting of Tobacco Laboratory Network (Toblabnet)	
3	Regional Training Workshop On Sequencing And External Quality Assurance (EQA) For COVID-194	
4	Mitigation of Biological Threat Projects Coordination and ASEAN Health Security Stakeholders Meeting	Bangkok Thailand
5	Regional Consultative Meeting On Strengthening Regional Initiatives In ASEAN On Covid-19 Response And Other Public Health Emergencies: Knowledge Sharing And Way Forward (GIZ Supported Projects).	
6	Regional Consultative Meeting On Strengthening Regional Initiatives In ASEAN On Covid-19 Response And Other Public Health Emergencies: Knowledge Sharing And Way Forward (GIZ Supported Projects).	
7	Enhancing RPHL Network Partnership Meeting	
8	South East Asia Genomic Conference 2022	Bali, Indonesia
9	Workshop on Strengthening Laboratory Services for Antimicrobial Resistant Surveillance in Leprosy	Karigiri, India
10	Improving The Tricycle Protocol : Upscaling to National Monitoring, Detection of CPE and WGS Pipelines for one health surveillance (TRIUMPH)	Utrecht, Netherlands
11	Training on Using Modern Molecular Genetic Technologies For Biosafety	Vladivostok, Russia
12	1st ASEAN-ROK International Training Course-Capacity Building for Infectious Disease	South Korea
13	Training Program In Public Health Pathogen Genomics Sequencing	Melbourne, Australia
14	Expert Training On The Preparation Of Proficiency Testing Material For *E.Coli* In Shellfish And Virology Testing	United Kingdom

In addition, NPHL staff have also attended attachment or hands-on training at other institutions or universities if the need arises. As part of accreditation and MOH requirements, in-house training was also conducted for an introduction to new or improved methods and as a refresher course for the current method in ensuring the technical competency is well maintained. At the same time, modifications of test methods or newly develop tests were also shared among PHLs, especially during Technical Working Group Meetings (MTMKA or TWG) as part of technology transfer and test method standardization.

As part of the yearly target, various new types of laboratory tests in Virology, Bacteriology, and Biochemistry. Food Microbiology and other disciplines were successfully developed. Other new scopes of services such as Entomology and Non-Communicable Diseases has also continuously expanded and are being strengthened. These are to increase the capacity and capability of pathogen and or causative agent detection and identification at NPHL. Table 2.6.2 is an example of the improved test method and newly developed tests offered by NPHL.

Keeping up with the latest technology, the molecular method has been widely used in various laboratories in NPHL for pathogen or gene detection as part of the confirmatory test or specialized tests such as Multi Locus Sequence Typing (MLST), Spoligotyping, or Whole Genome Sequencing (WGS). These methods are widely applied in Virology, Bacteriology, TB, Food Microbiology, and others to detect pathogens such as Leptospira sp., Corynebacterium diphtheriae, Bordetella pertussis, Mycobacterium tuberculosis, Dengue, Enterovirus, Influenza-like Illness (ILI) and Measles. Each laboratory has its own expert team in conducting molecular tests.

Given previous involvement in various disease outbreaks, pandemics, and public health crises, NPHL staffs are well-equipped and well-trained to manage high-risk samples of known as well as unknown causative agents. Other critical areas include epidemiology and statistical analysis, laboratory quality assurance, laboratory biosafety, and security are continuously being strengthened. In addition, the capacity of the in-house Laboratory Information System (*Sistem Informasi Makmal Kesihatan Awam*) is also being enhanced to manage big scale real-time data of potential pandemics or any public health emergencies.

Table 2.6.2: List of Examples of New or Improved Test Methods Developed and Offered By NPHL.

NO	LIST OF TEST	SECTION	METHOD
1	Detection of Carbapenemase Producing Enterobacterales (CPE) using selective MacConkey agar supplemented with 0.5 ug/ml Ertapenem for primary screening in diagnostic laboratories.	Bacteriology	Culture
2	Detection of Bordetella parapertussis by using singleplex Real-Time PCR	Bacteriology	Molecular
3	Genotyping of Salmonella ser Enteritidis by Whole Genome Sequencing method	Bacteriology	Molecular
4	Processing of Environmental Sampel for Identification and Enumeration of Aerobic Bacteria	Bacteriology	Culture
5	Detection of Extended Spectrum Beta Lactamase (ESBL) Producing E.coli using selective MacConkey agar supplemented with 4ug/ml Cefotaxime for primary screening in diagnostic laboratories.	Bacteriology	Culture
6	Detection of Neisseria meningitidis, Haemophilus influenzae and Streptococcus pneumoniae by Real Time PCR (qPCR) Assay	Bacteriology	Molecular
7	PCR-TB (modified using in-house probe)	TB	Molecular
8	Detection of Multi Drug Resistant TB using Real-time PCR	TB	Molecular
9	Second-line Drug Sensitivity Test Linezolid	TB	Culture
10	Detection of Methanol in Blood	Biochemistry	HPLC
11	Alcohol screening	Biochemistry	HPLC
12	Adenosine deaminase	Biochemistry	
13	Detection of Vitamin B1 in Blood	Biochemistry	HPLC
14	Nicotine determination	Biochemistry	
15	Propylene glycol, glycerol in HTP cigarette	Biochemistry	
16	Pathogen detection in mosquitos by PCR method (Dengue, Chikungunya, JE, Zika)	Entomology	Molecular
17	Developing new method for genotyping of Chikungunya virus	Virology	Molecular
18	Developing multiplex RT-PCR for detection of Enteroviruses (Pan EV, EV71, CA16 & CA6)	Virology	Molecular
19	Developing realtime RT-PCR for detection monkeypox strain Congo Basin & Generic MPXV	Virology	Molecular
20	Realtime RT-PCR for Environmental Surveillance of COVID-19 on Wastewater	Virology	Molecular
21	Realtime RT-PCR Parvovirus B19	Virology	Molecular
22	Realtime RT-PCR Marburg virus	Virology	Molecular
23	Realtime RT-PCR Rotavirus	Virology	Molecular

2.7 Laboratory Information System

The Public Health Laboratory Information System (PHLIS) is a software application designed for reporting laboratory test results and data analysis of a variety of conditions of Public Health importance. It is one of the critical components of public health data management and has a high impact on the effectiveness of public health action. One of the main challenges faced by many Public Health Laboratories is the absence of a LIS that is equipped with public health laboratory requirements. Most of the LIS was developed to cater to the Clinical and Research Laboratories. Given the differences in work processes which involved primarily confirmatory and specialized testing as well as wide variation in sample type, public health laboratories required a different and broader scope of LIS to fulfill and support its services.

In view of this, NPHL has taken the initiative to develop the first version of the PHLIS in 2002 which was successfully completed in 2005. This first version (SMIKA V1) was built as an offline system equipped with a standalone database for each public health laboratory. The system was named *Sistem Informasi Makmal Kesihatan Awam* or SIMKA. In response to the H1N1 Pandemic that required online real-time data sharing on laboratory test results, a new version of PHLIS was developed in 2009 to support the H1N1 pandemic data management. This system which was later known as H1N1 Pandemic Management System; was developed in-house by the Information Technology Unit and Virology Team under the direct supervision of the Director of NPHL.

Since its development, SIMKA has been continuously upgraded to fulfill the public health laboratory requirement. Limited laboratory tests and laboratory modules were listed under SIMKA V1. In 2013, the system was upgraded to SIMKA Version 2 (SIMKA V2) as an online system with a centralized database. The client module has also been added to the system enabling the tracing and distribution of test results to the respective clients. Tuberculosis , Dengue. Measles, Hand Foot Mouth Disease (HFMD) modules were later incorporated into the SIMKA V2.

The SIMKA V2 has been expanded into SIMKA V3 with more laboratory modules added to it. Prior to the COVID-19 Pandemic, an online central sample registration module was created to facilitate data entry for the preanalytical component of laboratory testing. The end-to-end work process covering sample registration from the requestor at the field and online result checking was later completed under SIMKA V3.

In addition, a continuous effort is also being invested toward improving the infrastructure component of the system including a secondary server database, high-spec laptops, and desktops, adequate internet capability, system security as well as application software to support high-impact and real-time data analysis as well as reporting capability. A proposal to increase the number of IT staff has also been submitted to support the operational requirement of the system.

The evolution of the Public Health Laboratory Information System is shown in Figure 2.7.1 below.

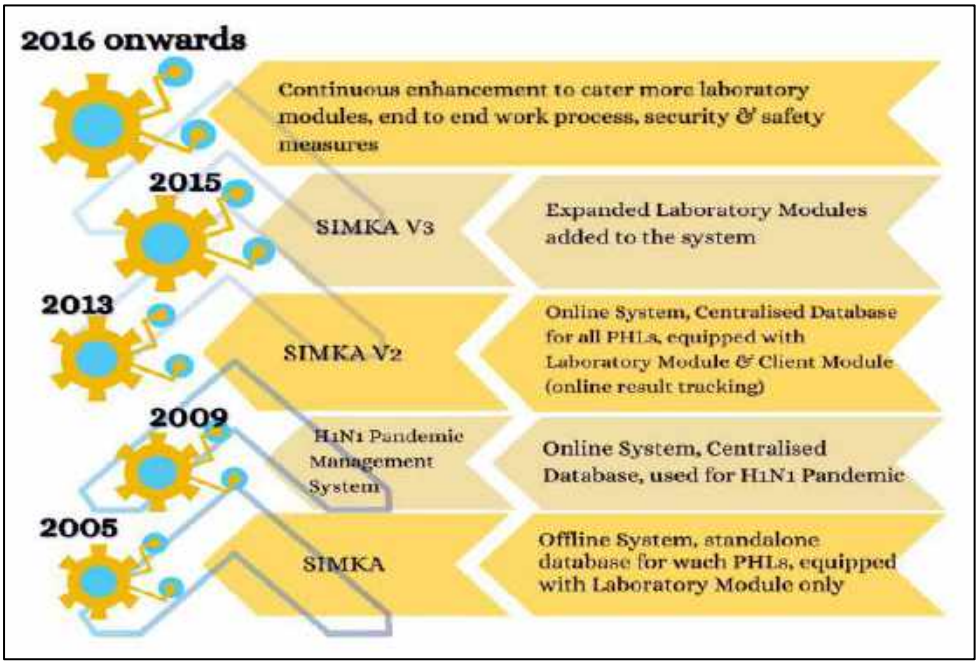


Figure 2.7.1: The Evolution of the Public Health Laboratory Information System, an in-house product of NPHL.

Moving forward, SIMKA will be further enhanced and to be equipped with new testing and services modules to support the operational requirements of the Public Health Reference Laboratory of the National Centre of Disease Control Malaysia.

COVID-19 PANDEMIC MEMORABILIA

Photo showing Discussion session involving Epidemiology and IT Team with NPHL Director on SIMKA during the Pandemic

2.8 Business Continuity Plan

The Business Continuity Plan (BCP) is an important initiative implemented by the Malaysian Government to ensure continuity in the service delivery system of the public sector. Each government agency is required to develop the Business Continuity Plan as set out in the MS ISO 27001: 2007 Information Security Management Systems (ISMS) and MAMPU Director General's Directive Year 2010. The BCP is composed of three main components; the Emergency Response Plan (ERP), the Crisis Communication Plan (CCP), and the ICT Information & Communication Technology Disaster Recovery Plan (ICT DRP).

In order to facilitate the deployment of BCP in the public sector, the Director General of MAMPU has issued a directive to all public sector agencies dated 22nd January 2010 entitled '*Pengurusan Kesinambungan Perkhidmatan Agensi Sektor Awam*' (MAMPU, 2010b). This document provides the milestones, policy, and guidelines for BCP implementation in public sector agencies. Following the fire accident that killed six patients at the intensive care unit (ICU) of the Sultanah Aminah Hospital, Johor Bahru in 2016, the Ministry of Health Malaysia (MOH) has strengthened the BCP in all health facilities including National Public Health Laboratory (NPHL).

In line with this, the BCP of NPHL was developed in 2016 and coordinated by the Head of the Epidemiology Division which was under the direct purview of the Director of NPHL. The ERP team is led by the Head of the Administrative Section, the ICT Data Recovery Plan team is led by the head of the Information & Communication Technology (ICT) Section and the CCP team is led by the Head of the Laboratory Improvement & Regulation Section. The team member of ERP, ICT DRP, and CCP were represented by appointed officers from each division of NPHL.

The NPHL's BCP is aimed to minimize the impact of a disruption or disaster to the service delivery, to ensure the continuity of the

services provided, and to ensure compliance with best practices such as MS ISO/IEC 27001:2007 Information Security Management Systems

As one of the reference laboratories for the country, NPHL is highly infrastructure-dependent and predicated on uninterrupted access to many laboratory services. These include intact building envelopes, continuous climate control, utilities, sample delivery networks, core support facilities, laboratory information technology systems, special waste management and hazardous materials, emergency response, and highly technically skilled personnel. Breakdowns in any one of these elements can cause serious disruption to ongoing diagnostic and analytical services laboratory, and extended failures in some of these areas (i.e., loss of electrical power, fire, floods) may eventually lead to irreparable damages to equipment, infrastructure, and unique collections of samples and specimens.

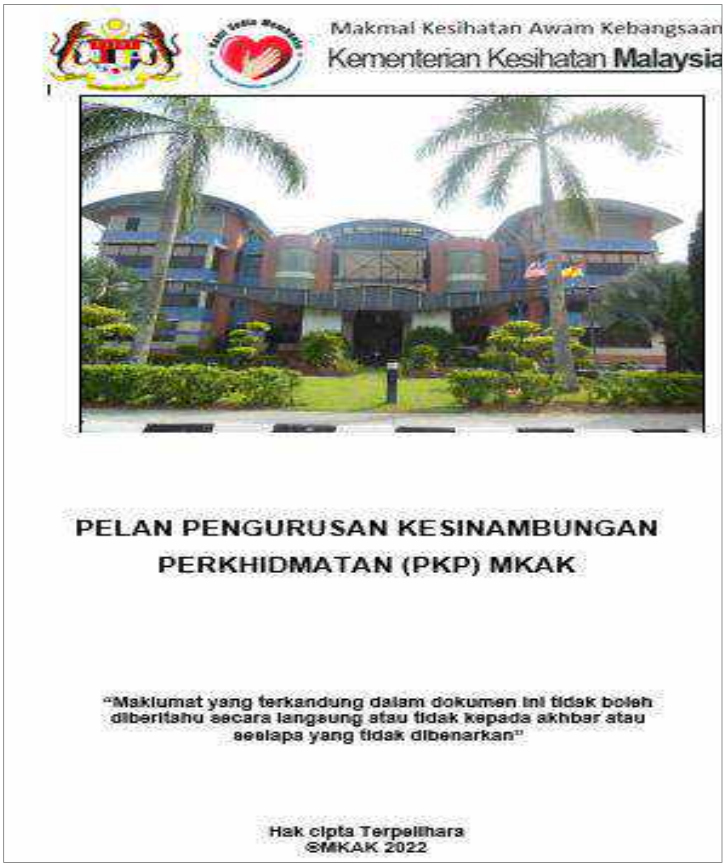


Figure 2.8.1: Revised Business Continuity Plan of NPHL, 2022

Hence the BCP provides an overview of key continuity of operations issues potentially faced by the laboratory. It is designed to aid laboratory managers and personnel in considering the additional protection and steps that should be taken to protect laboratory personnel and the valuable laboratory activities and output being conducted. The governance structure of NPHL's BCP is shown in Figure 2.8.2 below.

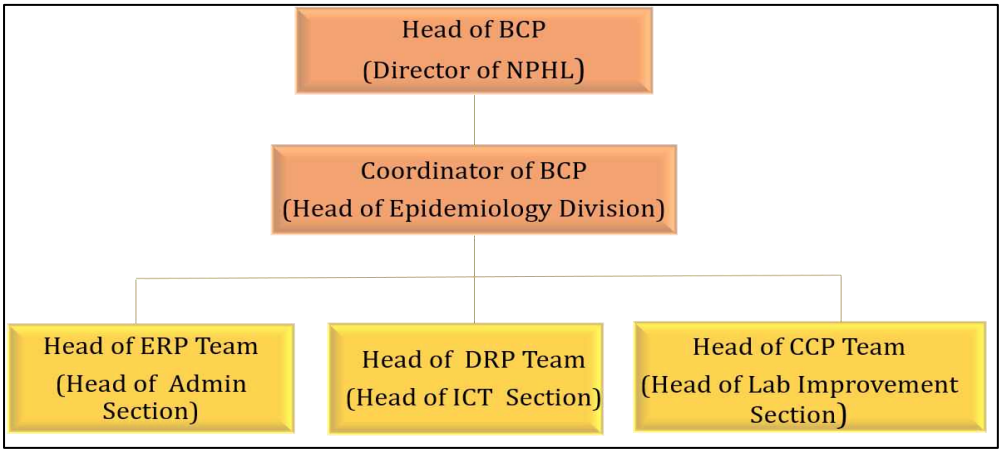


Figure 2.8.2: Governance structure of NPHL's BCP

In brief, the ERP component of BCP specified the general responsibilities and duties of the designated personnel and all staff during Emergencies and potential Emergencies. The ICT Recovery Plan is aimed to prevent the loss of physical ICT assets, software, and data/information, minimize downtime related to ICT and keep the business running in the event of a disaster.

The CCP provides policies and procedures to coordinate communication within the organization, between organizations and other external agencies including the media, regulatory bodies, customers, suppliers, and stakeholders during the occurrence of a crisis/disaster or controversial issues that requires an explanation to the public to prevent threats to public order and ensure the critical

services of an organization continue. The subcommittee under the Emergency Response Team (ERT), Disaster Recover Team (DRT) & the Crisis Communication Team (CCT) of NPHL's BCP and line of command and activation flow of NPHL'BCP are shown in Figure 2.8.3 and Figure 2.8.4 below.

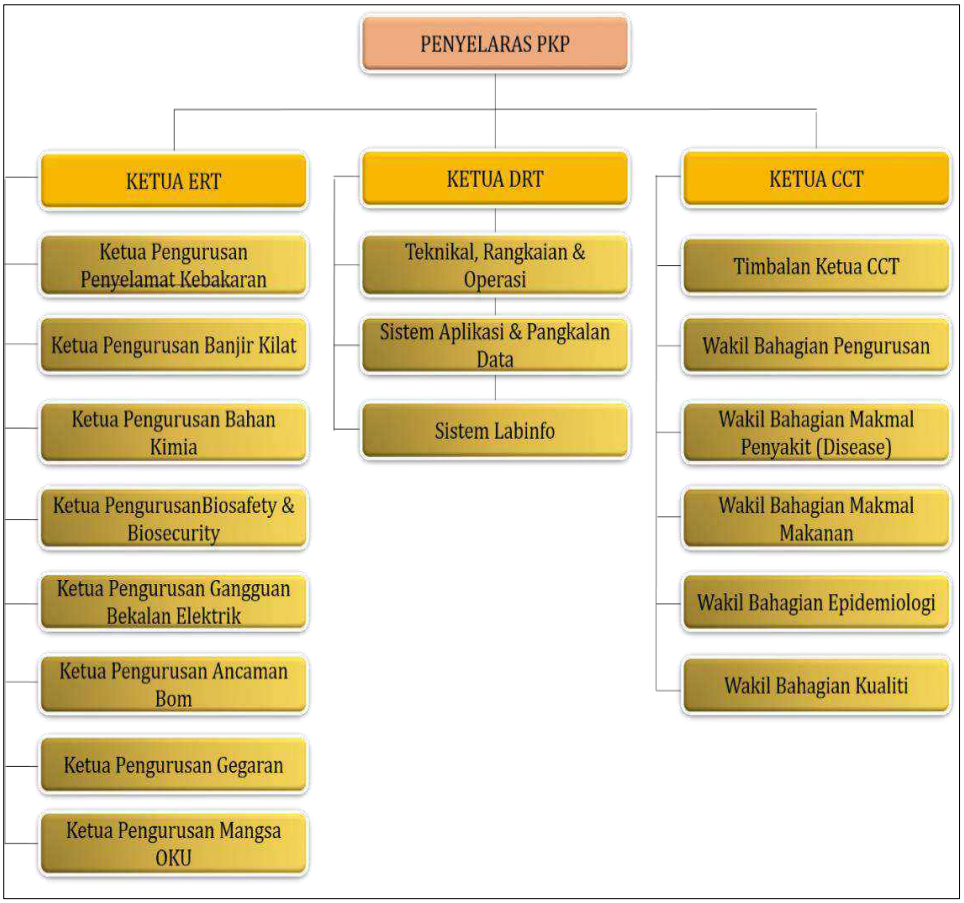


Figure 2.8.3: Subcommittee under ERT, DRT & CCT of NPHL's BCP.

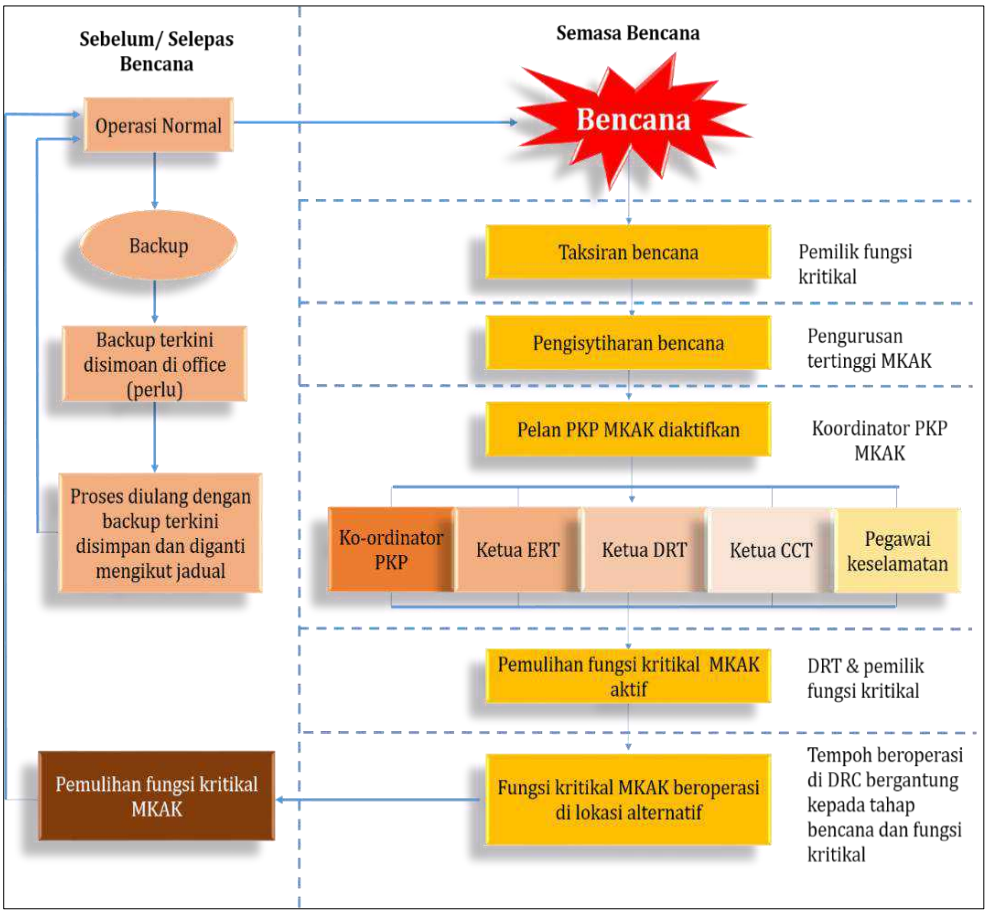


Figure 2.8.4: Line of command and activation flow of NPHL's BCP

The plan will be revised accordingly to suit with the new requirement and future role of NPHL.

List of Reference

1. https://www.intanbk.intan.my

2.9 Laboratory Biosafety & Biosecurity

The lessons learned from the 2014 Ebola epidemic became the impetus for the National Public Health Laboratory to maintain a constant state of Laboratory Biosafety and Biosecurity readiness in the event of another infectious disease outbreak in the immediate future.

In 2015, the NPHL reorganized the membership and rebranded the Biosafety Sub-Committee under the NPHL Occupational Health and Safety Committee to the Institutional Biosafety & Biosecurity Committee (IBBC). The IBBC comprises of several Science Officers from the Disease and Food Division who are trained, competent, and professionally certified by the Malaysian Biosafety & Biosecurity Association (MBBA) and international organizations such as the International Federation of Biosafety Associations (IFBA). All planning and implementation of biosafety and biosecurity activities in NPHL are managed and supervised by IBBC. The structure of IBBC in the NPHL Occupational Health and Safety Committee is shown in Figure 2.9.1 below.

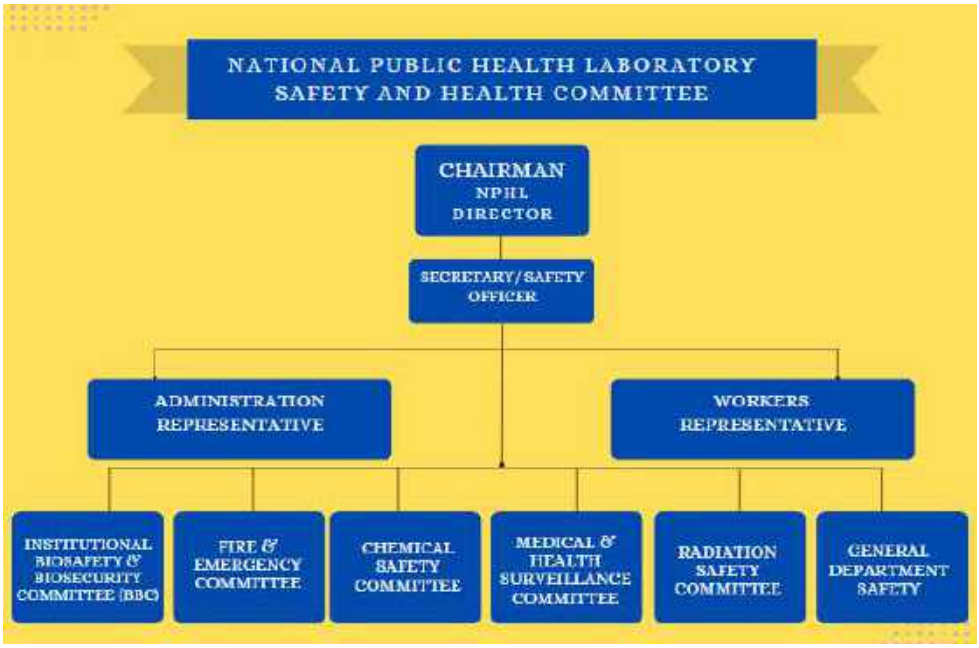


Figure 2.9.1: The Institutional Biosafety and Biosecurity Committee (IBBC) under the NPHL Occupational Health & Safety Committee.

The risk assessment activities at the NPHL were first initiated at the end of 2014. Following this, it was conducted annually on all laboratory testing procedures for infectious substances to determine the bio risk level and in order to apply the appropriate mitigation measures for the reduction of bio risks to the laboratory personnel. At the same time, to strengthen and ensure continuity in bio-risk self-assessment activities for all laboratories, training for officers and laboratory personnel are conducted regularly.

Proper assessment of the need for the right Personal Protective Equipment (PPE) to be worn was conducted by using the risk assessment. This is to avoid wastage of resources, ascertain the current number of available PPE, and ensure that the PPE stockpile was sufficient at all times at the NPHL. IBBC also worked closely with other Regional Public Health Laboratories to assist each other in maintaining PPE stockpiles.

The IBBC is also responsible for making the purchase of PPEs such as gloves and respirators according to the required specifications and according to user-specific needs. This was to ensure the PPE equipment purchased met the NIOSH standards for quality.

The IBBC conducts annual biosafety training series for all laboratory personnel in donning and doffing of PPE, decontamination and waste management, biological safety cabinet, and the operation and maintenance of safety equipment (Figure 2.9.2 (a) and (b)). Attendance of the laboratory personnel is compulsory in order to ensure that laboratory biosafety and biosecurity practices are adhered to by all involved in the handling of microbiological agents including infectious agents.

Figure 2.92 (a)

Figure 2.92 (b)

Figure 2.92 (a) and (b): Biosafety and Biosecurity hands-on training activities conducted at the NPHL for laboratory personnel.

2.10 Material Transfer Agreement

As a national reference laboratory for investigating outbreaks, disease surveillance, and public health crisis, NPHL is a national hub for biological agents and critical data. Functioning as a bio-depository center or biobanking, all transfers of biological agents and associated data are governed by a Material Transfer Agreement under the specific term of reference to safeguarding the right of the institution, requestor, and the country.

The MTA of NPHL was developed in collaboration with Legal Advisor, MOH in 2018 and was later presented in the EXCO Meeting of Public Health Program in the subsequent year. It is a legal contract that defines the terms and conditions which govern the transfer of material (bio and non-bio) and its derivatives as well as relevant data or classified information between NPHL and the requester/ recipient. The MTA specifies the rights of the provider and the recipient with regard to the material or data being shared. The document also specifies important areas including the role or responsibility of both parties, the type of material/ data being shared, quantity and purpose of sharing, limitation of use including the requirement of material disposal, and an Intellectual Property Right (IPR). An example of the MTA document is shown in Figure 2.10.1 below.

Figure 2.10.1: Material Transfer Agreement of NPHL, an official document for sharing of material (bio & non-bio) and associated data

In addition, the implementation of MTA by NPHL has supported the enforcement of relevant acts, national and international commitments as well as global initiatives including the Access to Biological Resources and Benefit Sharing Act 2017 [Act795), Patent Act 1983 (Act 291), Convention on Biological Diversity (CBD), Nagoya Protocol and Biohub- a Global System for Sharing Biological Material with Epidemic or Pandemic Potential by World Health Organization (WHO). Moving forwards, the MTA is to be further improved and be used as one of the official documents governing transferring and sharing of bio/ non-bio material or data nationally. Figure 2.10.2 shows the condition and scenario where MTA is applicable and Figure 2.10.3 shows the MTA process's flow.

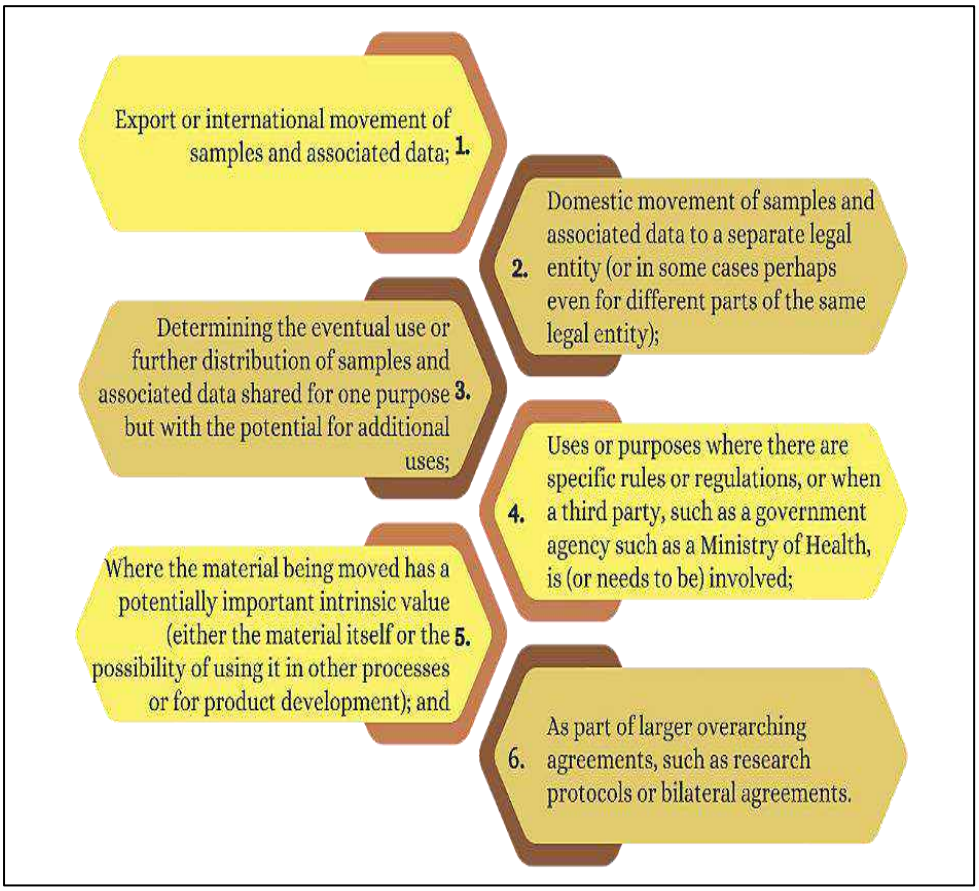


Figure 2.10.2: Condition and scenario where MTA is applicable

Figure 2.10. 3: The flow of MTA process

CHAPTER 3

DISCOVERY OF MALAYSIA 1ST COVID-19 CASE

WRITERS

CHAPTER 3.0

Dr Esah binti Md Ali
Pn Siti Noraini binti Md Isa

3.0 Discovery Malaysia 1st COVID-19 case

Following the increasing number of unknown respiratory illnesses in Wuhan, China early October 2019, NPHL Malaysia has taken proactive measures to strengthen our laboratory preparedness dealing with the potential spreading of the outbreak to Malaysia. These include reviewing and validating laboratory protocol of unknown pathogens, increasing our capacity for molecular testing, reviewing stockpiling laboratory supplies, the readiness of the laboratory Rapid Response Team (RRT), and strengthening biosafety and biosecurity requirements for overall handling and management concerning high-risk specimens or unknown agent.

Figure 3.1: National Public Health Laboratory, a reference laboratory for the pandemic situated in Kampung Melayu Sungai Buloh, approximately, 2 km from Hospital Sungai Buloh, Selangor

As the national reference laboratory for the investigation of outbreaks and public health crises, NPHL was the main laboratory that conduct confirmatory testing for COVID-19. On the 24th of January 2020, MOH through the National Preparedness and Response Centre (CPRC) announced that eight (8) close contacts linked to the first COVID-19 confirmed case in Singapore were quarantined In Johor Bahru. The tourists reportedly entered Malaysia via Singapore on the 23rd of January

2020. Samples of all close contact were sent to NPHL on the same day for analysis.

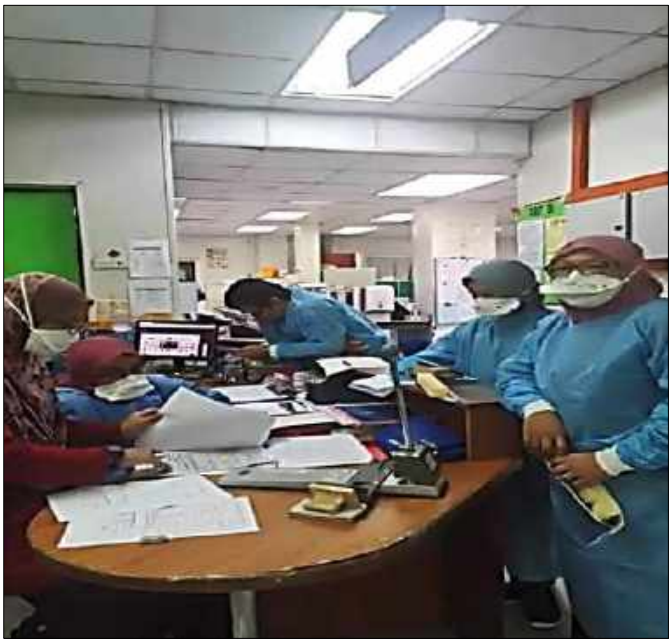


Figure 3.2: Picture showed on call staffs anxiously waiting for the first COVID-19 samples to arrive on the night of 24th January 2020.

After the registration and inspection processes were completed by the Sample Management Unit team, samples were transferred directly to the Virology Molecular Laboratory for the RT-PCR test. This method is the Gold Standard for COVID-19 confirmatory testing and briefly involved extraction, amplification, and identification of the tested viral components. The testing procedures were performed according to the testing protocol produced by WHO. In addition, the laboratory biosafety & biosecurity aspects were strictly adhered to and maintained throughout the procedures to control and minimize the potential risk of cross-infection.

At approximately 1130 pm, 24th of January 2020, the RT-PCR confirmed three (3) out of eight samples tested positive for SARS-CoV-2. This result showed a significant achievement for NPHL as the first laboratory in Malaysia to successfully identified and confirmed the first COVID-19 case in Malaysia.

Figure 3.3 The officers shown were the on-call team who conducted the RT-PCR test on the first COVID-19 cases in Malaysia at the Molecular Laboratory of Virology Section, NPHL.

The test results were officially recorded in *Sistem Informasi Makmal Kesihatan Awam* (SIMKA) OUTBREAK; an in-house LIS developed by NPHL. SIMKA OUTBREAK has been mandated by MOH Malaysia as the country's official LIS for the COVID-19 Pandemic on the 21st of October 2020. The SIMKA development was technically led by the Information Technology Unit in collaboration with the Epidemiology and Virology Team of NPHL.

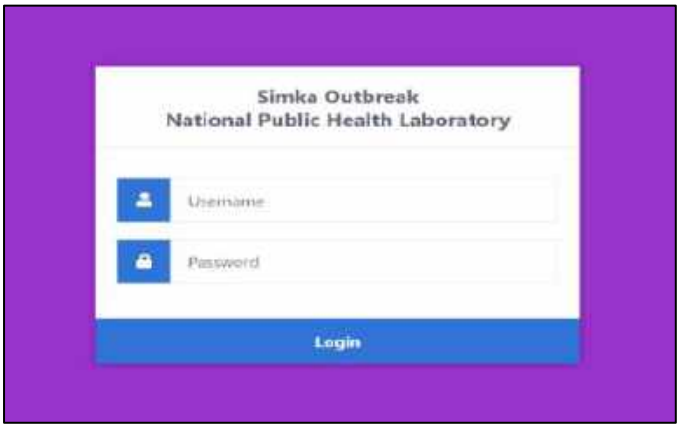


Figure 3.4: Login page of SIMKA; a web-based system recognized by MOH Malaysia as an official system for the Pandemic.

Figure 3.5: Mohd Addin @ Rusken Ruslan, an Information Technology Assistant Officers, leading the Coding System development & administrator of SIMKA.

Figure 3.6 : Study visit on work process and COVID-19 data flow at Point of Entry, KLIA

Figure 3.7 : The Epidemiology and IT Team that directly involved in SIMKA development and nationwide pandemic data analysis

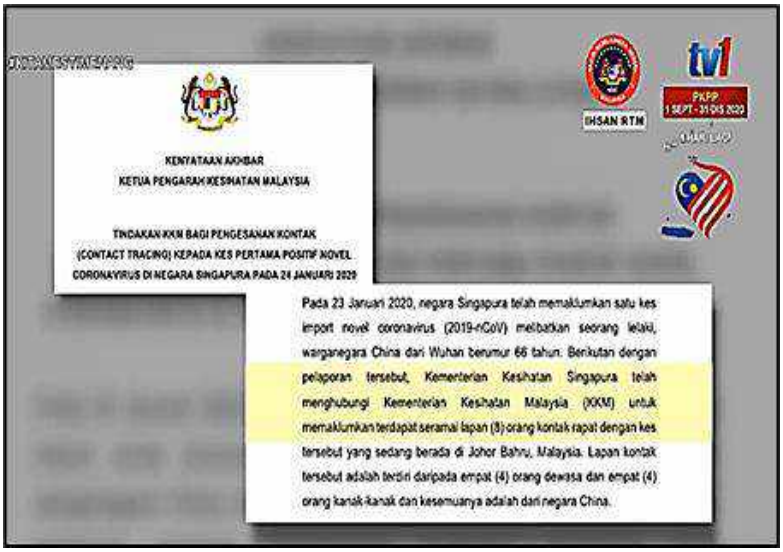


Figure 3.8: Notification of the first positive case of COVID-19 by the Director of Health, Malaysia

In addition, NPHL was also the first laboratory in Malaysia that produced live cultures of the SARS-CoV-2 virus in media cells; Vero 6 Cell line and conducted isolate examination using Transmission Electron Microscope (Figure 3.9).

Figure 3.9 : Selvanesan A/L Sengol, Head of the Virus Isolation Unit conducting virus examination using Electron Microscope

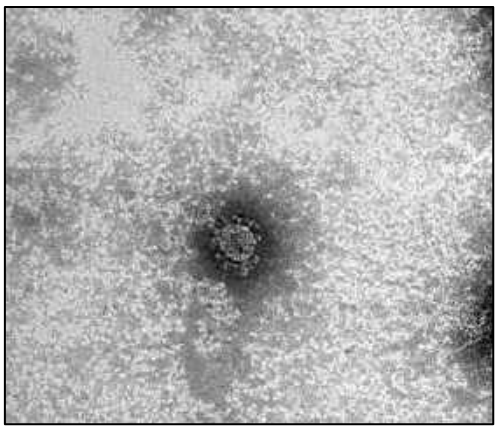


Figure 3.10 : Image of SARS-CoV-2 Virus captured using Transmission Electron Microscope (FEI, Tecnai spirit G2 120kv)

Figure 3.11: Dr. Hani Mat Husin, Director of NPHL that successfully spearheaded NPHL managing COVID-19 Pandemic

With these excellent achievements, NPHL will continue to grow as one of the leading laboratories contributing to strengthening public health laboratories services at the national as well as international levels.

 # LAB WARRIOR!!!!

 # KEEP MOVING!!!

 # KEEP FIGHTING!!!

CHAPTER 4

RESPONDING TO COVID-19 PANDEMIC

WRITERS

CHAPTER	NAME
4.1	Pn Yu Kie A/P Chem, En Selvanesan A/L Sengol, Cik Zirwatul Adilah binti Aziz
4.2	Dr Donal Huda binti Nasril, Dr Wan Amani Wan Abdul Azim
4.3.1	Dr Donal Huda binti Nasril, Dr Wan Amani binti Wan Abdul Azim
4.3.2	Dr Wan Amani binti Wan Abdul Azim, Dr Donal Huda binti Nasril , Dr Esah binti Md Ali
4.3.3	Dr Norfazillah binti Ab Manan, En Khairul Azan bin Hashim
4.3.4	En Selvanesan A/L Sengol, Dr Esah Md Ali, Nor Suhaili Suhaimi
4.4	Dr Mimi Rodzaimah binti Abdul Karim, Dr Santhi A/P Subramaniam, Dr Nor Zahrin binti Hasran
4.5	Dr Donal Huda binti Nasril, Dr Esah binti Md Ali, Pn Nur Shafinas binti Uyeup
4.6	Dr Nor Zahrin binti Hasran, En Selvanesan A/L Sengol
4.7	Pn Yu Kie A/P Chem, En Selvanesan A/L Sengol, En Kamal Hisham bin Kamarul Zaman, Pn Rehan Shuhada binti Abu Bakar
4.8	Dr Joshita Hephzibah A/P Jothimanickam, Pn Pusparani A/P Ramasamy
4.9	Dr Donal Huda binti Nasril, Dr Wan Amani binti Wan Abdul Azim, En Selvanesan A/L Sengol, Dr Esah Md Ali
4.10	Dr Mimi Rodzaimah binti Abd. Karim, Pn Salfaryna binti Alzahari, Pn Siti Fairuz binti Mar Ramli
4.11	Dr Donal Huda binti Nasril, Dr Wan Amani binti Wan Abdul Azim
4.12	Dr Joshita Hephzibah A/P Jothimanickam

4.1 Management of COVID-19 Sample

NPHL was and still is one of the main laboratories which manage a high number of COVID-19 samples on a daily basis, receiving the samples from public health facilities in the Central region which covered Klang Valley area, Negeri Sembilan and Malacca, and some parts of Pahang district. During the COVID-19 pandemic, NPHL occasionally received samples from other Regional PHL such as Johor Bahru, Ipoh, Kota Bharu, and Kota Kinabalu when these laboratories have reached their maximum daily capacity or when encountering other problems such as a shortage of consumables and reagent or having contamination issue. Arrangements were made to transfer their excessive samples to NPHL which has a bigger capacity. This is to ensure the Laboratory Turn Around Time (LTAT) of the COVID-19 test was within the acceptable time frame.

As all the samples were biohazards, therefore throughout the samples handling process, good laboratory techniques and standard operating procedures were used by the skilled and trained laboratory personnel which has helped to minimize risks and potential hazards. This required proper and appropriate Personal Protective Equipment (PPE) to be used all the time while handling the samples. The PPE included disposable gloves, a face shield, and a laboratory coat or gown, but may also include eye protection and other equipment based on risk assessment. A proper procedure to remove PPE was strictly adhered to by the laboratory personnel.

The first encounter with samples was at the Samples Receiving Unit (*Unit Penerimaan Sampel-UPS*) of NPHL. Once the samples arrived at UPS, the staff will check the specimens along with the testing request application from the requestor (respective health facilities) either using the manual form or via the electronic test ordering systems. Once they were cleared, the Virus Isolation Laboratory staff were contacted to transfer the specimen to the laboratory for testing. A dedicated route was used to transport the SARS-CoV-2 samples from the UPS to the Virus Isolation Laboratory (VIL) to separate them from the general staff route as shown in Figure 4.1.1 below.

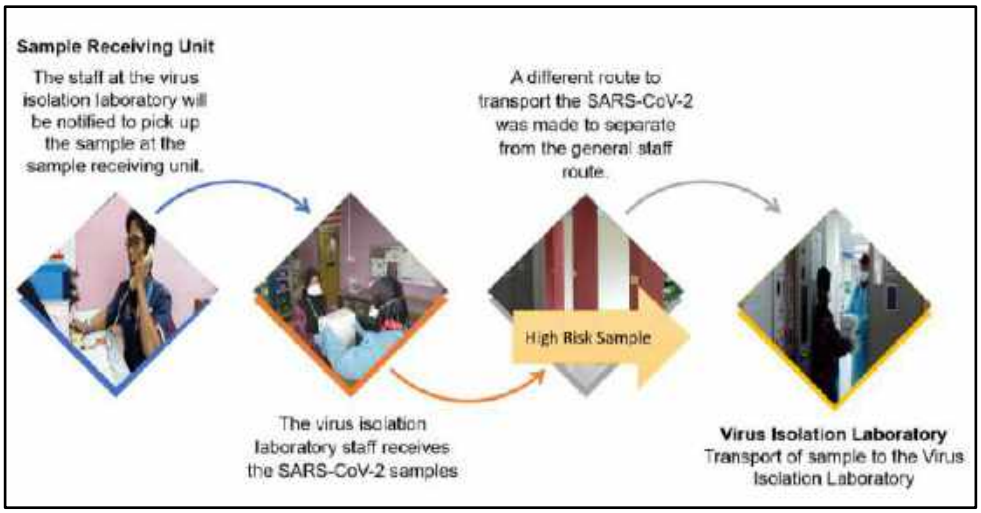


Figure 4.1.1: The workflow of handling SARS-CoV-2 samples from the Sample Receiving Unit to the Virus Isolation Laboratory of NPHL.

Malaysia has classified SARS-CoV-2 as a risk group 3 biological agent. However, to ensure sufficient testing capacity, as well as continuity of testing for COVID-19, the non-propagative diagnostic work involving RT-PCR for SARS-CoV-2 was conducted at Biological Safety Level 2 Laboratory (BSL) 2 with Biological Safety Level 3 Laboratory (BSL3) practices. Whereas, viral culture work was conducted in a BSL3 laboratory.

The samples were handled in the Biosafety Cabinet Class II type A2 in the laboratory to start the RT-PCR process. The first step is the RNA Extraction from the samples which includes three steps of lysis, washing, and elution. This was followed by the preparation of the master mix for RT-PCR in a clean room and the amplification process was done in a separate room to prevent cross-contamination of the RNA. This RT-PCR testing took two hours to complete and the detection is intended to confirm the presence of SARS-CoV-2 in the samples. The sample results were analyzed and verified in the SIMKA system to be accessed by the requestor later. These processes were simplified in Figure 4.1.2 below.

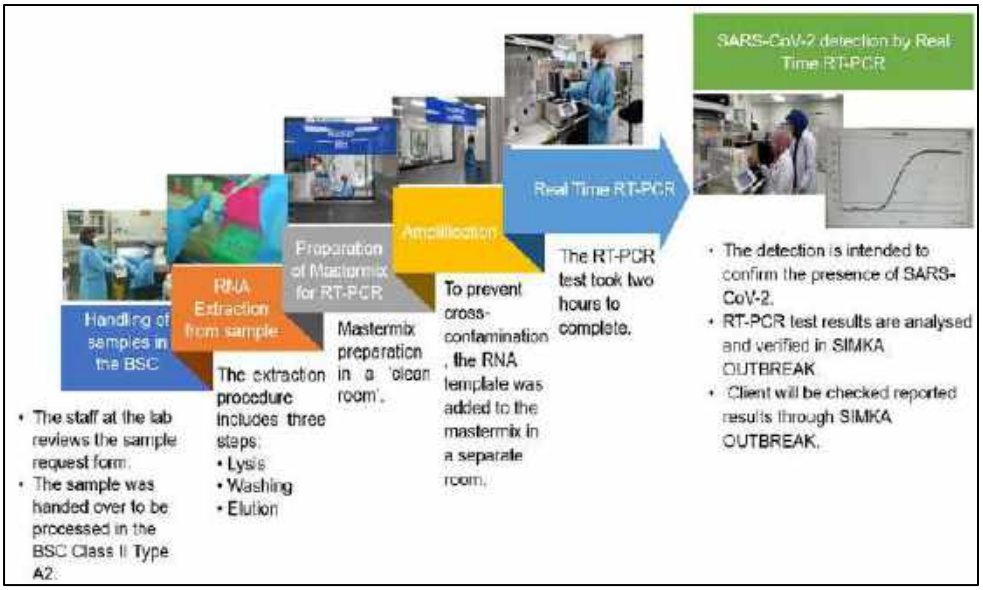


Figure 4.1.2: The process of RT-PCR in the laboratory.

In the beginning, all samples detected SARS-CoV-2 virus by real-time RT-PCR were cultured and isolated. The isolation work was done in BSL3 by trained science officers and medical laboratory technologists from the Virus Isolation Unit (Figure 4.1.3).

Figure 4.1.3: Virus isolation process in BSL3 Laboratory.

The detected samples and cultures were examined under Transmission Electron Microscope. The true ultrastructure of the SAR-CoV-2 were captured and published in the book with the title: Malaysian Health sector response to COVID-19 Pandemic in Year 2020 and also has been published in NPHL monthly bulletin (Figure 4.1.4).

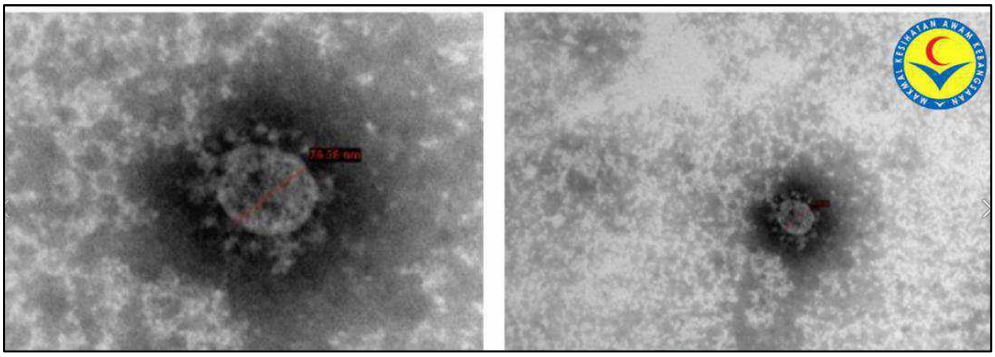


Figure 4.1.4: The true ultrastructure of the SAR-CoV-2 was examined and captured under Transmission Electron Microscope.

The COVID-19 Sample management at NPHL involves various processes and settings. It was done based on the Standard Operating Procedures of the laboratory by the skilled and trained laboratory personnel. The summary of the whole process of COVID-19 sample management at NPHL were shown in Figure 4.1.5 below.

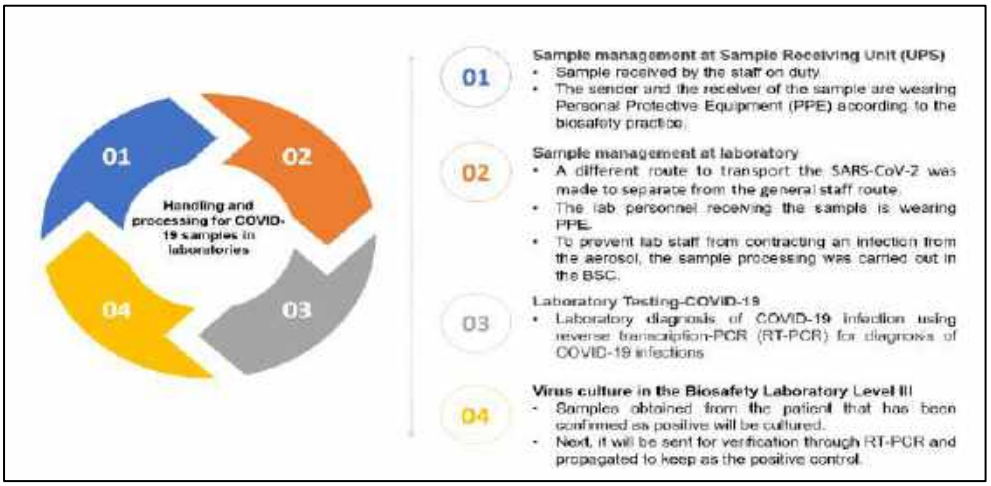


Figure 4.1.5: COVID-19 Sample management at NPHL.

4.2 Standardized Protocol and Technology Transfer

National Public Health Laboratory (NPHL) has been undertaking PCR testing for SARS-CoV-2 since the beginning of the pandemic in early January 2020. This initial capacity was expanded utilizing PHL laboratories, government hospitals, and private laboratories which have appropriate facilities. Due to the need to increase the testing capability enormously, NPHL was assigned to take the lead in providing technical guidance on molecular methods for detecting and identifying SARS-CoV-2.

After the detection of Malaysia's first imported SARS-CoV-2 from the samples receives from Regional PHL Johor Bahru (PHLJB), the validated WHO protocol was shared with PHLJB on 26 January 2020 during the training at NPHL. This laboratory protocol aims to establish PCR testing in the regional PHLJB to safeguard the influx of the Southern Border during the first import case from Singapore and contact tracing.

In order to increase the country's laboratory testing capacity for SARS-CoV-2 and ensure that all laboratory in Malaysia is using a standardization method and report on SARS-CoV-2 detection, the protocol, reagents, and consumables were also shared with the International Medical University (IMU) in March 2020. On 27 March, IMU was the first university that tested suspected samples of COVID-19 received from NPHL. IMU screened these COVID-19 samples as NPHL has been overwhelmed with an enormous volume of samples received on daily basis, especially during the Movement Control Order (MCO) between March to April 2020.

As the urge for more testing capacity is increasing, *Hospital Angkatan Tentera Tuanku Mizan* (HATTM) and Veterinary Research Institute (VRI) had offered their help in SARS-CoV-2 testing. Both institutions are members of the National Technical Advisory of Health Laboratories, Ministry of Health which was established in 2014 under the Malaysian Strategy for Emerging Diseases (MySED) Workplan (2012-2015) in full filling the requirement of the International Health

Regulation (IHR) 2005. Being part of the team members, all laboratories meet on regular basis to discuss any related issues pertaining to the laboratory. This networking has helped in sharing information including the protocols that we needed to be finalized.

NPHL have conducted SARS-CoV-2 PCR testing training for both HATTM and VRI in April 2020. At the end of the training, the WHO protocol was also been shared with them. By increasing the number of laboratories that could conduct SARS-CoV-2 testing, it could aid the country in COVID-19 testing as the demand is increasing exponentially.

Figure 4.2.1: PCR Reagents used for detection of SARS-CoV-2 virus.

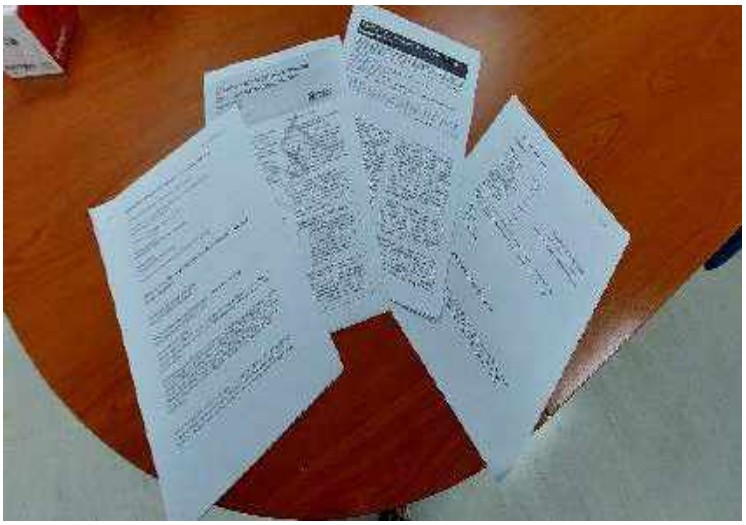


Figure 4.2.2: WHO Reference Realtime RT-PCR protocol used for detection of SARS-CoV-2 virus.

4.3 Surge Capacity Response

4.3.1 Interagency Training

MOH personnel were trained in several aspects and scopes to ensure they can meet the expectation while combating this pandemic. The scope includes the laboratory test (diagnostic), sample collection, data management, online system SIMKA (*Sistem Informasi Makmal Kesihatan Awam*), and use of Personnel Protective Equipment (PPE) conducted to Regional PHL, other government, university, and private laboratories. These technical trainings have been intensified and expanded beyond Ministry of Health facilities in order to ensure that all the laboratories handling COVID-19 samples are having the same understanding of pre-analytical and analytical requirements of the testing; specimen collection, packaging, and transportation, and safe use of Personal Protective Equipment (PPE), biosafety and security as well as data management which includes test request, tracing of result, result entry and others.

Training on laboratory capacity and capability had begun as early as January 2020. In the earlier part, only NPHL staff were trained in handling molecular testing for COVID-19.

Figure 4.3.1.1: Laboratory Training for COVID-19 Testing to NPHL personnel.

The first official training on the detection of COVID-19 by PCR method to PHRL was conducted on 26 January 2020 to PHL Johor Bahru (PHL JB) using BERLIN Protocol (WHO) following the collection of suspicious samples from eight (8) contact of the positive case in Singapore. Few other trainings were conducted for other Regional PHL ensuring their capacity and capability to face the pandemic. A series of technical training focusing on molecular testing was then expanded to all Regional PHL as early January 2020.

Figure 4.3.1.2: Inaugural COVID-19 training to PHL Johor Bharu (Regional PHL) to safeguard influx of Southern Border – 26 January 2020.

Figure 4.3.1.3: Introduction to laboratory procedures of COVID-19 testing to staff of Tuanku Mizan Millitary Hospital on 17th March 2020.

As SARS CoV-2 are level 3 organism, training on the usage of Biosafety Laboratory Level 3 (BSL-3) when handling the high-impact virus was also included in the training sessions. The Institution of Biosafety and Biosecurity (IBBC) team has looked into training on biosafety and biosecurity requirements and practices in the laboratory, with reference to WHO and CDC guidelines on handling high-risk organisms, transportation requirements of the biological material, disposal of samples and other.

Figure 4.3.1.4: A series of training was conducted for private hospitals, general practitioners (GP), and others to ensure on correct usage and disposal of PPE by Biosafety and Biosecurity Team NPHL.

Figure 4.3.1.5: Training on correct donning and doffing of PPE.

Besides laboratory tests and specimen handling, Information technology was also important during the COVID-19 pandemic as all the laboratory test results need to be validated in a timely. Transcription errors shall be minimized and results released within the specified time to enable the requestors to take immediate measures. Laboratory personnel was also trained on the management of COVID-19 data, how to use the online system SIMKA for test requests, sample registration, monitoring, and tracing of laboratory results was also conducted by the Information Technology (IT) team from NPHL.

Figure 4.3.1.6: Training on the SIMKA Outbreak: an official Laboratory Information System (LIS) for COVID-19 Pandemic

4.3.2 Surge Capacity Response: Quality Monitoring & Networking

The national laboratory system in Malaysia consists of multiple agencies from MOH facilities such as PHL and health clinic which is under Public Health Division, pathology laboratory in the hospitals which is under Medical Division, laboratory under Food, Quality and Safety Division and institutions such as IMR which is under Research & Technical Support Division. These laboratories come together under MOH management. Apart from this, there are also government laboratories and non-MOH facilities under other agencies such as veterinary, wildlife, universities, private hospitals, and laboratories. The interrelation of laboratories in Malaysia can be simplified in Figure 4.3.2.1 below.

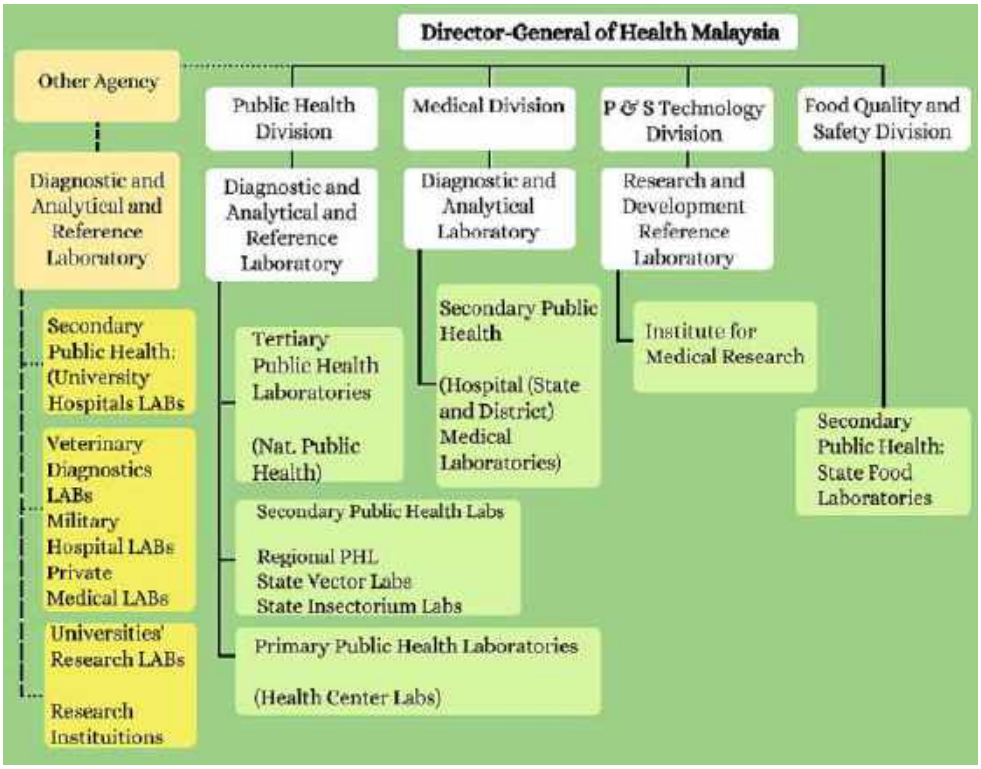


Figure 4.3.2.1: Level and category of laboratories in the National Laboratory System in Malaysia.

NPHL played an essential role through its active involvement in the daily National Crisis Preparedness and Response Centre (CPRC) meeting attended by MOH's top management and all state health directors nationwide. With the blessing of the Director General, The Special Laboratory Team Committee for COVID-19 (JPKMCOVID-19) was established in July 2020 under the National Laboratory Technical Advisory Committee (LTAC). Several personnel from NPHL have been appointed to be part of the committee consisting of pathologists, clinical microbiologists, scientists, public health physicians and medical officers from multiple agencies including NPHL, IMR, Hospital, and MOH headquarters.

The JPKMCOVID-19 committee was responsible for developing guidelines, monitoring, and management related to laboratories as well as monitoring the nationwide capacity and capability testing for COVID-19. Its main activity was ensuring that new laboratories in both government and private facilities were suitable and qualified to conduct RT-PCR tests for COVID-19 through technical evaluation and laboratory visits.

Any new private laboratory that planned to offer RT-PCR tests for COVID-19 must abide by the requirements and performance acceding to certain criteria before being approved to conduct the test. The JPKMCOVID-19 committee would appoint experts to visit the laboratory to determine the feasibility of the laboratory before they were allowed to offer the service. Areas that were looked at including Standard Operating Procedure (SOP), storage of specimens, temperature chart monitoring, maintenance, trained personnel, and verification method. In assuring the quality of test results, the laboratory was recommended to participate in the External Quality Assurance Program upon application. For non-accredited laboratories, the laboratories were advised to register for MS ISO15189 within 1 year from the approval date. Blinded samples were provided by NPHL to the laboratory that had passed the site visit. Approval only is given once the laboratories fully filled and passed all the requirements that were listed. Sharing of blinded samples was governed by the Material Transfer Agreement (MTA) of NPHL. The flow of work for

the application of a private laboratory to perform PCR COVID-19 till approval is shown in Figure 4.3.2.2 below.

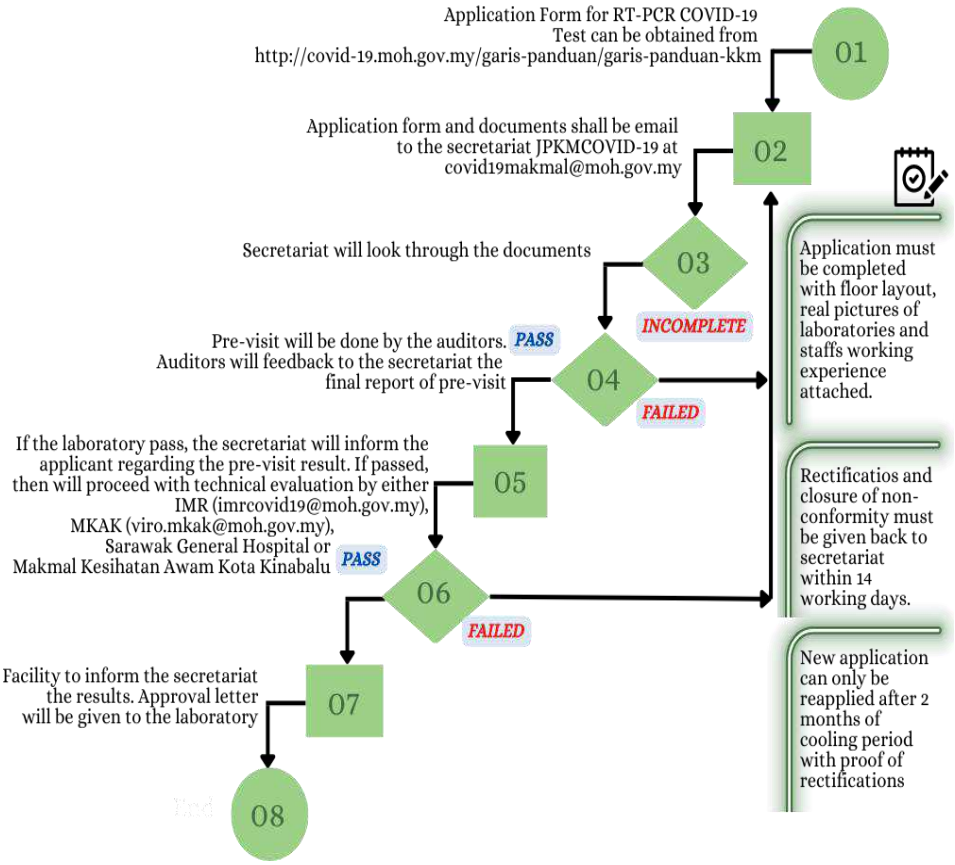


Figure 4.3.2.2: Flow of work for the application of private laboratory to perform PCR COVID-19.

During the JPKMCOVID-19 establishment, as many as 52 new private laboratories have been approved and NPHL personnel have been involved in several of the evaluation sessions as shown in Figure 4.3.2.3 below. The quality monitoring of the laboratories performing PCR COVID-19 is an important aspect in making sure these laboratories were on par

and able to be included in the country's laboratory capacity for COVID-19 testing.

Figure 4.3.2.3: One of the evaluation sessions of the private laboratory.

NPHL through the JPKMCOVID-19 team was involved in collaborative efforts with other government institutions, universities, and private entities in which the partnership and collaboration had harmoniously supported the expansion of COVID-19 testing across the country. The team persistently explored every opportunity to increase the national diagnostic capacity. NPHL has been involved in several meetings and discussions with relevant agencies to increase the nationwide laboratories' capacity and capability. A joint effort occurred with the Ministry of Higher Education (MOHE – in charge of university hospitals) to mobilize university laboratories, the Malaysian Genome Institute (MGI) laboratory which is under the Ministry of Science, Technology, and Innovation (MOSTI) as well as hospitals under Ministry of Defence to be part of the nationwide laboratory networking for the testing of COVID-19.

This networking among these agencies has expanded our nationwide laboratory capacity testing from 300 testing per day in January 2020 to more than 140,000 testing per day by January 2022.

Although in the initial phase, the government health facilities lead the country in the number of testing capacities, the number of private laboratories that were approved have been increased dramatically since middle of the year 2020. This increased the number of testing that was offered by them and thus increased the nationwide testing capacities as shown in Table 4.3.2.1 below.

Table 4.3.2.1: Laboratories capacities from January 2020 to January 2022 according to the type of facilities.

Facilities	Jan-20	Jul-20	Jan-21	Jul-21	Jan-22
NPHL	200	1,500	2,000	2,500	4,000
MOH Hospital	0	4,500	8,500	12,800	13,800
Regional PHL	0	3,200	5,500	7,800	9,200
IMR & CRC	100	5,000	5,200	6,000	6,400
ATM, MOSTI	0	200	390	530	530
Universities	0	1,000	2,400	3,400	3,400
Private labs	0	21,800	52,200	99,900	10,5900
TOTAL	300	37,200	76,190	132,930	143,230

The JPKMCOVID-19 activities and contributions were presented during the yearly National Laboratory Technical Advisory Committee meeting (Figure 4.3.2.4). As Malaysia currently move towards the endemic phase, JPKMCOVID-19 was set to dissolve during the NLTAC meeting on August 2022 and officially dissolved in September 2022 (Figure 4.3.2.5).

Figure 4.3.2.4: National Laboratory Technical Advisory Committee meeting on 11 August 2022.

Figure 4.3.2.5: JPKMCOVID-19 final meeting on 21 September 2022.

4.3.3 Surge Capacity Response: Public-Private Partnership

As COVID-19 cases were escalating, the number of samples among the COVID-19 suspected cases and contacts of the COVID-19 cases also increased especially in Klang Valley region. Thus, at a certain point, the number of samples that NPHL received was beyond the laboratory capacity. These samples need to be tested within 48 hours to allow public health measures to be taken accordingly to contain the outbreak and transmission. The public-private partnership has helped NPHL in dealing with the surge in capacity demand.

With the networking that NPHL had with other government laboratory facilities, the NPHL's samples were sent to these facilities when these samples exceed NPHL's maximum capacity. MOH hospitals, universities' laboratories under the Ministry of Higher Education, Malaysia Genomic Institute (Ministry of Science, Technology, and Innovation), and *Hospital Angkatan Tentera Tuanku Mizan* (Ministry of Defence) given the support and cooperation that were needed during this crucial time. These government laboratory facilities have helped and taken a part in testing the surplus samples that NPHL has received.

As the number of samples that NPHL received daily was not consistent, arrangements were made on daily basis according to the capacity of NPHL on that day and the capacity of the other government facilities. Information on the number of samples that the government facilities were able to receive was gathered by NPHL and arrangements were made to transport the samples to them. NPHL was responsible to ensure the government laboratories were fully utilized before reaching out to the private laboratories. When other government facilities were unable to receive NPHL samples, exceeding their capacity, arrangements were made with the private facilities. The arrangement to send some NPHL samples to the private facilities was called The Outsourcing Services and this service was used not only by NPHL but also by other government facilities to ensure the samples LTAT were kept within 48 hours. Figure 4.3.3.1 shows the flow of these Public Private Partnership Processes in NPHL.

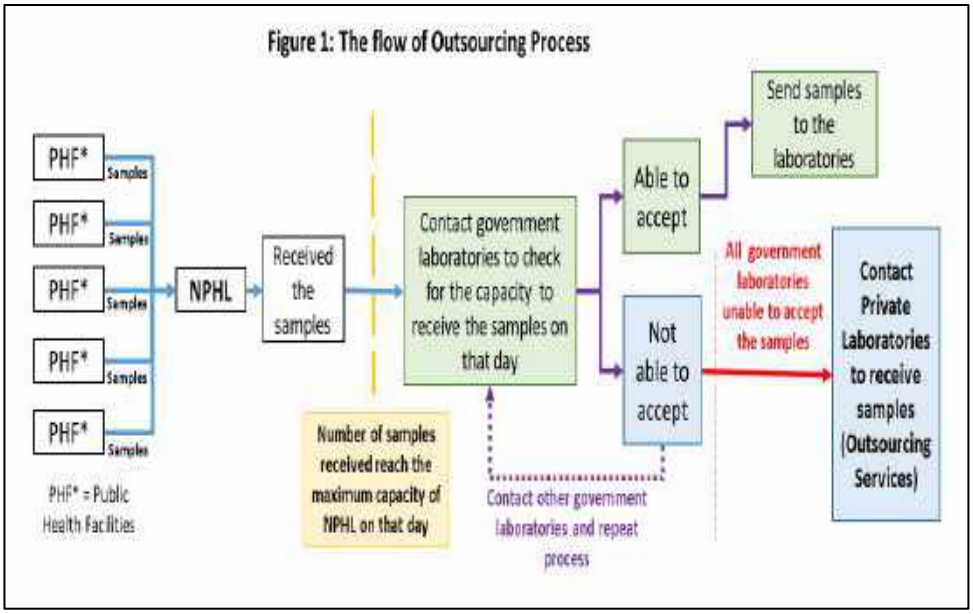


Figure 4.3.31: The flow of the Public Private Partnership Process in NPHL.

An agreement or contract was made between private laboratories and MOH for this Outsourcing Service which allows these private laboratories to receive samples from any MOH facilities. NPHL was involved in providing the Terms of Reference (TOR) for these services as well as the technical advisor. The TOR includes the agreeable payment, the flow of the outsourcing services, the process of reporting the results of the samples within the time allocated, and the penalty that shall be endured by the private laboratories should they fail to full fill certain criteria.

The Outsourcing Services with the Private Laboratories had its phases according to the situation and NPHL's role and responsibilities also expanded as time progressed. In the early phase, besides providing the TOR for the services, NPHL only plays a role as a user for this service. In the later phase, NPHL was also involved and responsible for the paperwork for the approval of these services, technical consultation for the user, provider, and stakeholder, monitoring the services that were provided by the private laboratories, monitoring the allocation that was

given to the State Health Department as the user, monitoring the quota given to the private laboratories as well as requesting for additional quota and budget requirement for this service. Figure 4.3.3.2 showed the summary of the role and responsibilities of NPHL throughout the Outsourcing Service involving these private laboratories.

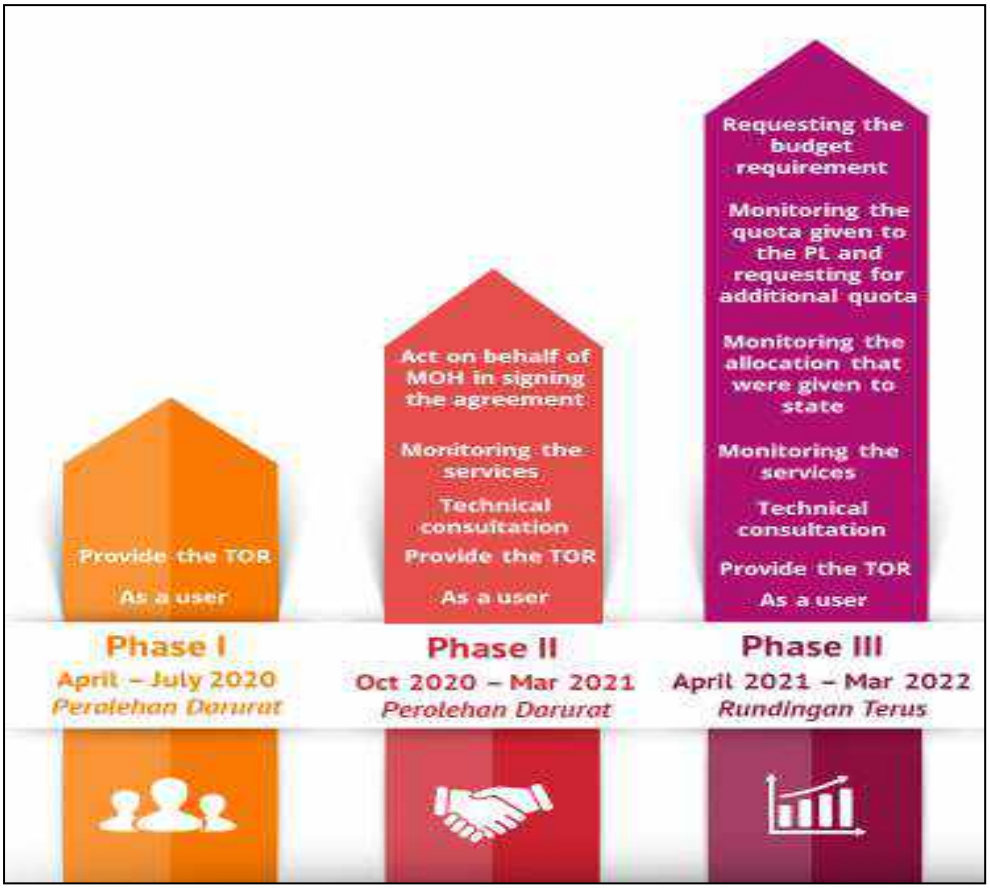


Figure 4.3.3.2: The expansion role and responsibilities of NPHL throughout the outsourcing service involving the private laboratories.

As a service user, a team in NPHL has to go thru several steps to verify the services that were provided by the private laboratories before payment can be made to them as shown in Figure 4.3.3.3.

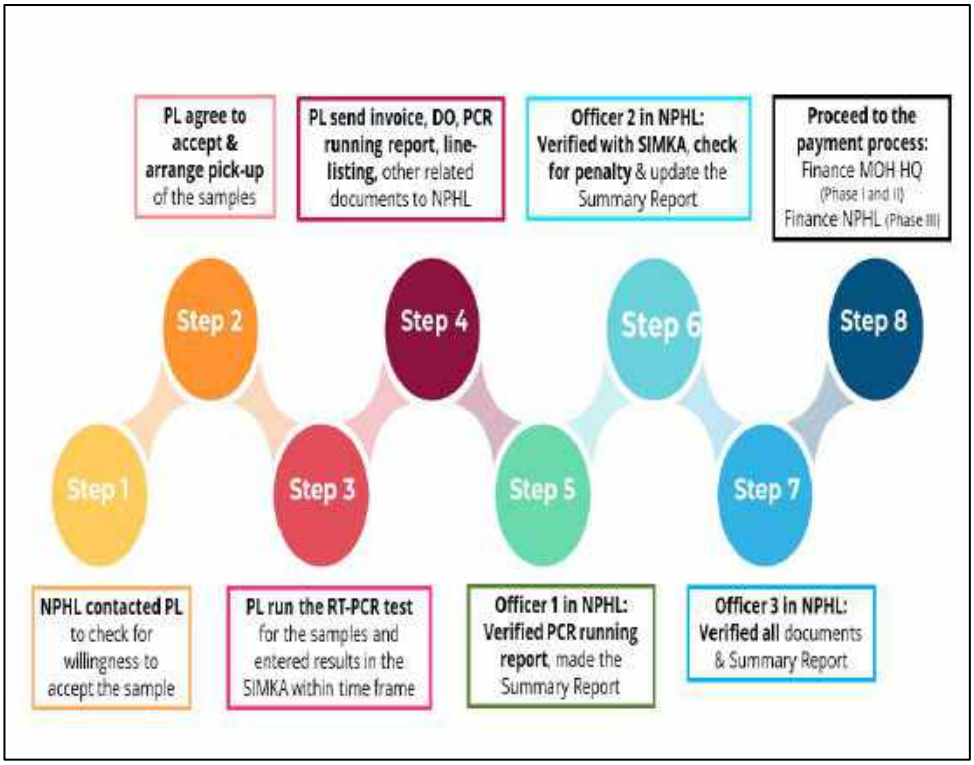


Figure 4.3.3.3: Steps from samples being outsourced from NPHL until payment received by private laboratories.

The outsourcing services is important as MOH internal capacity is limited during the pandemic at a certain of time. The Outsourcing Services have provided the necessary response to scale up the national laboratory services.

4.3.4 Surge Capacity Response: Laboratory Service Expansion

Following the detection of Malaysia's first COVID-19 case, twenty-two (22) more cases were detected as this was declared as Malaysia's first wave. The second wave broke out on 27th February after 11 days of no new cases (1). Cases were escalating and became apparent in the middle of March and this was brought by the Sri Petaling cluster as shown in Figure 4.3.4.1 below (2).

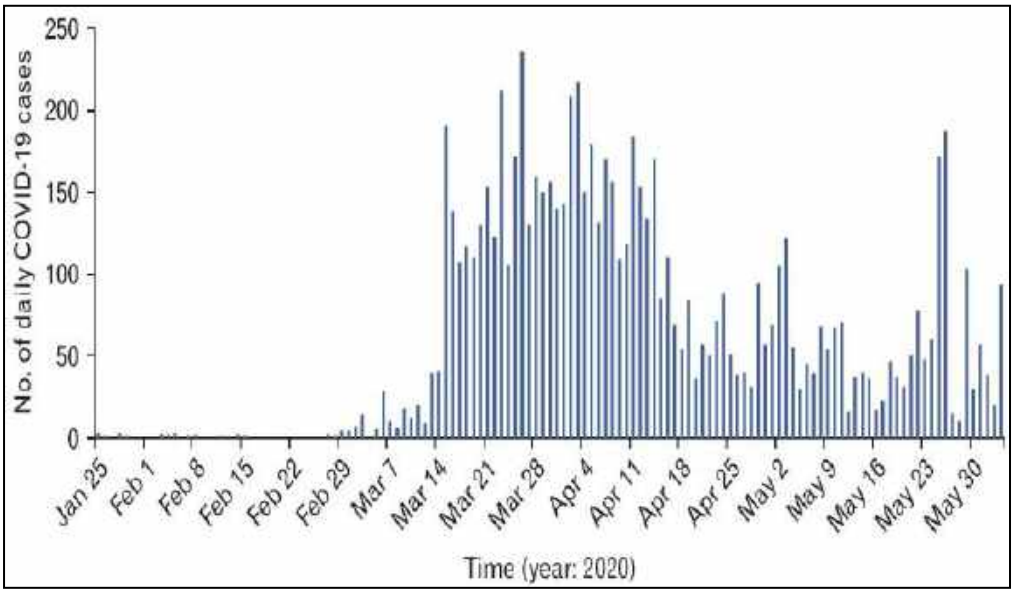


Figure 4.3.4.1: Trend of COVID-19 cases in the year 2020 (2)

As most of the cases and clusters were concentrated in Klang Valley and Central Region, hence the number of samples received by NPHL has also increased. In response to this, the NPHL laboratory services need to be expanded to cope with the increasing workload. Since the sample preparation, extraction, and master mix work were done in a manual process during the early phase, the RT-PCR testing led by the Virology Section Team required an additional number of skilled laboratory personnel. Internal staff mobilization was immediately done to support the services. This involved mobilization of laboratory

personnel within and across divisions in NPHL. Staff from the Bacteriology, Tuberculosis & Leprosy, Parasitology, Biochemistry, and Entomology Sections of the Disease Division as well as from the Food and Quality Divisions added to the main team to conduct RT-PCR tests. This effort was to make sure the LTAT of the samples was kept within 48 hours. The numbers of RT-PCR of SARS-CoV-2 done in NPHL according to Epidemiology Week in the year 2020 was shown in Figure 4.3.4.2 below.

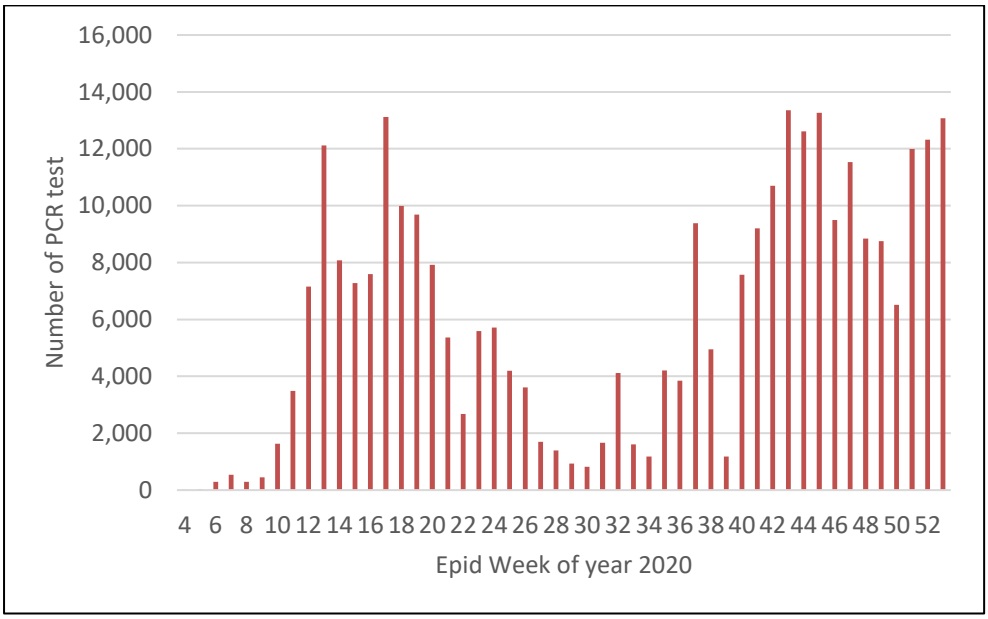


Figure 4.3.4.2: Numbers of RT-PCR of SARS-CoV-2 done in NPHL according to Epidemiology Week in the year 2020 (SIMKA)

Apart from human resources aspects, there was a need for the equipment and space to be expanded following the increased number of samples and testing. Other laboratories that were used for testing beyond the Virology Laboratory are the Bacteriology, Tuberculosis, and Parasitology laboratories from Disease Division. Other than that, two other laboratories (food molecular and food microbiology) from Food Division as well Quality Laboratory were used for the sample preparation and sample extraction process.

MOH had given the support that was needed for NPHL to procure equipment, reagent, and disposables to help in the expansion of the laboratory. In the mid of the pandemic, NPHL procured automated sample processing equipment which include the auto extractor, liquid landler, and a few real-time thermocyclers (PCR Machine). To smooth the testing process supporting equipment such as the chiller, freezer, incubator, centrifuge, vortex mixer, and other small equipment were also procured. Apart from this, NPHL also received laboratory equipment and consumables from international agencies such as WHO and International Atomic Agency Association (IAEA).

In the early pandemic, Malaysian Genome Institute (MGI) supported MOH by placing their mobile BSL 3 laboratory at NPHL to help in the laboratory expansion (Figure 4.3.4.3) to increase the capacity of testing. However, the placement of mobile BSL 3 was temporary due to logistic issues and was removed a few months later.

Figure 4.3.4.3: Mobile BSL 3 that was placed by MGI at NPHL during the early phase of pandemic

The capacity of NPHL was further increased when NPHL was approved to set up a modular laboratory. This has increased the additional testing capacity of 1500 to 2000 samples per day. NPHL secured two sets of PCR semi-automated systems and placed the equipment in the cabin (Modular laboratory) which was specially constructed near the futsal field. The L shape modular laboratory was designed and built to accommodate both semi-auto and fully automated equipment. The framework of the laboratory was built at the factory and later relocated to NPHL which took two months to complete (Figure 4.3.4.4).

Figure 4.3.4.4: Relocation of modular laboratory in NPHL

The summary of NPHL laboratory expansion was shown in Figure 4.3.4.5 below.

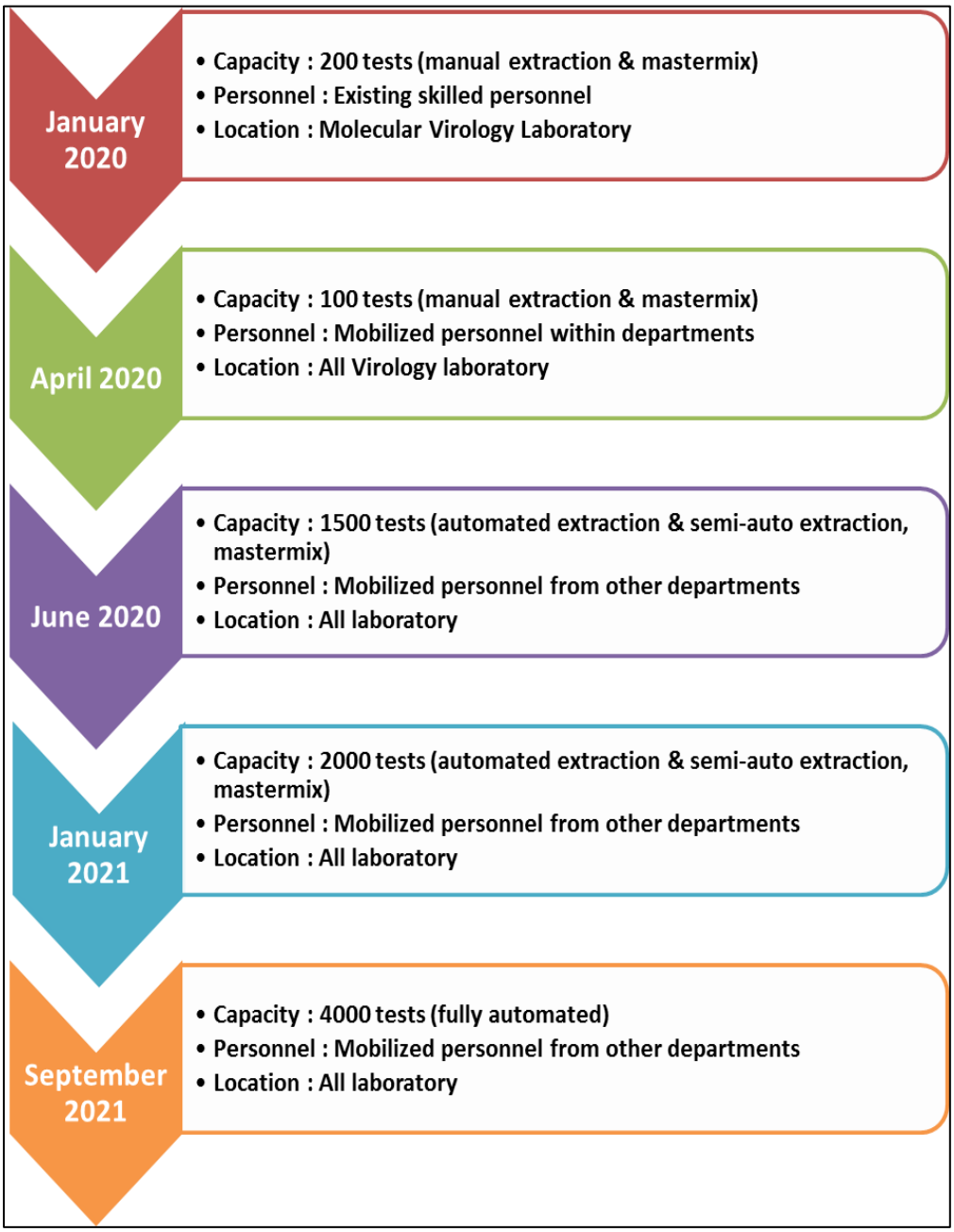


Figure 4.3.4.5: The timeline of laboratory expansion in testing capacity, human resources, and laboratory involvement

As part of the laboratory mitigation strategy, for COVID-19, one (1) molecular laboratory was built in the Regional Public Health Laboratory Kota Kinabalu Sabah during the Pandemic. This project was conducted in collaboration with the Department of Engineering, MOH, Sabah State Health Department, and JKR Sabah, and coordinated by Project Team, NPHL. In addition, NPHL has also helped to increase the testing capacity at the Point of Entry (POE), Kuala Lumpur International Airport (KLIA).

Figure 4.3.4.6: Laboratory Equipment received from International Donor

Figure 4.3.4.7: Laboratory under construction

Figure 4.3.4.8: New Molecular Laboratory completed and operationalized built for Regional Public Health Laboratory Sabah

Figure 4.3.4.9: Mobilization of Biosafety Cabinet and Tender & Commissioning Process with KLIA medical team at Kuala Lumpur International Airport

Reference

1. Ng CFS, Seposo XT, Moi ML, Tajudin MABA, Madaniyazi L, Sahani M. Characteristics of COVID-19 epidemic and control measures to curb transmission in Malaysia. Int J Infect Dis. 2020 Dec;101:409-411. doi: 10.1016/j.ijid.2020.10.027. Epub 2020 Oct 17. Erratum in: Int J Infect Dis. 2021 Feb;103:642. PMID: 33075527; PMCID: PMC7567666.
2. Amaran S, Kamaruzaman AZM, Mohd Esa NY, Sulaiman Z. Malaysia Healthcare Early Response in Combatting COVID-19 Pandemic in 2020. Korean J Fam Med. 2021 Nov;42(6):425-437. doi: 10.4082/kjfm.20.0117. Epub 2021 Nov 20. PMID: 34871483; PMCID: PMC8648488.

4.4 Expansion Laboratory Surveillance System

In response to the COVID-19 pandemic, NPHL has expanded the laboratory-based surveillance system to monitor and captured the data as much as possible. The ILI surveillance has been expanded as well as enhanced the SARI Surveillance. The pre-operative and pre-admission screenings were also included as part of COVID-19 surveillance.

ILI Surveillance

The number of sentinel clinics remained the same until there was the need to increase. During the mid-year of 2020, COVID-19 cases were low or almost nil in Malaysia. Strengthening surveillance was important to detect and contain outbreaks in order to protect those most at risk of severe and poor outcomes in the community. Thus, the MOH has decided to increase the number of sentinel sites for this purpose totaling 26 sentinel sites with the criteria remaining the same.

Over the 1-year course of time, the number of sentinel sites escalated to 41 sentinel sites in October 2021. There was added value in this quantum change. First, the sentinel sites were selected to represent the community as a whole regardless of rural or urban. Secondly, instead of testing only for the SARS-CoV-2 virus, it was also a high time to detect Influenza viruses (A and B). Not only managing a pandemic was the priority of the country of that time but proper detection of disease-causing organisms is very critical in controlling the course of outbreaks and avoiding large-scale epidemics.

The latter was an important advancement as surveillance data shows there was an increment in the Influenza positivity rate detected in sentinel sites. After considering the capacity and capability of the public health laboratories to process the collected samples, additional sentinel sites were augmented as shown in Figure 4.4.1. Currently, the country has 59 sentinel sites are operating throughout the country

using the same case definition and criteria. The number of samples received for this surveillance is shown in Figure 4.4.2 below.

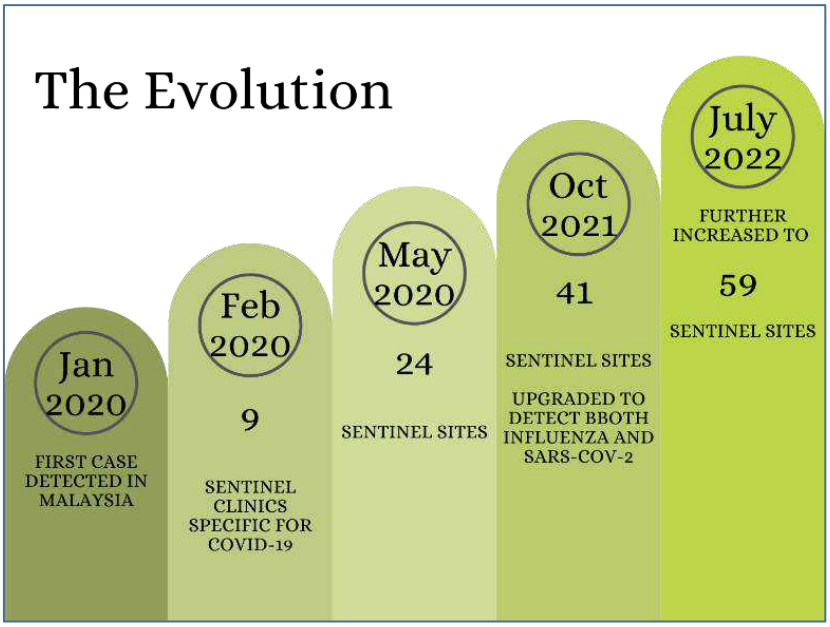


Figure 4.4.1: The evolution of Sentinel Sites (clinic) for COVID-19. Surveillance.

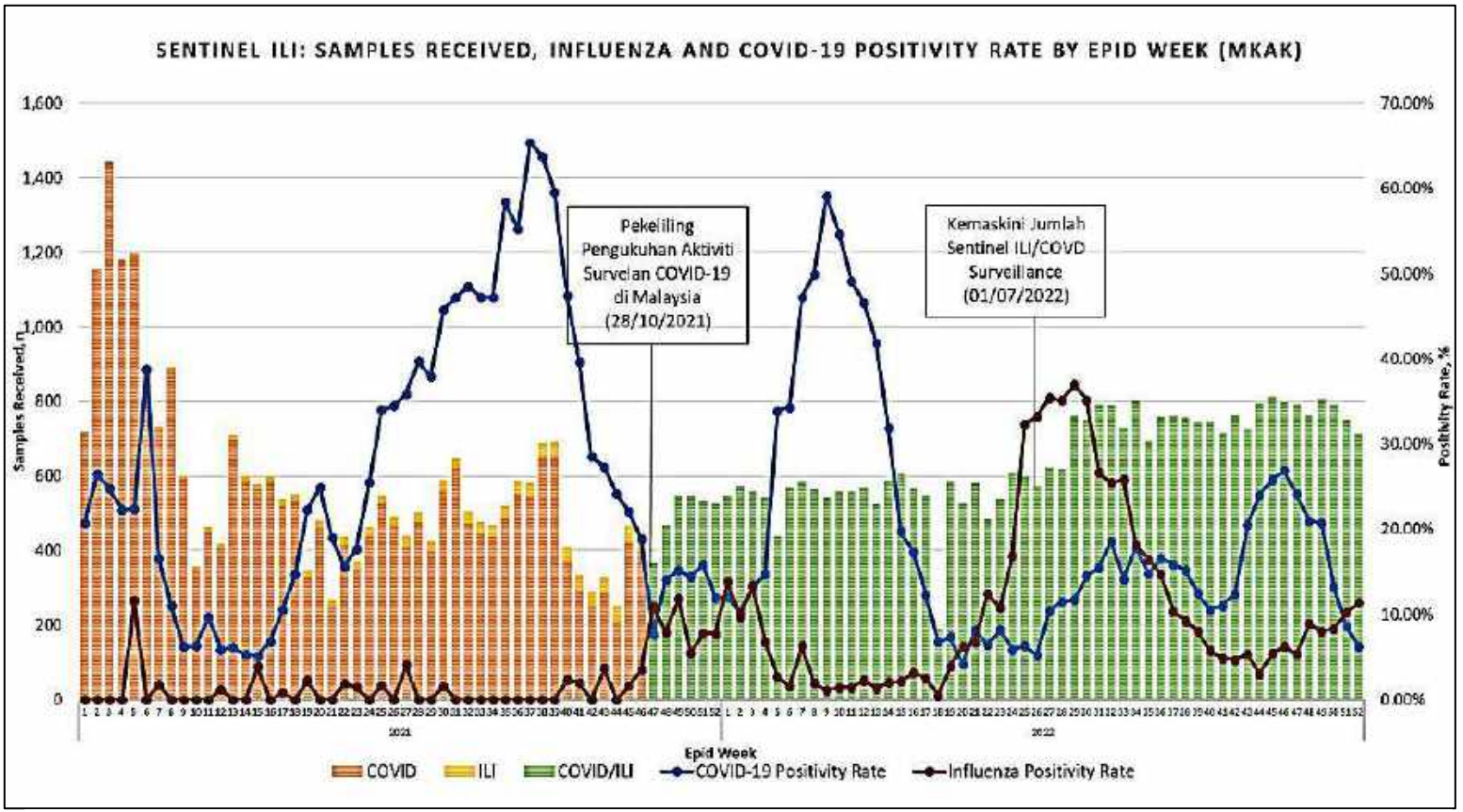


Figure 4.4.2: Sample received, Influenza, COVID-19 Positivity Rate by Epid Week for ILI Surveillance, 2022, Reported by NPHL.

SARI Surveillance

The number of Malaysia's reported COVID-19 cases was at a surge by August 2020, and the likelihood of community transmission. The World Health Organization (WHO) has modified the COVID-19 suspect case definition to include severe acute respiratory infection and advises testing of all severe acute respiratory illness (SARI) cases. The WHO case definition of severe acute respiratory infections (SARI) is anyone with acute respiratory infection with symptoms within 10 days of presentation, cough, fever, and hospitalization. It is important to understand to integrate testing for SARS-CoV-2 for a better understanding of the presence of undetected cases among SARI patients. This initiative will inform country control and response effort, and provide nations with situational analysis, risk assessment as well as the capacity of the health system to respond to the outbreak. The majority of Member States of WHO have sentinel surveillance systems for influenza-like illness (ILI) and SARI and they take part in the Global Influenza Surveillance and Response System (GISRS). Leveraging this system for COVID-19 is an advantage because patients can be investigated with a similar clinical presentation to COVID-19 who are hospitalized.

There were 18 hospitals nationwide selected for SARI surveillance. The criteria were also set for sample management from the hospital to the testing laboratory, Institute of Medical Research (IMR). Besides fulfilling the definition other criteria were samples taken either by NP and OP swab, sputum or aspirate, and 5 samples per week. The number of samples received for this surveillance is shown in Figure 4.4.3 below.

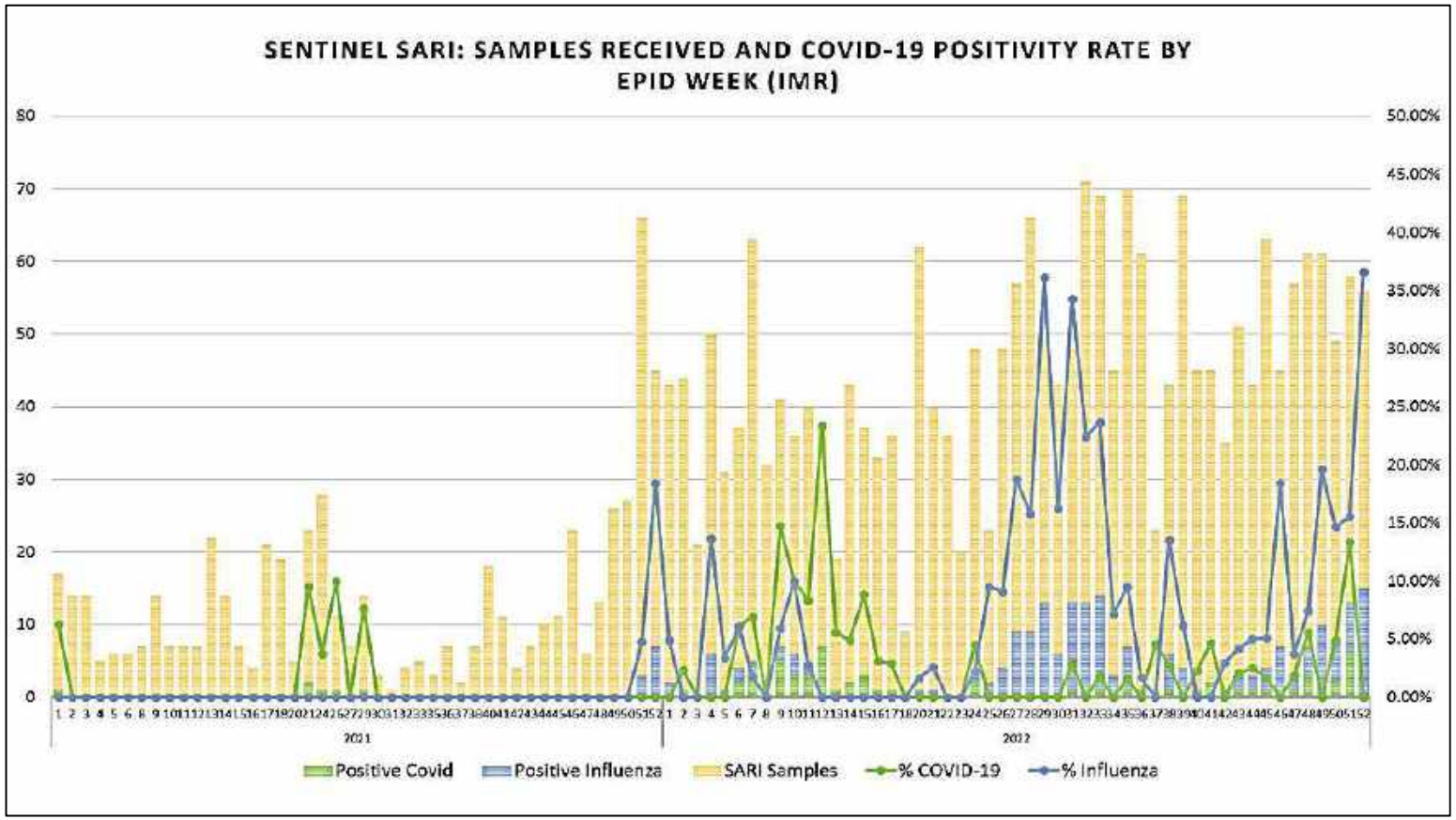


Figure 4.4.3: Samples received, Influenza and COVID-19 Positivity Rate by Epid Week for SARI Surveillance, 2022, Reported by IMR.

Pre-admission and Pre-operation Screening as Additional Surveillance

The Pre-admission and Pre-operation Screening were started in mid-2020 with the purpose to detect COVID-19 cases among patients that will be admitted or attending any operation/daycare procedure in the MOH hospital. This was to prevent the patients become the source of transmission in MOH hospitals if they become undetected COVID-19 patients. The screening uses both testing modalities which were the RTK-Ag professional that can give fast and rapid results and also PCR for the hospital that has the capability to run these samples at their own setting.

As the screening was done in the MOH hospital, these data were data captured by the Medical Division of MOH. These data will then share with NPHL for further analysis and reporting it as part of the Laboratory-Based Surveillance System (Figure 4.4.4 and Figure 4.4.5).

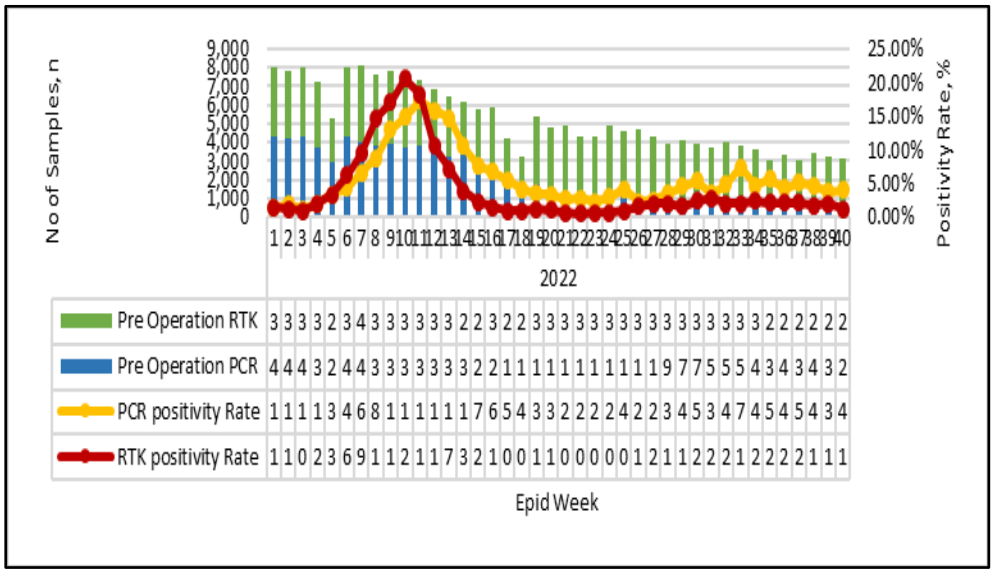


Figure 4.4.4: Pre-Operation Surveillance: Total PCR and RTK-Ag (P) samples and Positivity Rates by Epid Week.

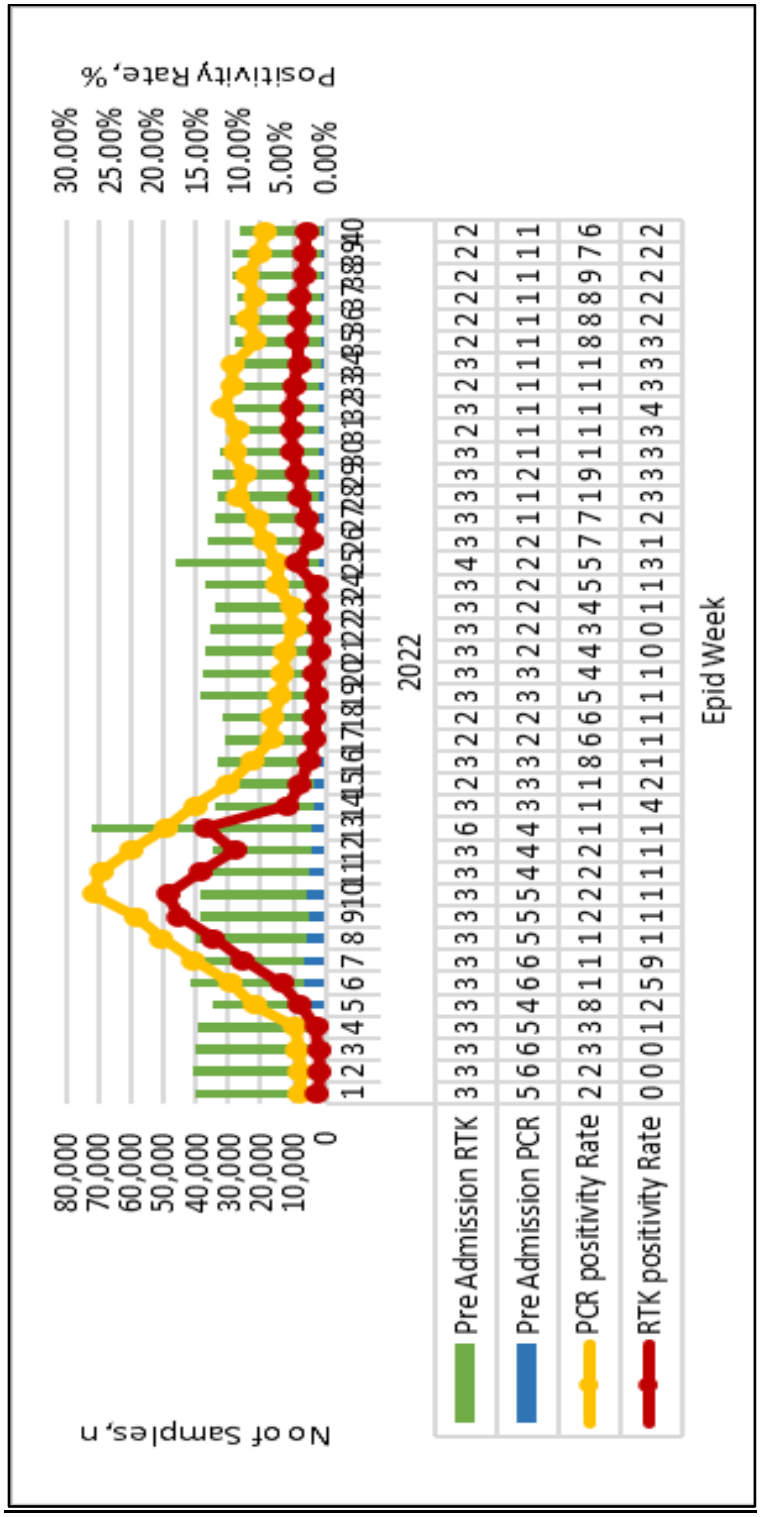


Figure 4.4.5: Pre-Admission Surveillance: Total PCR and RTK-Ag (P) samples and Positivity Rates by Epid Week.

4.5 Laboratory Resource Procurement

During the emergency state of the COVID-19 Pandemic, most of the procurement of reagents and assets was done under direct negotiation via central procurements. NPHL and IMR has taken lead on the procurement of the consumables, reagents, and assets for COVID-19 under central procurement of MOH to be used by government facilities such as health clinics and hospitals. Items such as consumables, reagents for RT-PCR, rapid test kits, personal protective equipment, swabs & Viral Transport Media, containers for deep throat saliva (DTS), and assets for molecular testing.

Procurement during COVID-19 Pandemic was conducted using disaster procurement protocol to ensure uninterrupted laboratory supplies to all laboratories and facilities under MOH. The main issue and challenges that need to be overcome during this process such as logistics, prices increase, high demand, disease burden, kit optimisation and outsourcing. During the early pandemic, there was a huge problem with the transportation of reagents and assets worldwide. This has delayed the reagent supply during the Movement Control Order (MCO).

Besides reagents, disaster procurement was also, conducted for improving the capacity and capability of the laboratory test via central purchasing of items such as the real-time thermal cycler, automated extractor machine, liquid handler, and fully automated PCR machine had speed up the laboratory capacity in handling a large amount of sample for COVID-19 testing. These were done mainly by NPHL and IMR to ensure uniformity of equipment and technology used at the MOH facility for COVID-19 testing, at the same time it greatly helps the laboratory in comparing their test result when needed.

Fully automation or semi-automation of COVID-19 tests in the laboratory are greatly increased the laboratory capacity while speed up testing capacity, reducing pipetting error, minimizing possible cross-contamination and reducing the dependency on human resources. NPHL

also procured a fully automated system that has increased the capacity of testing up to 5000 tests per day.

Figure 4.5.1: Meeting on Mapping of Stockpiling and Preparation for Disaster Procurement.

Figure 4.5.2: The interview process for disaster procurement with the local supplier conducted by NPHL.

The procurement not only involved the reagents and consumables for the testing procedure (Figure 4.5.3) but also laboratory assets and equipment that were procured to increase the laboratory capacity and offer advanced technologies testing (Figure 4.5.4). The example of items that were procured by NPHL during the pandemic COVID-19 are shown in Figure 4.5.5 below.

Figure 4.5.3: The reagents and consumables (VTM and Rapid Test Kit) that were procured during the pandemic COVID-19.

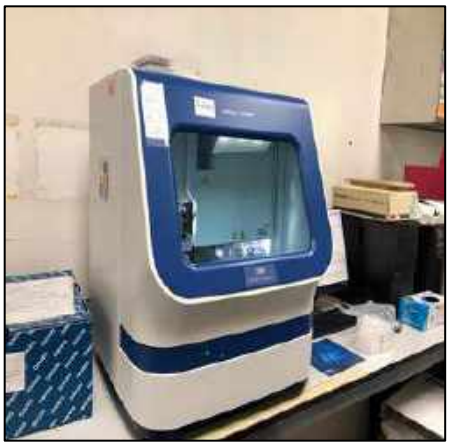


Figure 4.5.4: The laboratory assets and equipment that were procured during pandemic COVID-19.

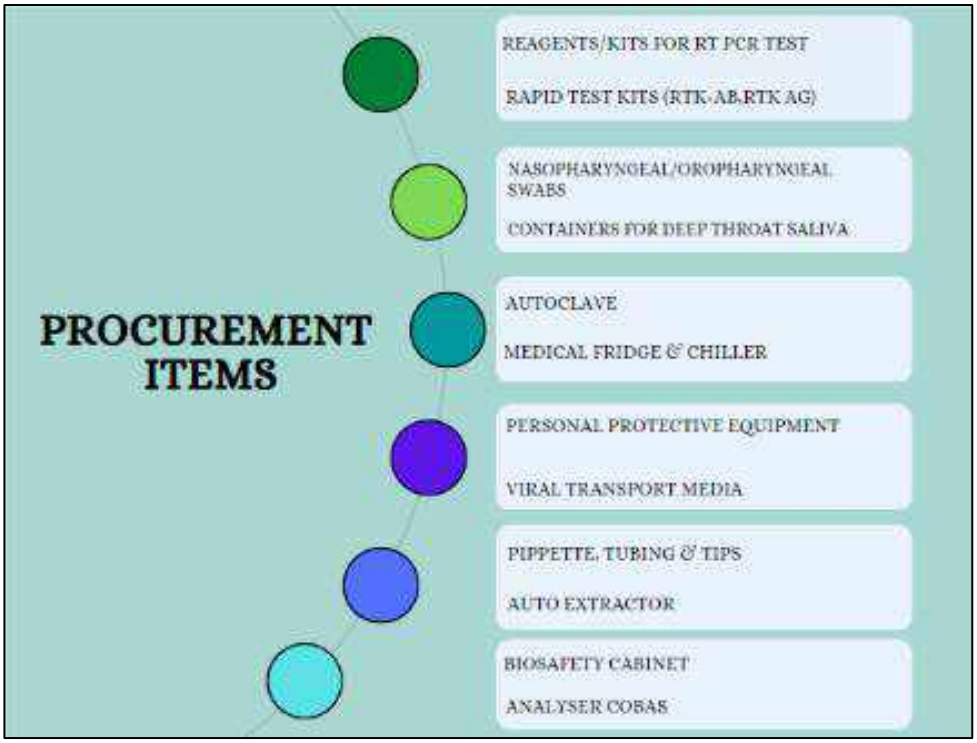


Figure 4.5.5: Examples of items that were procured by NPHL during the pandemic COVID-19.

A dedicated team in NPHL was given the responsibility in managing the procurement including managing the storage and distribution of the items to other MOH facilities. As only selected facilities are dealing with procurement, locality of storage centres were identified for items purchased under disaster procurement. The items were properly kept and the movement of items was monitored and recorded. The first-in-first-out practice was implemented and generally governed by product expiry date. Whilst COVID-19 cases continue to increase, these stocks were closely monitored to ensure a sufficient quantity of stockpiles available at all times.

The goal of central procurement is to ensure a stable and uninterrupted supply of items during disaster or emergency uses. As most of the countries were greatly affected with the pandemic, shortages of supplies were faced globally due to high demand, movement control

orders, as well as travel restrictions, and temporary closing of major industries including the production of laboratory supplies and PPE, were posed a great challenge in procuring laboratory and medical items during pandemic.

Figure 4.5.6 :Storage of procurement item.

Figure 4.5.7: Reviewing records for stockpiling by the Administrative Team of NPHL.

A dedicated team of NPHL involving the Technical Laboratory Team, Finance Team and Administrative Team were the main key players in making the Laboratory Resource Procurement process went smoothly without any hiccups (Figure 4.5.8).

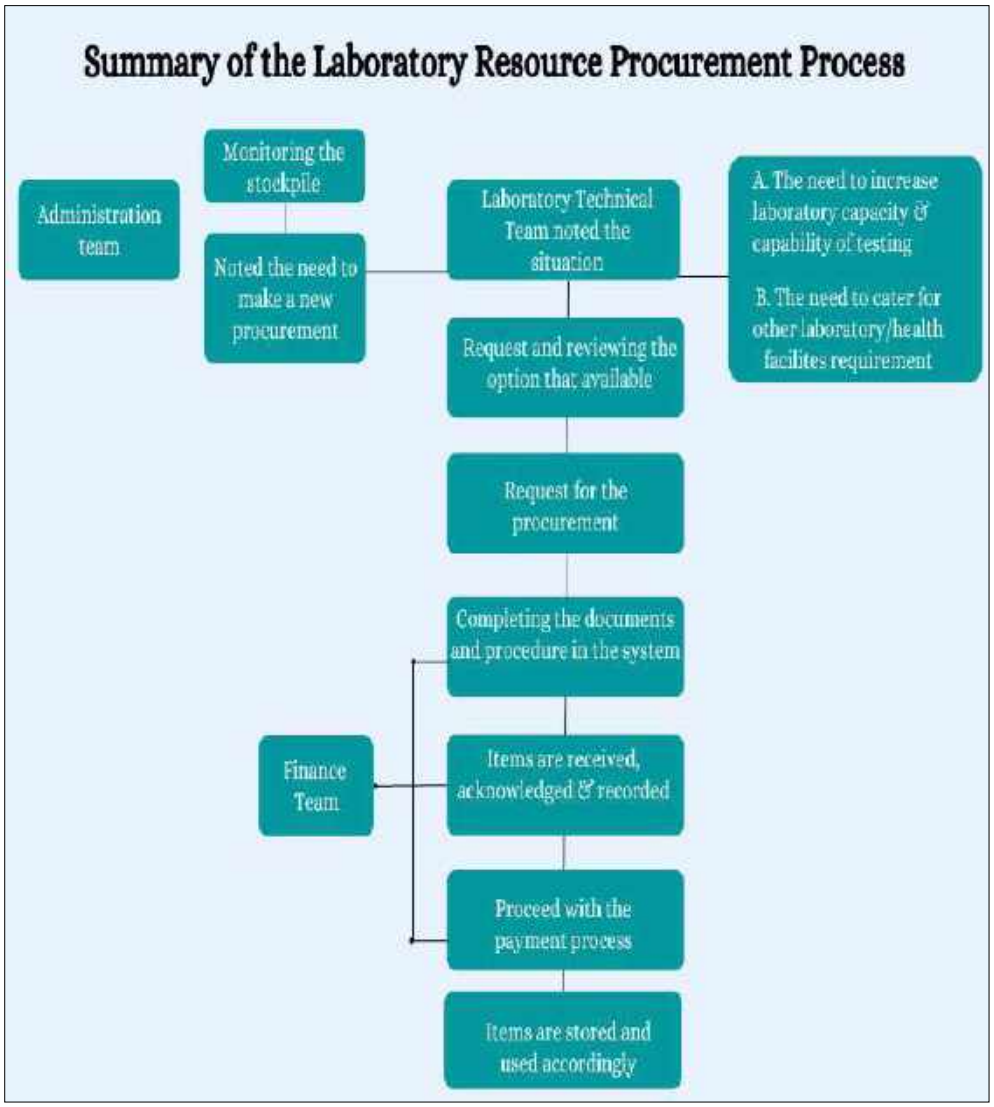


Figure 4.5.8: Summary of the Laboratory Resource Procurement process in NPHL.

4.6 Production of Biological Material

In detecting of the SARS-CoV-2 virus during the COVID-19 pandemic, it depends on the quality of the sample specimen and the conditions under which the specimen is transported and stored before being processed in the laboratory. This is because, unless stored in an ultra-low temperature freezer or in liquid nitrogen, virus samples, and especially RNA virus samples, are prone to degradation. However, such cooling equipment is seldom available in the field due to their cumbersome size, weight, and in the case of freezers, high energy consumption (1). Therefore, these samples need to be put in a media or solution that is able to preserve virus specimens after collection so that the samples can be transported and analyzed in a laboratory at a later time.

Viral Transport Medium (VTM) a chemical preservative that can be used at ambient temperature; allows the safe transfer of viruses including SARS-CoV-2 for diagnostic tests, further research, including conventional cell culture methods and molecular biology techniques (2). Aside from getting the supply from the commercial supplier, the VTM also can be produced in-house for laboratory settings following a high standard procedure which requires the VTM must sustain viral integrity and suppress contaminating microorganisms that might interfere with diagnosis (3). NPHL has been involved in in-house VTM production prior to the pandemic and has produced on average between 5,000 to 6,000 units of VTM bottles per year.

However, the sudden arrival of the COVID-19 pandemic placed significant stresses on supply chains including VTM (4). Malaysia was also not spared from the lack of supply of VTM locally due to the high demand and the country's lockdown measures which prevent the VTM stock from come-in during the beginning of the pandemic. In view of this, NPHL has massively increased the production of the in-house VTM up to 186,000 units of VTM bottles in 2020. The peak production was between March to May 2020 (an average of 55,000 VTM bottles per month) during the surge of cases and slowly reduced once the supply was under control. The in-

house VTM that was produced by NPHL used a glass container as compared with other commercial VTM as shown in Figure 4.6.1 below.

Figure 4.6.1 (a)

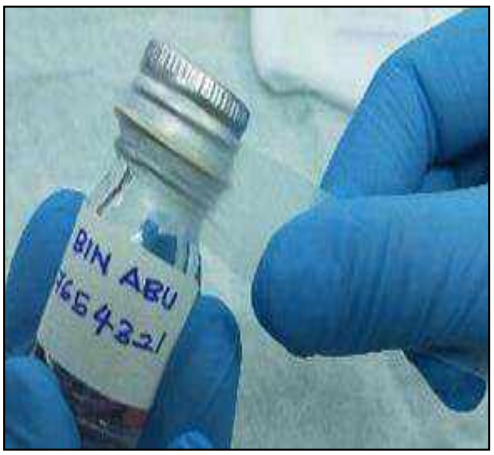


Figure 4.6.1 (b)

Figure 4.6.1: Commercial VTM (a) versus the in-house VTM by NPHL (b)

To cater to this massive production, another laboratory facility which includes Vaccine Laboratory has been used for this purpose. Some modifications include the setting of temperature to fit the requirement of quality control of the VTM production as well as the need to cater to the demand at that time. The NPHL Viral Transport Media (VTM) Preparation Procedure includes a certain type and amount of reagents, specific equipment and apparatus, and steps in preparation for the solution. Figure 4.6.2 (a) and (b) showed the involvement of NPHL personnel during the process of VTM production.

Figure 4.6.2 (a)

Figure 4.6.2 (b)

Figure 4.6.2: (a) and (b) Process of in-house production of VTM in NPHL.

Besides the VTM, NPHL is also involved in the production and storage of the SARS-CoV-2-positive strains. After the detection of Malaysia's first positive SARS-CoV-2 case, the sample was kept as a positive control stockpile. Positive control validation is carried out by proceeding to virus isolation, RT-PCR and sequencing to ensure that the isolate is the real SARS-CoV-2 virus.

After the validation test was successful, this positive control was used in every SARS-CoV-2 RT-PCR test. The performance of this positive control was monitored every day by plotting the CT value graph (Figure 4.6.3 (a) and (b) In addition, positive control is also used to monitor the reagent used. If the positive control graph is invalid (high CT value or no CT), troubleshooting for the positive control and reagent is carried out to investigate the failure.

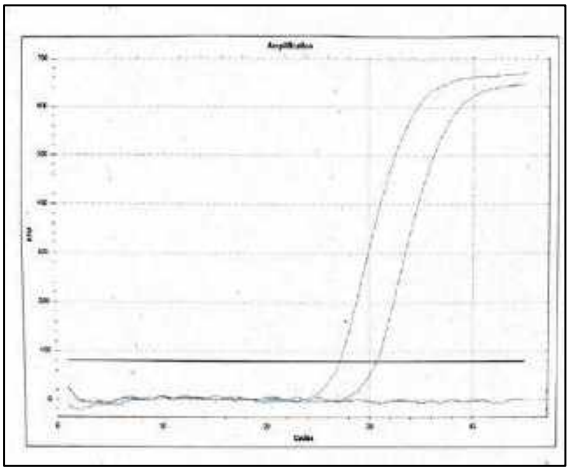


Figure 4.6.3 (a) *Figure 4.6.3 (b)*

Figure 4.6.3 (a) and (b) Pan Corona Assay & RT-PCR E gene establishment.

NPHL also provided these positive control and extracted RNAs to other laboratories such as Pantai Premier Pathology Sdn Bhd, Neogenix Laboratoire Sdn Bhd, Clinipath (M) Sdn Bhd, MKAJB, MKAKK, Bp Healthcare Group Glenmarie, Hosp Tuanku Mizan and Makmal Keselamatan dan Bahagian Kualiti Makanan Selangor. NPHL was also involved in providing quality control panel testing to new private laboratories to test their competency before these laboratories were approved to offer the RT-PCR testing service.

References

1. FAQs on Viral Transport Media During COVID-19". https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-viral-transport-media-during-covid-19
2. COVID-19 : Viral Transport Medium (VTM) for diagnosis https://www.clinisciences.com/en/read/newsletter-26/covid-19-viral-transport-medium-2267.html
3. Standard Operating Procedure (SOP) for the preparation of VTM (SOP#:DSR-052-04), SOP#: DSR-052-05, Centers for Disease Control and Prevention
4. McAuley, J., Fraser, C., Paraskeva, E. et al. Optimal preparation of SARS-CoV-2 viral transport medium for culture. Virol J 18, 53 (2021). https://doi.org/10.1186/s12985-021-01525-z

4.7 Innovation and Specialize Diagnostic

As times progress, the testing method of SARS-COV-2 has been expanding more than just simple SARS-COV-2 detection thru conventional RT-PCR and virus isolation thru culture. Further tests were offered and provided to help give the input that was needed for the country to manage the pandemic.

Whole Genome Sequence (WGS) was one of the further tests of SARS-COV-2 that allows scientists to classify a virus as a particular variant and determine its lineage. Genome sequencing for SARS-COV-2 is about developing a complete picture of a virus's RNA and it is a laboratory procedure that determines the order of bases in the genome of an organism in one process (1). It involves obtaining positive SARS-COV-2 samples and generating a complete RNA sequence of that virus from that sample. Although WGS has largely been used as a research tool since the 1990s, this method was not made easily available due to the costing and equipment that was required (2). For NPHL, this method was not being applied in our setting due to a lack of equipment and proper training.

During this pandemic, WGS was the next step of testing that was sought after the detection of the SARS-COV-2 virus and genomic surveillance has been a key component of public health efforts throughout the COVID-19 pandemic (1). The increasing number of variant of concern (VOC) and the variant of interest (VOI) has transformed the need for sequencing technologies to fully map out the circulation variants in Malaysia. In view of this, NPHL again was given a big task and mandate to prove that this institution is capable to build up its capacity in a very short period during this pandemic COVID-19.

NPHL developed the capacity and capability to perform WGS in May 2020 on a small scale after receiving the sequencer instrument, Illumina MiSeq, and later increase the capacity to perform more samples for WGS. NPHL personnel from Molecular Unit officers and technicians were trained immediately through web-based training modules. Within a short period, NPHL was able to offer the WGS testing and short fragment

sequence test. NPHL sequence capacity was further improved as NPHL receive another unit of sequencer machine of Oxford Nanopore Technology - MinION that was contributed by WHO in the mid-year of 2022. The machine that was used for the sequencing process in NPHL were shown in Figure 4.7.1 (a) and (b).

(a): Illumina MiSeq

(b): Oxford Nanopore Technology

Figure 4.7.1 (a) and (b): Sequencer machine available in NPHL.

Up till November 2022, about 797 samples were performed WGS at NPHL. NPHL is one of the facilities in Malaysia that has been contributing in giving the genomic data sequences of SARS-CoV-2 in the Global Initiative on Sharing Avian Influenza Data (GISAID). GISAID is an international website database that provides a platform for sharing genomic data sequences of SARS-CoV-2 globally. An example of one of the phylogenetic trees was shown in Figure 4.7.2 below.

Figure 4.7.2: Example of the phylogenetic tree of that was done in NPHL.

In the mid-year of 2021, as Malaysia moved towards living with COVID-19 disease, the Malaysian government decided to reopen the school where kids were required to attend their school physically as compared with the online classes previously. With the current policy to detect COVID-19 cases and isolate them still remaining relevant at that time, the testing method needs to improvise to meet the current condition. As PCR testing still deems to be crucial as one of the surveillance among the school-going children groups, the sampling and testing strategy needs to be modified.

After reviewing international and consulting expert opinions, NPHL has proposed to introduce the pool-testing strategy for these school children. With this method, it will be able to reduce the testing cost, using less manpower thus saving the cost of PCR testing as a whole. A pool-testing approach may shorten the screening time and increase the test rate during times of limited test availability and inadequate reporting speed.

This pool-testing strategy combines samples from multiple people, pooled together and each pooled was tested once. If one pool of samples tested negative, the test was complete and all samples were declared negative or of SARS-CoV-2 undetected. If one pool of samples tested positive, then all samples in the pool were to be tested individually to identify the sample(s) that contributed to the positive pool. Figure 4.7.3 (a) dan (b) simplified this pool-testing strategy.

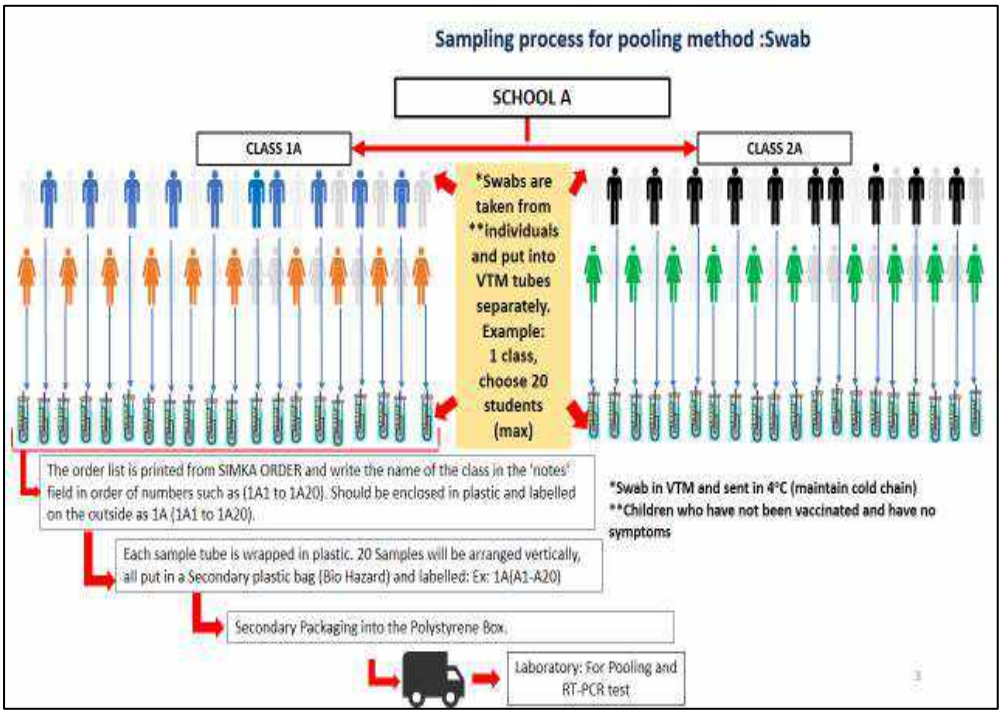


Figure 4.7.3 (a): Summary of pool-testing strategy swab sample.

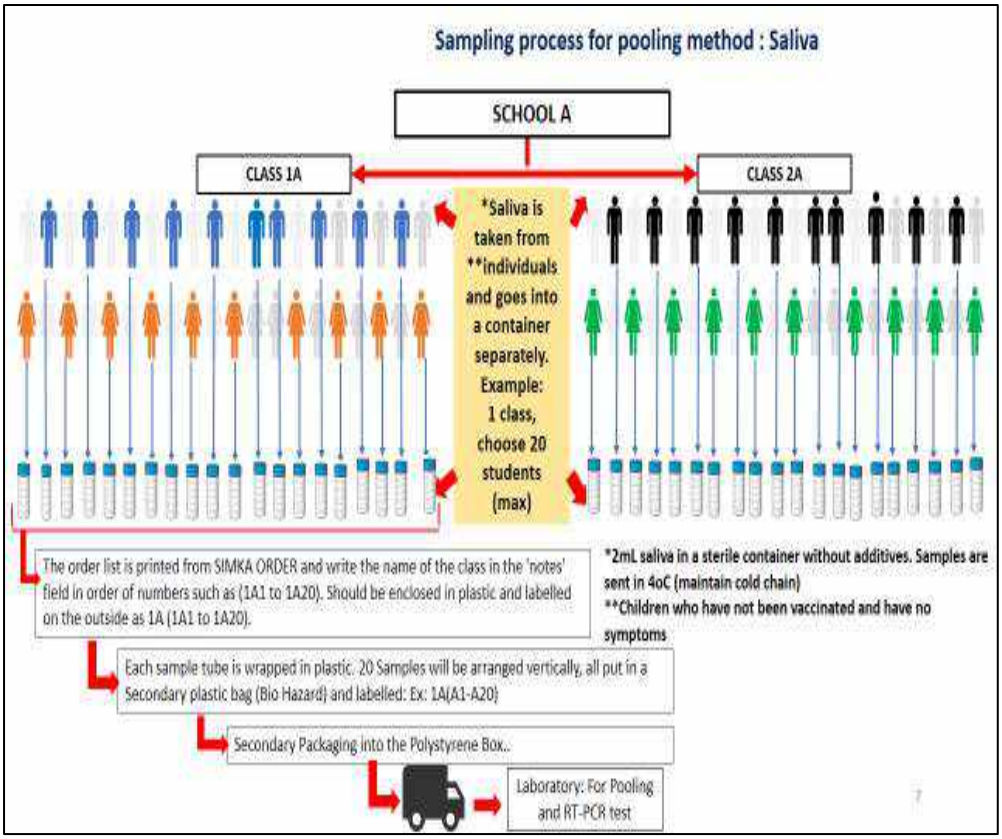


Figure 4.7.3 (b): Summary of pool-testing strategy saliva sample.

NPHL together with IMR were given the task to develop and validate this method. The NPHL team evaluated the pooling method using the saliva samples by using two to five samples and the method was optimized. Although this pool method was successfully tested and validated, there will be a risk of false negative results, especially among those low viral load samples. Considering this factor together with the sampling process among the school children, MOH later decided to emphasize screening among school children using self-test kits that were introduced soon after.

References

1. Centers for Diseases and Control Prevention (CDC), What is Genomic Surveillance?, Updated 2 December 2022, https://www.cdc.gov/coronavirus/2019-ncov/variants/genomic-surveillance.html
2. Ivan El CG, Cornel MC, Borry P, Hastings RJ, Fellmann F, Hodgson SV, Howard HC, Cambon-Thomsen A, Knoppers BM, Meijers-Heijboer H, Scheffer H, Tranebjaerg L, Dondorp W, de Wert GM; ESHG Public and Professional Policy Committee. Whole-genome sequencing in health care: recommendations of the European Society of Human Genetics. Eur J Hum Genet. 2013 Jun;21(6):580-4. doi: 10.1038/ejhg.2013.46. PMID: 23676617; PMCID: PMC3658192.

4.8 Rapid Response Team

The Rapid Response Team (RRT) of NPHL is a specialized team that response to the public health emergency / crisis requiring laboratory expertise. The team is led by public health specialist or designated officer and consist of medical officer, science officer and support staff which will be activated when needed/as required. The RRT is technically equipped with Biosafety and Biosecurity training including stringent donning and doffing of the PPE and handling of high-risk samples. In the event of emergencies or crisis, RRT plays a major role predominantly in management of high-risk samples in the field.

In response to COVID-19 pandemic, the team was activated in several Humanitarian Assistance and Disaster Relief Mission. NPHL first mission involved a group of Malaysian evacuees from China at the Air Disaster Unit (ADU) KLIA on 4th February 2020. RRT collaborated with MOH, NADMA, Armed Forces, Air Forces and AKEPT to facilitate the massive sampling, isolation and quarantine exercise.

Throughout the pandemic, NPHL has involved in eight mission with the total of 898 evacuees from China, Italy, Iran and Indonesia as well as on site screening at the designated quarantine centre (AKEPT). Detail of the missions as shown in Table 4.8.1. During the mission, NPHL was involved in handling the specimen process (Figure 4.8.1).

Figure 4.8.1 Sampling activities in ADU, KLIA.

Table 4.8.1: Detail of Humanitarian Assistance and Disaster Relief Mission.

Date	*Country of origin*	*Testing site*	*No of RRT members involved*	*No of Evacuees*	*Positive Case*	*Negative Case*
4/2/2020	Wuhan, China First Evacuation	ADU	13	136	2	134
10/2/2020, Day 7 sampling		AKEPT	7	134	0	134
17/2/2020 Day 14 Sampling		AKEPT	6	96	0	96
26/2/2020	Wuhan, China Second Evacuation	ADU	8	92	0	92
22/3/2020	Italy	ADU	6	108	0	108
26/3/2020	Iran	ADU	8	102	0	102
28/4/2020	Indonesia	ADU	7	132	48	84
30/5/2020	MAEPS	ADU	4	98	46	52

As the parliament start to convene in July 2021, NPHL was also given the task to screen the Parliamentary representative, media staff as well as in-house staff with the aim to curb the spread of the COVID-19 pandemic throughout the parliamentary session till March 2022. Staff of Parliament Clinic and Federal Territory of Kuala Lumpur and Putrajaya Health Department were also involved in this exercise. For NPHL, the RRT is expanded beyond the technical team including IT and administrative personnel.

For ease of operation, *Manual Pengujian COVID-19 di Parlimen*" was developed to provide a comprehensive structure on the rotation schedule, work process, working layout, and biosafety procedures to guide the work process (Figure 4.8.2).

Figure 4.8.2: The manual that used as guideline for sampling activities in parliament.

Figure 4.8.3: Swabbing activities in the parliament prior the session started.

The activities involve two part. The first was the screening using RT-PCR test that was conducted three days prior to the Dewan Rakyat or Dewan Negara parliamentary sessions. Thru-out the one-year duration, NPHL has involved with six RT-PCR screening session. A number of NPHL personnel involve in the session which consist of registration process, sampling process (Figure 4.8.3), transporting the samples to NPHL for testing, run the test and verified the results.

Subsequently, twice weekly RTK Antigen screening test which was performed accordingly and only those who are tested negative were granted access to the Parliamentary building (Figure 4.8.4). Sample from positive cases were analyse and proceed with Rapid Molecular and further Genotyping Variant Screening test at NPHL.

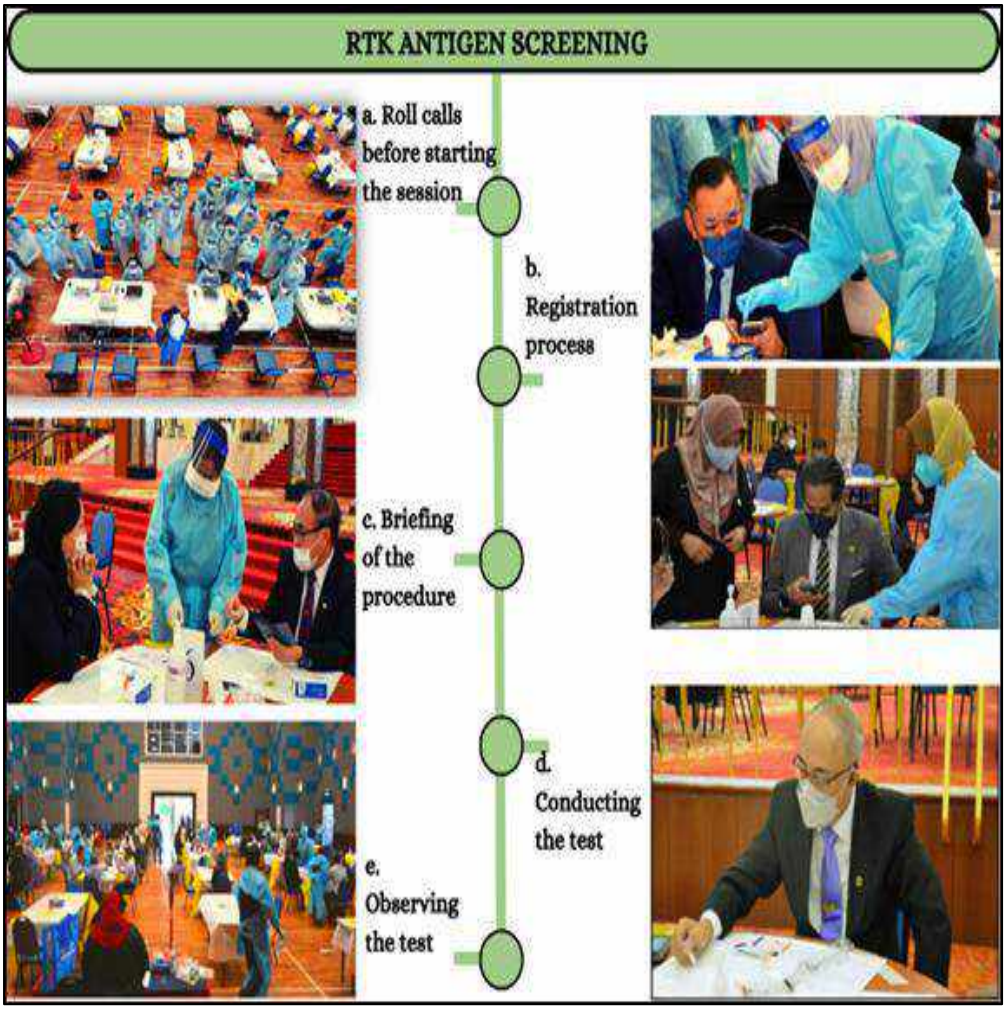


Figure 4.8.4: Activities during weekly RTK Antigen screening test at Parliament.

Throughout the 9 months, a total of six (6) PCR and thirty-five (35) RTK Antigen sessions were conducted. On average over 1000 screening tests was performed during each session giving an estimation of 3500 screening tests being conducted (Table 4.8.2).

Table 4.8.2: Parliament screening session with type of test, total number of people screened, total number of positive cases as well as the positivity rate.

COVID-19 SCREENING DONE AT NATIONAL PARLIAMENT				
Date	**Type of Test**	**Total Screened**	**Total Positive**	**Positivity Rate**
26-29/7/2021	RTK-Ag	1,308	10	0.8
10-11/9/2021	RT PCR	1,801	29	1.6
15-Sep-21	RTK-Ag	1,263	12	1.0
20-Sep-21	RTK-Ag	1,187	4	0.3
22-Sep-21	RTK-Ag	1,350	2	0.1
27-Sep-21	RTK-Ag	1,296	5	0.4
29-Sep-21	RTK-Ag	1,057	2	0.2
1-Oct-21	RT PCR	88	0	0.0
4-Oct-21	RTK-Ag	1,290	0	0.0
6-Oct-21	RTK-Ag	1,346	5	0.4
11-Oct-21	RTK-Ag	1,409	4	0.3
13-Oct-21	RTK-Ag	606	0	0.0
18-Oct-21	RTK-Ag	541	3	0.6
20-Oct-21	RTK-Ag	705	5	0.7
22-Oct-21	RT PCR	628	15	2.4
25-Oct-21	RTK-Ag	1111	4	0.4
27-Oct-21	RTK-Ag	1049	3	0.3
1-Nov-21	RTK-Ag	1000	4	0.4
3-Nov-21	RTK-Ag	932	5	0.5
8-Nov-21	RTK-Ag	936	1	0.1
10-Nov-21	RTK-Ag	933	2	0.2
15-Nov-21	RTK-Ag	1149	4	0.3
17-Nov-21	RTK-Ag	1035	0	0.0
22-Nov-21	RTK-Ag	1084	15	1.4
24-Nov-21	RTK-Ag	1166	8	0.7
29-Nov-21	RT PCR	631	25	4.0
	RTK-Ag	606	3	0.5
1-Dec-21	RTK-Ag	1012	2	0.2
6-Dec-21	RT PCR	507	5	1.0
8-Dec-21	RTK-Ag	1092	1	0.1
13-Dec-21	RTK-Ag	1113	4	0.4
15-Dec-21	RTK-Ag	1040	7	0.7
20-Dec-21	RTK-Ag	817	7	0.9
22-Dec-21	RTK-Ag	470	5	1.1
18/3/2022	RT PCR	58	16	27.6
2 Mac 2022	RTK-Ag	752	16	2.1
7 Mac 2022	RTK-Ag	777	16	2.1
16 Mac 2022	RTK-Ag	723	4	0.6
19/1/2022	RTK-Ag	36	0	0.0
21/3/2022	RTK-Ag	812	8	1.0
23 Mac 2022	RTK-Ag	816	7	0.9
PCR Screening				

4.9 Test Kit Evaluation

Since the beginning of the pandemic, manufactures had begun producing test kits and devices for COVID-19 diagnostics. All COVID-19 test kits that were brought into the country need to go through Special Access Route by Malaysian Medical Device Authority (MDA). The COVID-19 Test Kit would be approved for Conditional Approval by the consensus of the COVID-19 Test Kit Expert Committee and also based on the manufacturer reports, and analytical performance done in evaluation centres. In view of this, several health facilities were appointed by Ministry of Health to be the facilities that evaluate the COVID-19 kit.

NPHL was one of the first testing centres under the regulations of the Medical Device Act 2012 to carry out the wet evaluation on new rapid test kits and reagents for COVID-19. The Test Kit Evaluation Service was developed and Quality Department of NPHL was given responsibility as Evaluation Coordinator Secretariat to coordinate this new service in NPHL. A task force committee was established internally and an interim guideline has been developed to streamline the work process. A clear work line of evaluation process that has been revised. This involve processing the application documents from the requestor which was manage by the Evaluation Coordinator Secretariat, issuing invoice and payment process (Finance Section), followed by the technical team from Virology Section, Disease Department in conducting the evaluation, analyse the data and preparing the report, then finally submission of the report to MDA by Evaluation Coordinator Secretariat (Figure 4.9.1).

In conducting the evaluation of the kit, several processes were involved including collecting the samples from COVID-19 patients to be tested in the panel kit. For NPHL, as there was no in-house patient like some other evaluation centres, the team need acquired the positives COVID-19 samples from the COVID-19 quarantine centre (MAEPS and Pusat Kesihatan Kusta Negara) and COVID-19 Assessment Centers (Sungai Buloh Health Clinic, Melawati Stadium, Kajang Health Clinic) for the antigen testing (Figure 4.9.2 (a) and (b)). The negative samples were provided by NPHL staff especially from Disease and Food Department

who have been continuously supported the service by providing their own samples for negative control panel.

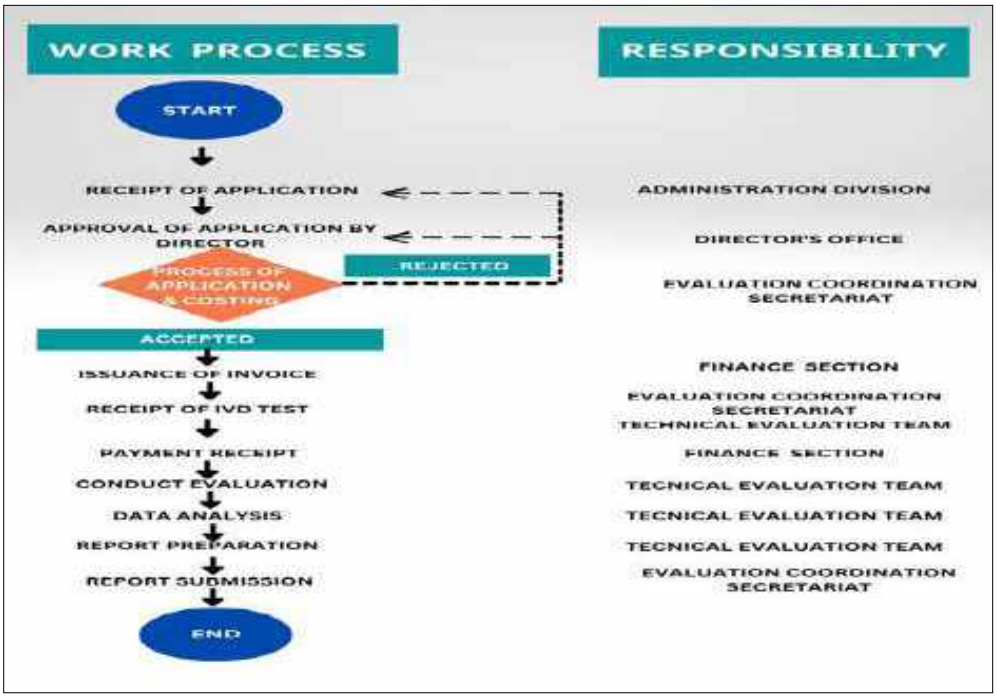


Figure 4.9.1: The flow process of the Evaluation Service of NPHL.

Figure 4.9.2 (a) *Figure 4.9.2 (b)*

Figure 4.9.2 (a) and (b): Collecting samples and evaluation at site by NPHL personnel at Quarantine Centre.

In the early phase of pandemic, serology test like ELISA or EIA were not available. NPHL had come to a new way of evaluation for rapid antibody test by doing inter kit comparison in the laboratory by evaluating several kits at the same time (Figure 4.9.3). The sensitivity and specificity was assessed based on majority of the kits' performances.

Figure 4.9.3: NPHL personnel was running inter kit comparisons in the laboratory.

NPHL started to receive the kits for evaluation in the middle of the year 2020. Among the first kits that have been received were the Rapid Antibody Test (RTK-Ab) kits. During that period, MOH health facilities have used the RTK-Ab kit to detect the presence of antibody in close contacts on day 13 of quarantine that were proved to be negative PCR on Day 1. However, due to the dynamic nature of the COVID-19 pandemic and based on the latest available evidence, rapid antibody test was no longer recommended to be used in the above setting.

Moving towards to the end of 2020, NPHL had begun to receive Rapid Antigen Test (RTK-Ag) kits professional use for evaluation. In the initial phase time, the RTK-Ag test were used to screen travelers at International Points of Entry and also used in hospitals for pre-operation and pre-admission screening. The usage was later expanded to the other primary health facilities to screen the COVID-19 case while waiting for the confirmation test of molecular. As the policy changes according to the current knowledge and circumstances, this kit has been used widely due

to its point-of-care nature and simple to use compared to molecular test. RTK-Ag test was highly used in multiple setting thus increase the demand of the evaluation of RTK-Ag kit.

In the middle of 2021, Self-Test Kit Antigen was approved as one of the testing methods of COVID-19 testing. The self-test kit was under RTK-Ag kit group but to be used as self-test. As Malaysia move towards empowering the communities by encouraging self-testing, this kit were highly in demand as it need to be made available to public not only in health facilities; but also in the pharmacy and selected retail premises.

Up to November 2022, the NPHL Evaluation Service have received a total of 249 kits from several type of kit including RTK-Ab kit, RTK-Ag kit, molecular as well as serology kits to be evaluated as shown in Table 4.9.1 below.

Table 4.9.1: Total number of test kit that have been evaluated by NPHL from 2020 to 2022 according to the type of kit.

Type of kit	***Number of Kit Being Evaluated***			
	2020	**2021**	**2022 (till Nov)**	**Total**
RTK-Ab	27	8	2	37
RTK-Ag (Professional & self-test)	14	97	39	150
Molecular	16	22	5	43
Serology	5	10	4	19
Total	**62**	**137**	**50**	**249**

In April 2022, NPHL has become the first evaluation center that been evaluated by MOH Internal Audit team and it act as a benchmark for other evaluation center. The audit recommended on the implementation of the application process using a system application or database that can be accessed by the applicants and NPHL. This process will reduce human

intervention and detect amendments or changes to application information. This in-house system is now in the making with the help of IT Section NPHL and expected to go live by the end of 2022.

Figure 4.9.4: Series of discussions involving the Technical Team, Pathologist, Epidemiology & Quality Team setting up Test Kit Evaluation Services at NPHL.

Figure 4.9.10: First Meeting with the representative of suppliers nationwide for test kit evaluation services as part of strengthening testing capacity and facilitating technology transfer for COVID-19.

4.10 Enhancement of SIMKA

SIMKA system was developed in 20025 to record all sample types for various tests be it for diagnostic, surveillance or outbreak. However, during this pandemic, there was a need to have a standardized formatting platform capturing the SARS-CoV-2 testing nationwide with proper variables to ease the recording, tracing, and analysis process. The IT team of NPHL has taken the responsibility to enhance the existing SIMKA system into SIMKA Outbreak version in April 2020 to fulfil the requirement that was needed.

Previously, all samples that were sent to the laboratories for testing need to be accompanied by a manual form that have the detail and information of the patients that was needed for the samples to be tested and to be traced back later. The patient's details were later typed into the system when samples arrived at the laboratories. However, as the number of samples for SARS-CoV-2 increased, the risk of typing errors of patient's details (name and identification numbers) in the manual forms and transferring the data to the system was high. This has caused problems in tracing the results and delayed public health action to take place. Realizing this, the IT team of NPHL has managed to introduce the sub-system called SIMKA Order in May 2020.

SIMKA Order workflow fulfilled the end-to-end requirement in which allows the requestor in the field to directly request the PCR testing to the laboratory via online. With the use of SIMKA Order request form, all demography information of the patients can be recorded and validated before the samples were sent to the laboratory thus will ease the steps for the laboratory. Once the samples reached the laboratories, the receiving counter can verify the orders via SIMKA Outbreak and accept the requests once the physical condition of the samples were checked. Samples then proceeded for PCR testing in the laboratories.

Once the laboratories have validated the PCR results, the results will then be pushed back to the system (Figure 4.10.1). This will enable the requestor to trace back the results and proceed for further public

health action. This SIMKA system and the flow process have been widely used by the requestor from all health facilities in government or private health facilities and agencies which can send their samples to any listed and approved laboratories among government and private facilities. This have helped in every aspect of managing the samples including during the outsourcing services and analysing process.

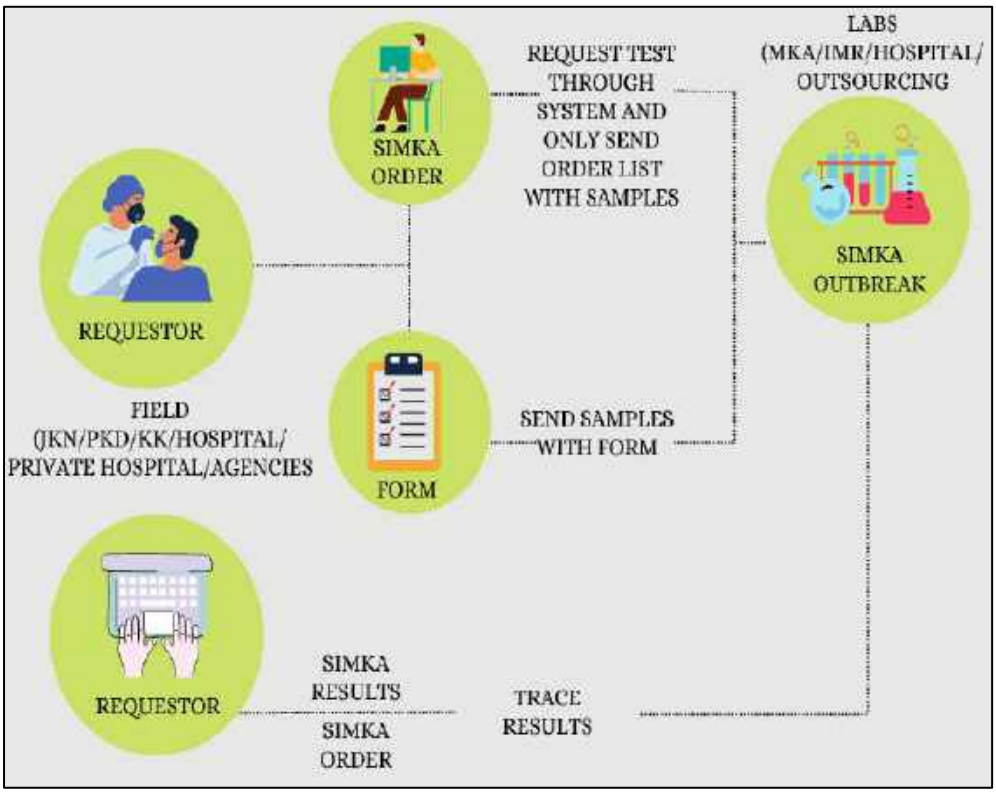


Figure 4.10.1: System flow from Requestor sending the samples to laboratories and using the SIMKA ORDER system until the results being tracked by Requestor.

The IT team of NPHL have worked hard from the beginning till now to make sure the SIMKA system can work well with the country's need and requirement (Figure 4.10.2). Not only to ease the laboratory and testing process, but SIMKA has also been the backbone of MOH in

providing the data source in regard to testing. As different tests of COVID-19 were made available, SIMKA also have been expanded by adding and capturing the data of other testing methods that were done by health facilities which include the data of RTK-Antibody and RTK-Antigen that were introduced in mid-year of 2020 and end-year of 2020 respectively. Team IT NPHL also has improvised the SIMKA features by developing the bulk function upload which has helped laboratories especially the private laboratories in uploading their test result from their own Laboratory Information System (LIS) to the SIMKA system.

SIMKA SYSTEM MILESTONE DURING MALAYSIA COVID-19 PANDEMIC

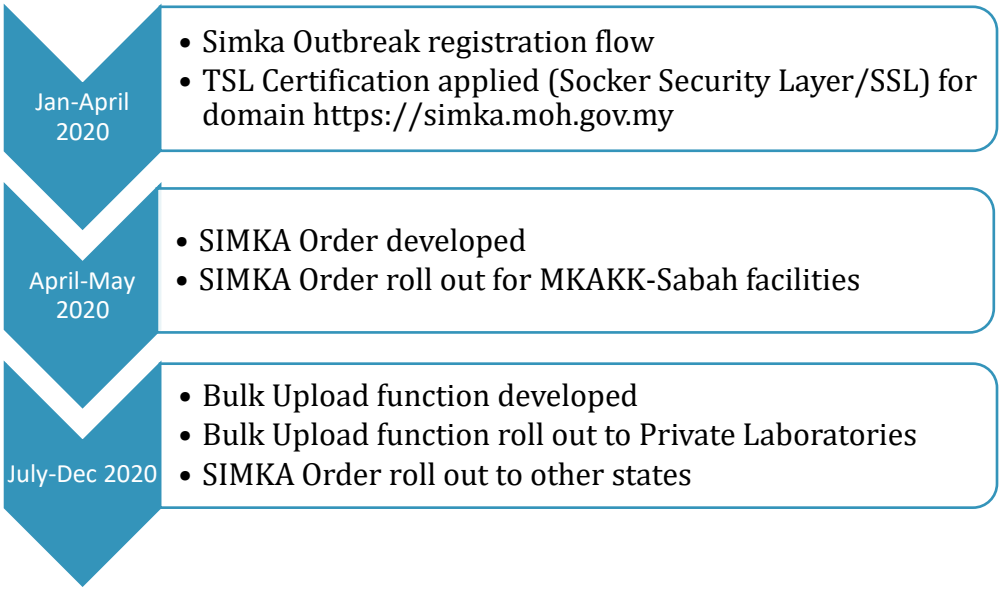


Figure 4.10.2: SIMKA System Milestone during Malaysia COVID-19 Pandemic

4.11 Laboratory Technical Advisory

In view that managing COVID-19 needs a proper and specific guideline covering all aspects, MOH has started to develop the National COVID-19 Management Guidelines as early as in January 2020 to be used as a reference for all. As laboratory and testing were part of the crucial management of COVID-19, dedicated personnel from multiple MOH facilities has been chosen to be part of the CPRC Laboratory team that were responsible to develop and the COVID-19 Management Guideline involving the management of samples, testing procedure for all testing method, laboratory set-up and other aspect involving testing and laboratories.

NPHL team which consists of Pathologist, Public Health Specialist and Science Officers were part of this team together with Pathologist from the Hospital and personnel from IMR were part of this CPRC Laboratory team. Several series of discussions have been done to develop the guidelines that were really crucial to be ready during the beginning of the pandemic (Figure 4.11.1). Among the guideline that has been developed during the early phase were Laboratory Biosafety Guidelines for Handling and Processing Specimens; Specimen Collection, Transportation and Storage, and Real-Time RT-PCR COVID-19 Testing.

Figure 4.11.1: Series of discussions among the team members of the Laboratory CPRC team.

As time progress, there is the need to review and updating the current laboratory guideline to make sure it is on par with the current knowledge, international requirement and Malaysia current situation. A dedicated team or committee were needed to take this responsibility to smooth up this process. Therefore, the National Laboratory Technical Committee COVID-19 was established for this purpose with several personnel from NPHL have been appointed to be part of this committee. Among of this committee task is to review and update the guideline as required as well as developing new guidelines involving an introduction of any new testing method. The COVID-19 Rapid Molecular Testing guideline; COVID-19 Rapid Test Kit Antigen (RTK-Ag) Testing for Professional Use and *Garis Panduan Pengurusan Penggunaan Kit Ujian Kendiri COVID-19* were among the new protocols of testing that have been developed to be used as reference for all.

All laboratory and sample testing related guidelines and protocols were listed as Annex 4 in the National COVID-19 Management Guidelines that can access by public in the MOH website. This Annex 4 guideline has been reviewed from time to time, updated accordingly and some of them has been removed as they were no longer relevant in current situation. Protocol of RTK-Antibody Testing in Health Facilities were among the guideline that was develop by the committee but then was removed as the RTK-Antibody was no longer be used in health facilities. Currently (up to Nov 2022), only 9 protocols were listed in Annex 4 (Figure 4.11.2).

NPHL also has been a part in giving the technical advisory during several occasion including routine CPRC technical meeting and other stake holder meeting. NPHL has given input in method of testing, screening, and confirmation test in developing the case definition of COVID-19 as well as the specific requirement in setting up laboratories or testing setting. NPHL also have been given input in the Inter Laboratory Comparison (ILC) execution and External Quality Assessment (EQA) of the laboratory that allows comparison of a laboratory's testing procedures to other laboratories either to a peer group of laboratories or to a reference laboratory.

Annex 4

Annex 4a	: Senarai Makmal Yang Menjalankan Ujian RT-PCR Bagi COVID-19
Annex 4b	: Laboratory Biosafety Guidelines For Handling And Processing Specimens
Annex 4c	: Specimen Collection, Transportation And Storage
Annex 4d	: Real-Time RT-PCR COVID-19 Testing
Annex 4e	: Application Procedure For Laboratories Offering RT-PCR COVID-19 Testing
Annex 4f	: COVID-19 Rapid Molecular Testing
Annex 4g	: COVID-19 Rapid Test Kit Antigen (RTK-Ag) Testing for Professional Use
Annex 4h	: Garis Panduan Pengurusan Penggunaan Kit Ujian Kendiri COVID-19
Annex 4i	: Protokol Ujian RTK-Antigen COVID-19 Kendiri Seliaan Secara Maya

Figure 4.11.2: Annex 4 in the National COVID-19 Management Guidelines (Updated Nov 2022).

COVID-19 PANDEMIC MEMORABILIA

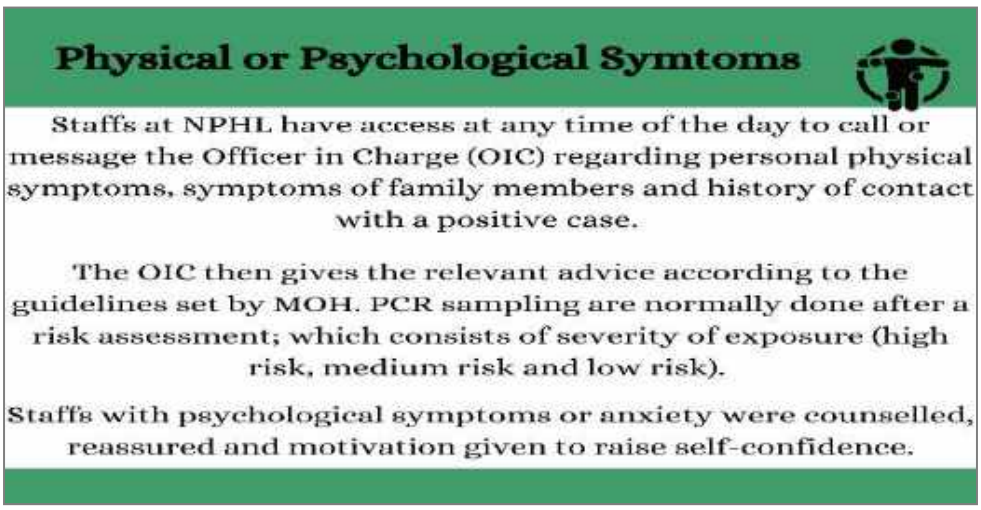
Photo Showing the Regional Training on Cold Box Validation for Sample Transportation conducted during the Pandemic COVID-19

4.12 Staff Empowerment and Wellbeing

Healthcare workers (HCW) play a vital role in the management of the COVID-19 pandemic such as laboratory sample testing, patient care which is either in-patient or out-patient, field investigations, data management, administrative measures, and others. There was an increase in the number of cases among HCW's during the 3rd wave which recorded more than 76.7% of the total number of HCW's with COVID-19 compared to the 2nd wave. Therefore, it was pertinent for all NPHL HCWs to strictly follow the Standard Operating Procedure (SOP) as highlighted in Annexe 21, released by the Ministry of Health (MOH) for HCWs at the workplace and outside the workplace. NPHL personnel were empowered with enough knowledge and information for their health and well-being.

In keeping with the SOPs by MOH, HCWs in NPHL were under the Healthcare Surveillance program to identify any health issues relating to COVID-19 (Figure 4.12.1).

NPHL personnel were empowered with the new Norms at the NPHL in order to ensure that they were protected from contracting or 'sharing' the virus with others (Figure 4.12.2).



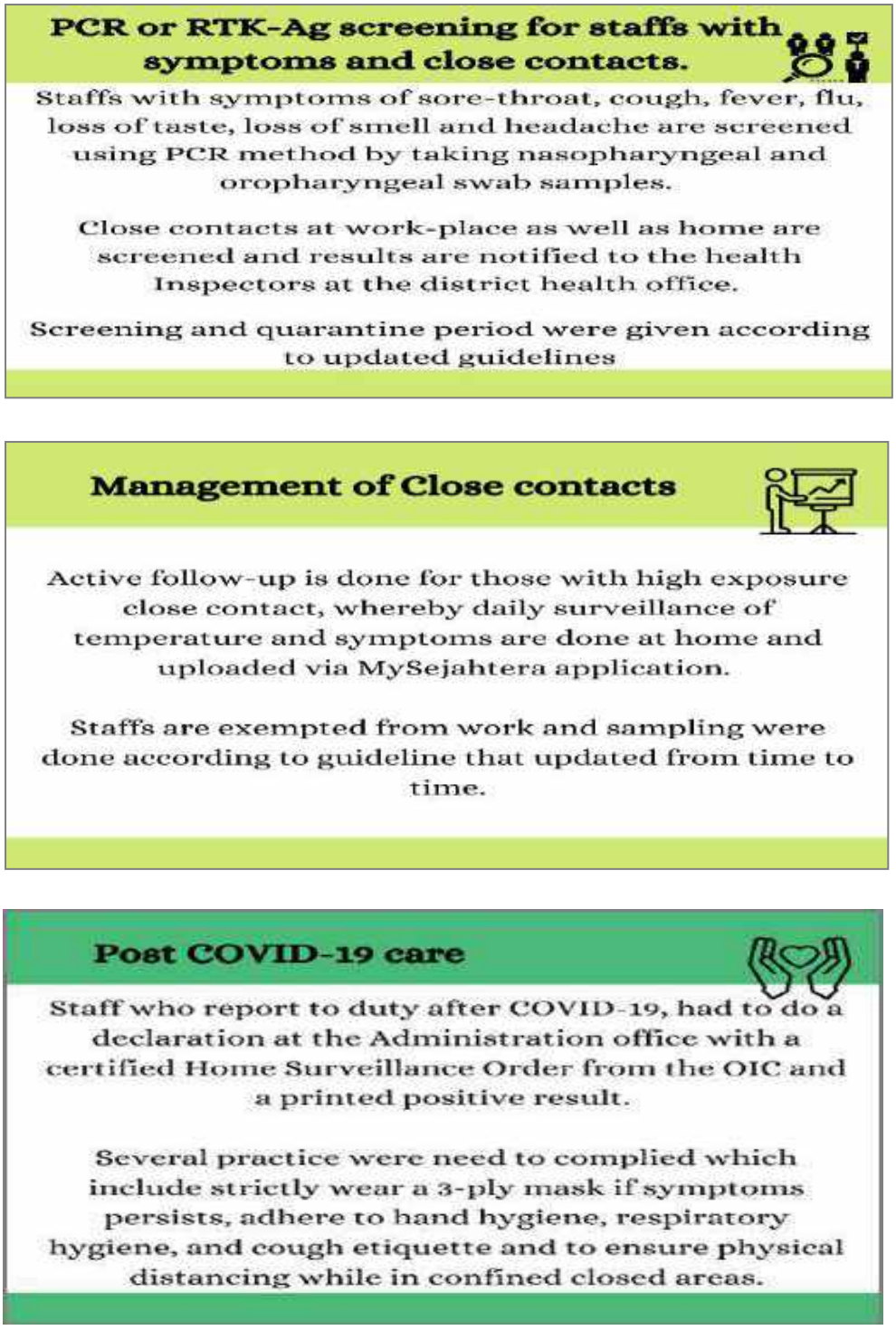


Figure 4.12.1: NPHL Healthcare Surveillance programme.

Figure 4.12.2: The new norms that were empowered to NPHL staff.

Sampling sessions for the targeted staff based on the requirement were done at the specific area by the trained NPHL personnel (Figure 4.12.3).

Figure 4.12.3: Sampling of staff at the gazebo by trained NPHL personnel.

Several sessions of Continuous Medical Education (CME) were conducted to empower and update the NPHL personnel regarding the management of healthcare workers (HCW) during the COVID-19 pandemic –Annex 21. To cover all aspects, the CMEs were done separately to entertain different targeted groups whose team is in charge of handling the HCW; the UPS handles the samples as well as all NPHL staffs (Table 4.12.1).

Table 4.12.1: Schedule CME for staff regarding Annex 21.

DATE/TIME	STAFFS
3/6/2021 @ 9.05 AM	ON-CALL - Team 1
4/6/2021 @ 9.05 AM	ON-CALL - Team 2
8/6/2021 @ 9.30 AM	UPS
9/6/2021 @ 9.05 AM	ON-CALL - Team 3
9/6/2021 @ 12.30 PM	CE @ Zoom - MKAK
10/6/202 1 @ 9.05 AM	ON-CALL - Team 4

Hands-on CMEs were also done for the officer who will be handling the sampling process which includes using the RTK-Ag kit (Figure 4.12.4).

Figure 4.12.4: CME session at the gazebo on sampling using RTK-Ag.

The screening activities of NPHL personnel were reported on a weekly basis to Unit Keselamatan Dan Kesihatan Pekerjaan (KPAS), MOH Disease Control Division. Table 4.12.2 summarize the activities that were done under the HCW Surveillance programme in NPHL from January 2021 to October 2021.

Table 4.12.2: Health surveillance activities from January 2021 to October 2021.

MONTH	STAFF SCREENED	CONTACT (FAMILY)	POSITIVE	NEGATIVE	TOTAL SCREENED
Jan-21	229	8	4 (1.7%)	233	237
Feb-21	163	17	8 (4.4%)	172	180
Mac-21	53	0	0	53	53
Apr-21	8	1	0	1	9
Mei-21	283	10	10 (3.4%)	283	293
Jun-21	53	9	3 (5.7%)	50	44
Jul-21	602	31	33 (5.2%)	594	633
Aug-2 1	281	15	16 (5.4%)	280	296
Sep-21	338	28	13 (3.6%)	353	366
Okt-2021	288	51	4 (1.2%)	339	343
TOTAL	**2298**	**170**	**91 (3.7%**	**2358**	**2454**

As our vaccination programme started in the first quarter of the year 2021, NPHL personnel received their 1st vaccination in March 2021 and completed their dose on April 2021. The coverage of completed the vaccine among NPHL personnel was 99.6% with one excluded with medical reasons. Later, NPHL personnel received their first booster in October 2021 with a coverage of 97.4% and this was followed by the second booster in the year 2022 (Figure 4.12.5).

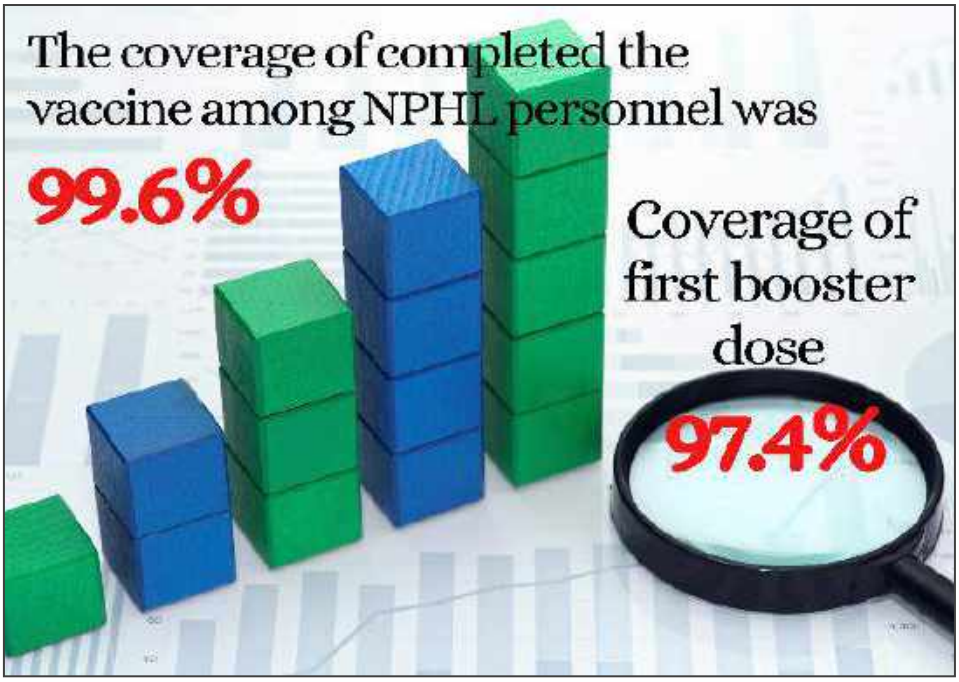


Figure 4.12.5: Vaccination status among NPHL personnel.

Led by the Occupational and Environmental Health Unit of NPHL, the vaccination program in NPHL was successful with the cooperation from several agencies including the Royal Police Arm Force, IKU and Klinik Kesihatan Sungai Buloh (KKSB) team (Figure 4.12.6).

Figure 4.12.6: Activities during NPHL COVID-19 vaccination program.

COVID-19 PANDEMIC MEMORABILIA

Photo Showing Technical Officers Conducting Virus Isolation in Biosafety Level 3 Laboratory during the Pandemic COVID-19

Photo Showing Officers managing COVID-19 samples in the temporary sample holding area outside the Sample Receiving Unit, NPHL set up during the Pandemic

CHAPTER 5
TOWARDS LIVING WITH THE VIRUS

WRITERS

CHAPTER	NAME
5.1	Dr Donal Huda binti Nasril Dr Norfazillah binti Ab Manan Dr Santhi A/P Subramaniam Pn Wan Noraini binti Wan Yussof
5.2	Dr Norfazillah binti Ab Manan En Selvanesan A/L Sengol Pn Kiroshika Pillai A/P Veel Pilay Pn Wan Noraini binti Wan Yusof Dr. Esah binti Md. Ali

5.1 National COVID-19 Testing Strategy

Living with the virus was the next huge step taken after one and a half years of the pandemic. By mid-2021, economic and education sectors have begun to function, and shortly after that, social activities and community restriction was uplifted fully, enabling lives to be restored. However, the COVID-19 threat was still relevant, and its people need to be protected and stay safe. Thus, detecting and stopping the transmission was still the utmost priority as much as public health is concern.

Therefore, an initiative National COVID-19 Testing Strategy was developed to provide the community with clear guidelines for COVID-19 testing. The objective of developing the National COVID-19 Testing Strategy (NTS) was to have a flexible testing strategy according to the changing epidemiology of COVID-19 in the country, to relook at resource availability and response to the health care system's capacity. Together with Disease Control Division, MOH, NPHL were directly involved in the development of this document especially in reviewing the testing modalities and the suitability of the methods to be used for specific sectors.

Literature reviews, continuous engagement with relevant agencies (Figure 5.1.1) and discussions with the universities and other stakeholders were done, gathering the required information in developing this document. NPHL also consulted with international bodies namely the WPRO and WHO for their thoughts and input. The hardworking NPHL team had continuously worked hard for two months pouring lots of effort, sweat, and tears into producing this document. The document not only outlined testing modalities confined to laboratory settings (molecular testing- PCR, pooling testing), but expanded to point of care testing which can be done at health service facilities (RTK-Ag Professional) and Self-Test Kit which has been proposed as part of community empowerment.

Figure 5.1.1: Engagement Session with Relevant Agencies

Considering all the factors, the NPHL has looked thoroughly at the availability and suitability of testing modalities and suggested recommendations for the use of specified sectors in the document. Figure 5.1.2.1 and 5.1.2.2 shows an example of testing strategies and recommendations in the Education Sector.

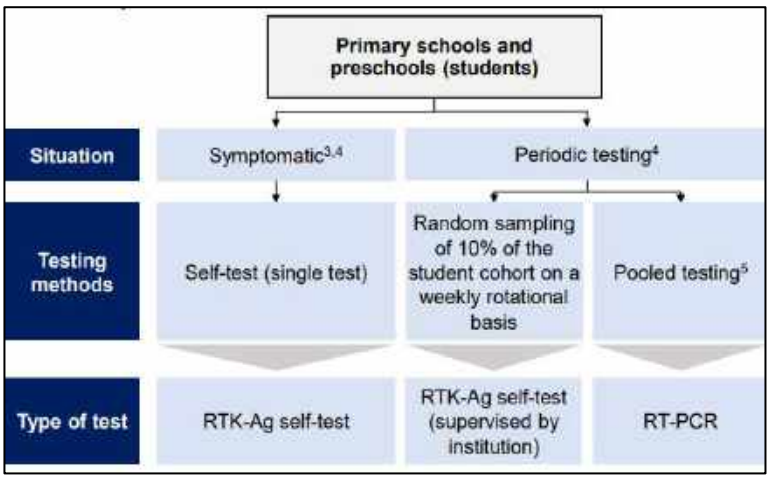


Figure 5.1.2.1 Testing strategies in the education sector (Primary schools & preschool)

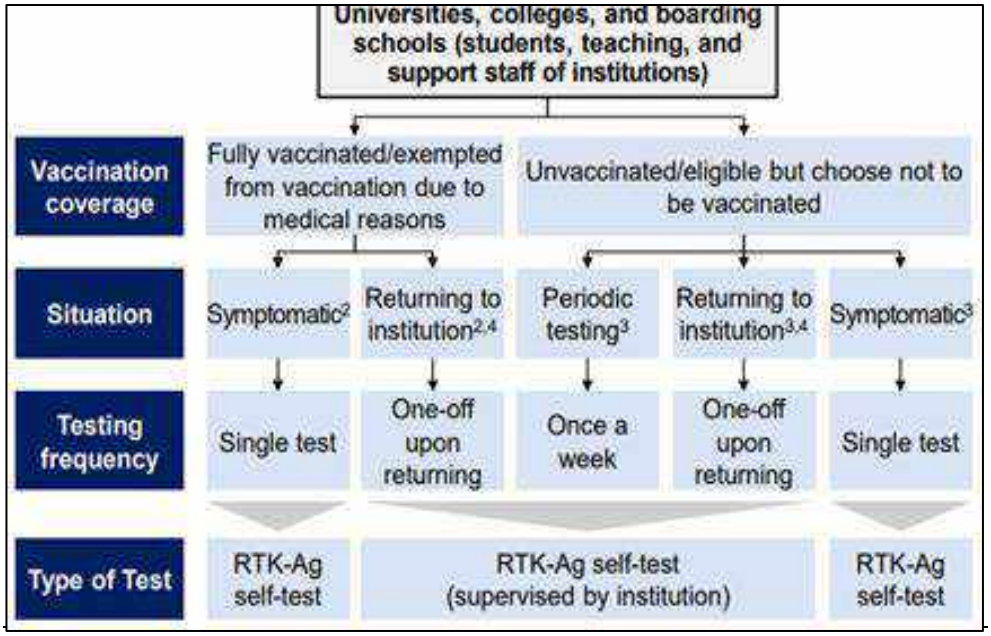


Figure 5.1.2.2 Testing strategies in the education sector (universities, colleges, & boarding schools)

The NTS draft was presented to top management in the MOH (Figure 5.1.3). Upon agreement, the NPHL team presented the document to the Honourable Minister of Health on 11th October 2021, for approval. The National COVID-19 Testing Strategy draft was finalized, officially launch and made available to the public on 26th November 2021 (Figure 5.1.4).

Figure 5.1.3: With the Honourable Minister of Health during the preparation of the final draft

Figure 5.1.4: National COVID-19 Testing Strategy.

5.2 Wastewater Surveillance COVID-19

As Malaysia moves towards the endemic phase, non-invasive and targeted population surveillance of COVID-19 were needed. Wastewater-based epidemiology for SARS-CoV-2 was accepted globally as supplementary surveillance and was recommended by World Health Organization (WHO) and Centers for Disease Control and Prevention (CDC) as the way forward in COVID-19 surveillance. Thus, Malaysia started the nationwide wastewater surveillance of COVID-19 in June 2022.

During the development of National Testing Strategy COVID-19 (NTS), it was noted that the surveillance program needs to be expanded beyond the clinical samples. Thus, NPHL as one of the core teams in developing the NTS, has studied further on this matter and sees the feasibility of environmental surveillance to be part of the COVID-19 surveillance program. The wastewater surveillance was later agreed by Disease Control Division, MOH to be listed under NTS surveillance program which was officially launched in November 2021.

In response to this, NPHL was given the responsibility to develop the surveillance program. A series of discussions were conducted with Institute for Medical Research (IMR) for method development and optimization of wastewater testing. In addition, a senior Science Officer and a Medical Laboratory Technologist have attended the training on laboratory processing of sewerage samples for the detection of SARS-CoV-2 at the National Water Research Institute of Malaysia (NAHRIM) in June 2021. Following this, NPHL has optimized the membrane filtration method used by NAHRIM.

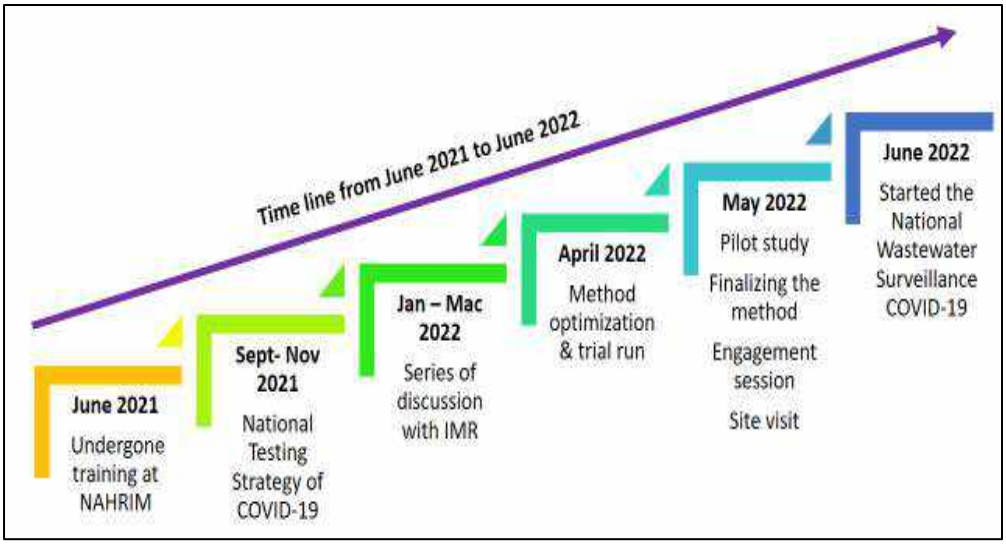


Figure 5.2.1: The Timeline for The Wastewater Surveillance COVID-19 Program.

Besides that, we have attempted several methods recommended by WHO for a trial run using our wastewater sample from the Polio sentinel site. Two methods of detection were used, Promega Direct Capture Concentration method and the in-house PEG precipitation method. Both methods successfully detected SARS-CoV-2 RNA from the tested samples. optimized. However, the Promega Direct Capture Concentration method using a binding column is less laborious and more reliable compared to the PEG precipitation method. At the same time, NPHL decided to use the RT- qPCR as the results were proven to be consistent for detection and cost-effective.

In May 2022, a technical team from NPHL was assigned to proceed with a pilot study focusing on four (4) sentinel sites, (Figure 5.2.2). The objective of this study is to see the feasibility of wastewater surveillance in the field and to finalize the method, reagent and equipment that were required for the surveillance program. The results showed that the wastewater was able to give the information needed to observe the COVID-19 trend in the community and also can as an early warning sign for an impending outbreak. This finding was presented to our honourable Minister of Health YB Khairy Jamaluddin and NPHL was given the blessing to proceed with Nationwide Wastewater Surveillance Program.

Fig 5.2.2: Site Visit, Discussion and Collection of Wastewaters for Pilot Study.

Concurrently, engagement sessions with the State Health Department (SHD), District Health Office (DHO) and the stakeholder were conducted by NPHL. It was decided that the surveillance program was put under the monitoring of the Surveillance Sector, Disease Control Division, MOH. In addition, one sentinel site for each state was selected by SHD for wastewater sampling. The sample will be collected by the DHO and sent weekly to NPHL, three times a month to be tested. The test result was analyzed and was final report distributed to the relevant stakeholders (Figure 5.2.3).

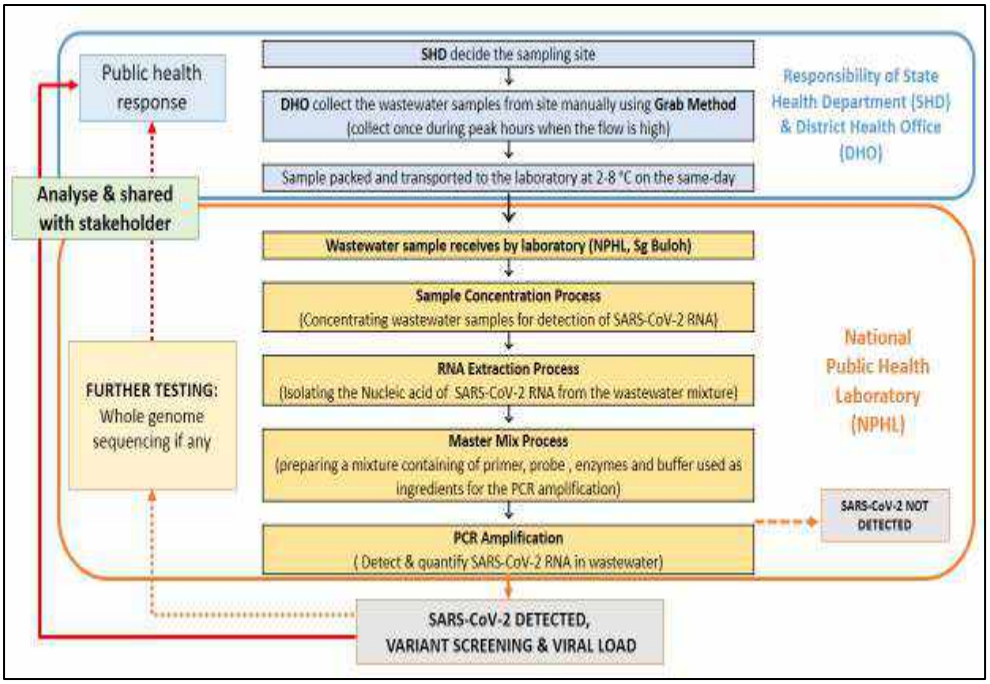


Figure 5.2.3: Algorithm in COVID-19 Wastewater Surveillance activity.

The Wastewater Surveillance for COVID-19 was later expanded to include sampling at the Point of Entry (POE). In May 2022, NPHL was tasked to test wastewater samples from aircraft, particularly from international flights at the POE. A site visit was initiated on 27th May 2022 to Kuala Lumpur International Airport (KLIA) together with the team from KLIA DHO, KLIA''s ground controller, Malaysia Airports Holdings Berhad (MAHB) (Figure 5.2.4). The flow of sampling was discussed during the visit and finalized at the subsequent meeting conducted on the 1st of June 2022. The sampling was done on weekly basis from targeted high-risk countries. The sampling process was conducted by KLIA DHO in collaboration with Airport Operations Control Centre (AOCC) and the Airport Ground Handler (Figure 5.2.5).

Figure 5.2.4: Site visits at Kuala Lumpur International Airport (KLIA).

The results of this surveillance activity were analyzed and the report was shared with all relevant stakeholders on weekly basis for further action. (Figure 5.2.6). The trend of viral load, variant screening from each sentinel site as well as sequencing results for samples that have lower CT-value were included as part of the surveillance report.

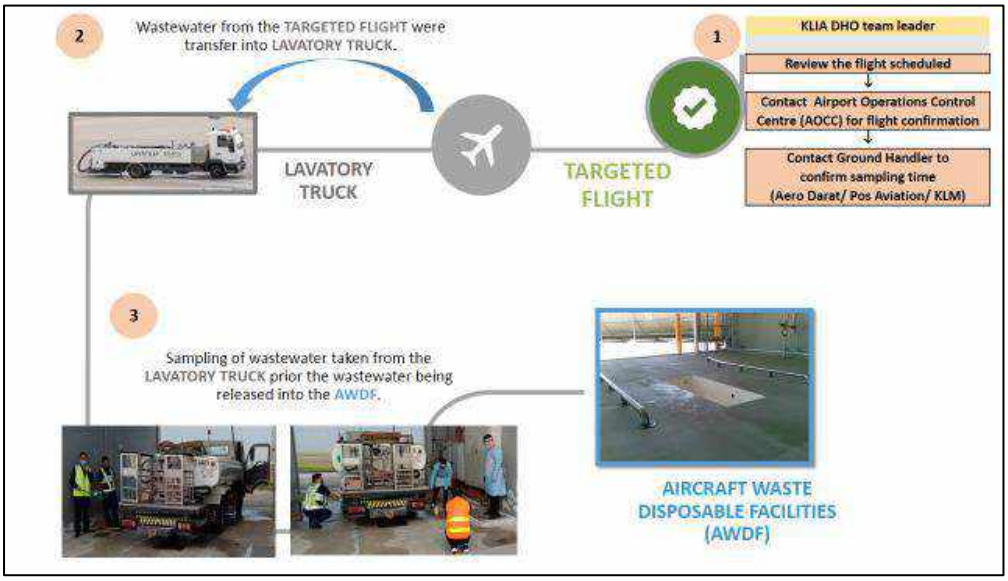
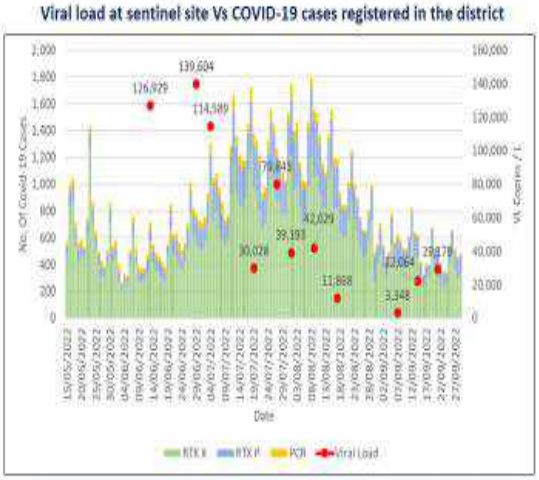


Figure 5.2.5: The Flow of Sampling of Aircraft Wastewater at Kuala Lumpur International Airport (KLIA).



Sampling Date At Sentinel Site	Results	
	Detection & Viral Load (VL)	Variant screening (Presumptive)
13/06/2022	DETECTED/ VL 126,929	Omicron
29/06/2022	DETECTED/ VL 139,604	Omicron
04/07/2022	DETECTED/ VL 114,589	Omicron
19/07/2022	DETECTED/ VL 30,028	Insufficient
27/07/2022	DETECTED/VL 79,843	Omicron
01/08/2022	DETECTED/VL 39,193	Omicron
09/08/2022	DETECTED/VL 42,029	Omicron
17/08/2022	DETECTED/VL 11,868	Omicron
07/09/2022	DETECTED/VL 3,348	Omicron
14/09/2022	DETECTED/VL 22,064	Omicron
21/09/2022	DETECTED/VL 29,179	Omicron

SAMPLING DATE AT KLIA	FLIGHTS	RESULTS			
		Detection	Viral Load copies/L	Variants screening (Presumptive)	Results WGS (Freyja method)
08 Jun 22	XXX	DETECTED	22,309	Omicron	Omicron BA.5: 100%
15 Jun 22	XXX	DETECTED	478,000	Omicron	Omicron BA.5: 86.2%, Omicron BA.2: 13.6%, *Other: 0.2%
22 Jun 22	XXX	DETECTED	3,828	Omicron	Omicron BA.5: 88.7%, Omicron BA.2: 11.0%, *Other: 0.4%

Figure 5.2.6: Snapshot of Surveillance Report Distributed to Stakeholders

CHAPTER 6
CHALLENGES AND LESSONS LEARNT

WRITERS

CHAPTER	NAME
6.1	Pn Yu Kie A/P Chem
	En Selvanesan A/L Sengol
6.2	Dr Mimi Rodzaimah binti Abd Karim
	Cik Nurul Huda Hazwane binti Rohani
	En Selvanesan A/L Sengol
6.3	Pn Salfaryna binti Alzahari
	Pn Siti Fairuz binti Mar Ramli
	En Mohd Hamidi bin Mohd Rani

6.1 Keeping Up with Technology

Many global clinical diagnostics companies had introduced a wide range of automated systems including liquid handling systems for no manual pipetting in COVID-19 PCR testing, walk-away systems from extraction to detection, fast extractor systems with no manual extraction steps, and many other systems. This advanced technology of instruments was designed to support high throughput laboratories to perform efficient COVID-19 testing. NPHL began with a manual system of extraction with a PCR thermocycler to support a laboratory capacity of 100-150 tests per day during the early stages of the pandemic. The capacity was gradually increased after the introduction of auto extractors and a Liquid Handling System that could be used with any COVID-19 assay workflow. The full automation (walk-away system) was introduced and used in the laboratory when the capacity was pushed to the target of 4,000 per day.

COVID-19 nucleic acid detection is the most widely used detection method for SARS-CoV-2. Commonly used nucleic acid detection methods include real-time polymerase chain reaction (PCR), loop-mediated isothermal amplification (LAMP) technology, second-generation sequencing (NGS) technology, and so on. In the early phase of the pandemic, NPHL began to perform routine RT-PCR and rapid molecular. In May 2020, the laboratory was moved into the biogenomic arena and bioinformatics by using next-generation sequencing technology, starting with the 1st generation of ABI 3500 Genetic Analyser, moving to 2nd generation Illumina MiSeq and then to the 3rd generation of Oxford Nanopore Sequencing to perform whole genome sequencing and genome analysis of SARS-COV-2. Our genomic surveillance is now able to detect potential Variant of Interest (VOI) and Variant of Concern (VOC) of SARS-CoV-2 and determined the Public Health Social Measures (PHSMs) and infection control measures. As of October 2022, NPHL has sequenced and shared 452 COVID-19 isolates in the GISAID database by using this sequencing approach.

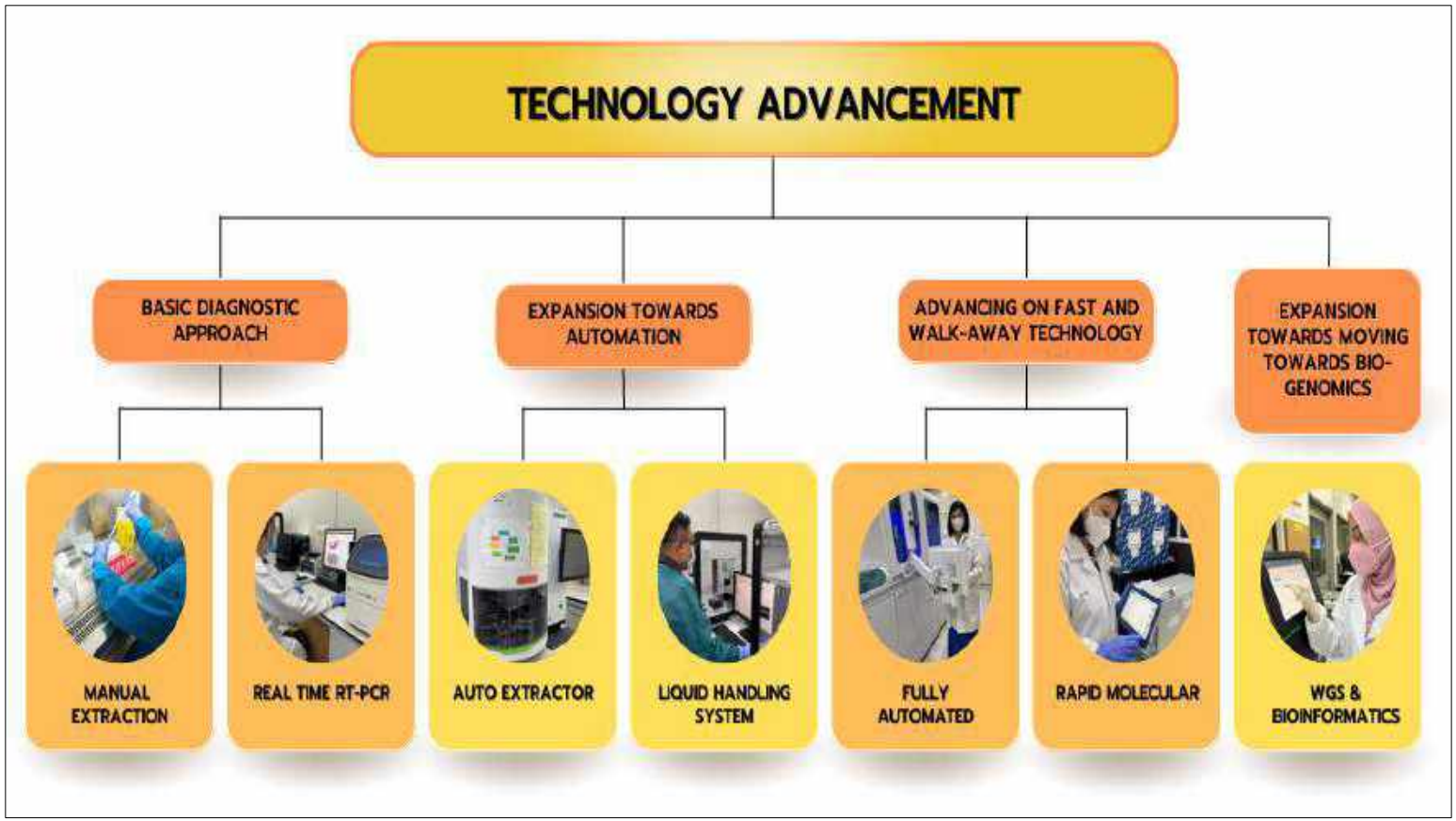


Figure 6.1.1: Technology advancement.

6.2 Resources Limitation

The COVID-19 pandemic requires sufficient public funding to ensure a comprehensive response. In the earlier stage of the COVID-19 pandemic, NPHL used the existing budget in developing the method for SARS-CoV-2 testing as well as training. In early year 2020, MOH was given the allocation for COVID- 19 pandemic, and laboratories including NPHL, IMR, and regional public health laboratory (PHL) were given priority in handling the pandemic. NPHL and IMR led in purchasing the requirement that was needed including equipment, reagents, and disposable items. These items were purchased through direct negotiation following the procurement guidelines by the purchasing committee from various ministries which includes the NPHL director and officers as the member.

Following the federal proclamation of emergency to contain the outbreak more effectively on January 2021, the government has announced specific emergency expenditure allocations to be used by relevant ministries and agencies. This has allowed the process of procurement within the existing allocation budget to be made through simplified approval mechanisms. The total emergency expenditure allocation and procurement of assets for NPHL, under COVID-19 fundraising (KUMPULAN WANG COVID-19) for year 2021 and 2022 are presented in Tables 1.1 and 1.2.

The allocation was used mainly for automated and advanced equipment to support the detection of viruses in time with high capacity and consumable items such as disposable personnel prospective equipment, reagents for RNA extraction, and detection by real-time RT-PCR for NPHL and other regional public health laboratories. Other than that, NPHL is also responsible for the procurement of swabs, viral transport medium, and rapid test kits for the nationwide requirement. The budget in year 2022 was also used to develop a whole sequence genotyping testing method and wastewater surveillance program.

Table 6.2.1: NPHL emergency expenditure allocation for year 2021 and 2022.

YEAR	2021	2022
Total allocation	RM 98,735,316.00	RM 53,731,040.00
Total expenditure	RM 98,735,278.75	RM 41,906,116.71
Percentage of expenditure	99.99%	80.00%

Table 6.2.2: NPHL Assets procurement allocation and expenditure for year 2021 and 2022.

YEAR	2021	2022
Total allocation	RM 2,816,840.00	RM 9,458,463.00
Total expenditure	RM 2,816,840.00	RM 9,310,525.26
Percentage of expenditure	RM 100%	98%

Human Resources Management

With increasing numbers of COVID-19 cases, NPHL and other regional public health laboratories were also burdened with thousands of samples for SAR-CoV-2 detection testing every day. In order to ensure the target of laboratory turn-around time (LTAT) for PCR test were within 72 hours, enough human resources were needed to fully maximize and optimize the laboratory capacity. NPHL had to mobilize staff from other divisions and sections to be involved in the 8 hours of on-call shifts which include the non-technical personnel to help with the non-technical affairs.

As internal mobilization was fully maximised, there was a need to have extra personnel in the workforce. NPHL proceed with the procedure to request for contract workers to be stationed and work in NPHL to full fill the demand and requirements. NPHL later received thirty-two (32) contract workers to NPHL which include six (6) science officers and 26 medical laboratory technologists.

In realizing that there were non-technical, NPHL requested mobilization from other government agencies to fill the gap. Soon, NPHL received contract doctors, a pharmacist from the MOH Headquarters, an officer from the Department of Chemistry, and personnel from training institutions that were mobilized in various tasks including analyzing data in the Epidemiology Department, NPHL, and verification of data.

Realizing that we cannot continue to rely on the external mobilization that can be called back to their original post, the Administration of NPHL proceed with the procedure and paperwork to hire a more stable workforce. NPHL later manage to hire sixteen (16) staff under Short-Term Employment Program (MySTEP) in year 2021 and 2022 to fill up the gap in various tasks.

In the early phase of the pandemic, extra hands were really needed urgently. NPHL were grateful to receive help from volunteer workers among the spouse of NPHL personnel. They have helped in registering the samples request form when NPHL was really in dire need as the

procedure of getting the help needed requires some time before it is processed and implemented.

Non -Profitable Contribution

The COVID-19 pandemic affects everyone regardless of individuals, companies, or agencies. Aware of their own limited abilities but able to contribute to those directly involved, NPHL has received donations from various agencies national and international.

Donations and contributions were largely disposable personnel perspective gears and equipment that were used regularly and have a high turnover number of usages. As the main task of laboratories was testing the COVID-19 samples, NPHL also received laboratory items including a centrifuge, micropipette, nucleic acid extraction kit, viral transport medium (VTM), primers, cabinet/hood, biohazard safety cabinet, rapid test kit, and swabs.

Some companies have given their Corporate Social Responsibility (CSR) contribution by placing their PCR extraction machine (King fisher, Chemagic, Biotreke and Maxwell) at NPHL as a loan unit to support the demand of high sample testing with no cost maintenance charged to NPHL.

Donations and contributions were also received from generous individuals that have provided the NPHL personnel with lunch and dinner for a token of appreciation to all the laboratory personnel that has worked hard continuously the clock, especially during the peak of the pandemic.

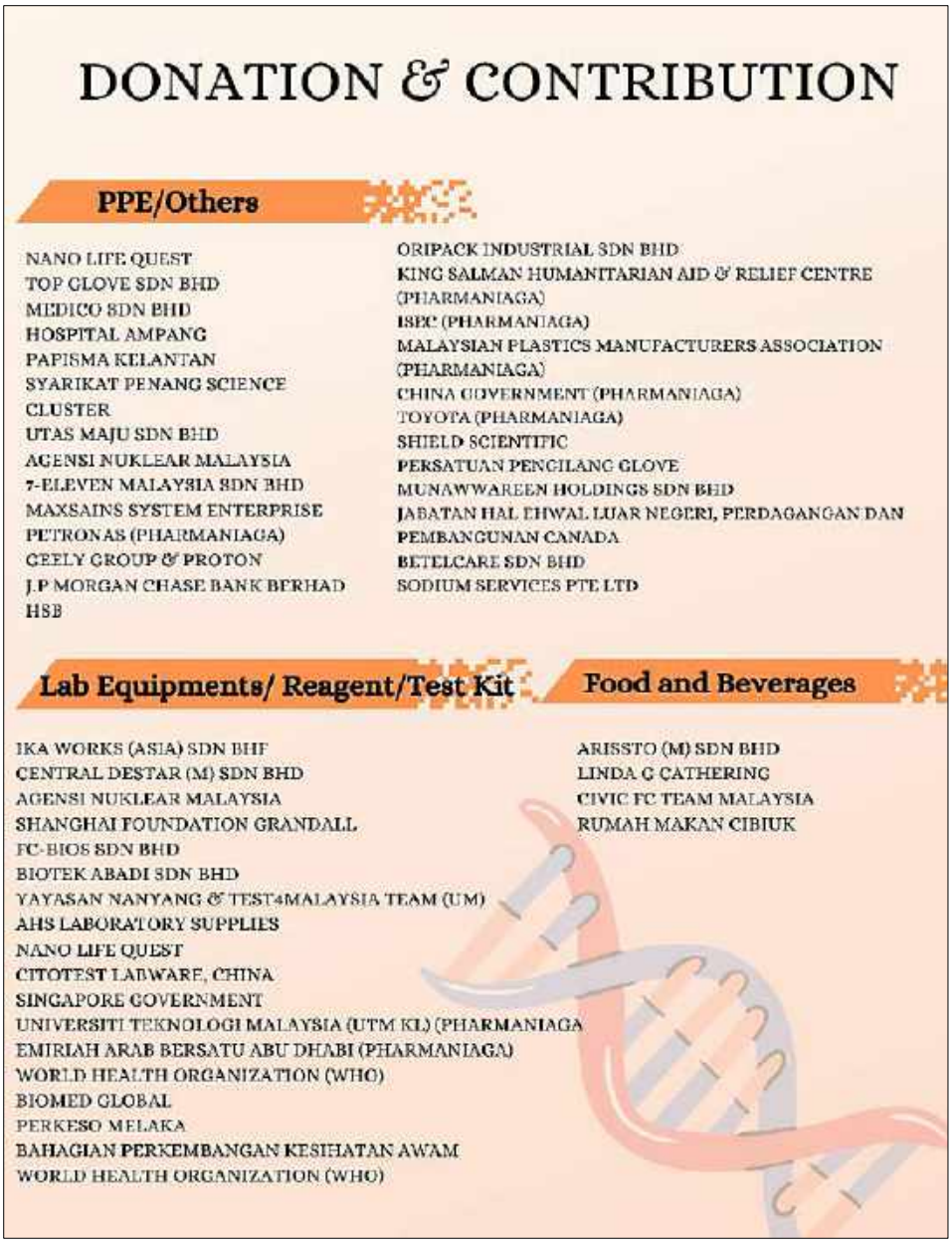
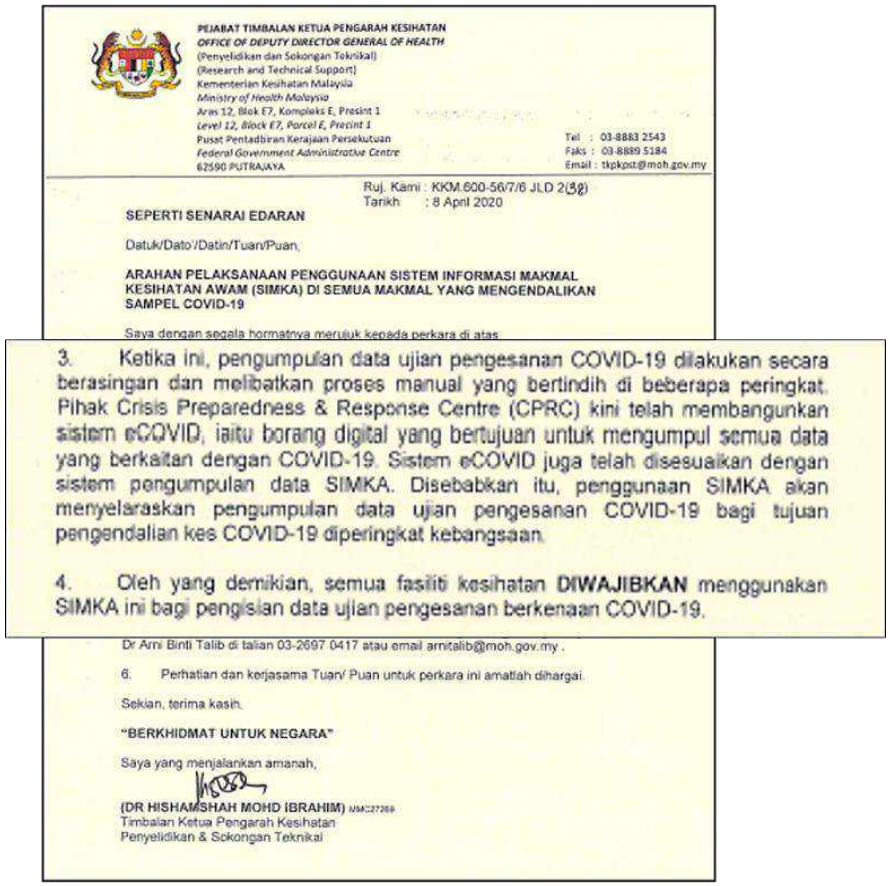


Figure 6.2.1: Donation & contribution.

6.3 Managing and Sharing Data

As SIMKA Outbreak is being mandated by the higher management of MOH as the main platform for capturing the laboratory results for COVID-19 testing (circulation of Arahan Penggunaan SIMKA Kepada Semua Fasiliti KKM Dan Bukan KKM by Timbalan Ketua Pengarah Kesihatan (Penyelidikan Dan Sokongan Teknikal) on 8 April 2020), all laboratories that offered and run the COVID-19 testing need to complied with it. This includes all MOH facilities, non-MOH government facilities such as Malaysian Genome Institute (MGI) under MOSTI, MINDEF facilities, universities under the Ministry of Higher Education; as well as private laboratories.



PEJABAT TIMBALAN KETUA PENGARAH KESIHATAN
OFFICE OF DEPUTY DIRECTOR GENERAL OF HEALTH
(Penyelidikan dan Sokongan Teknikal)
(Research and Technical Support)
Kementerian Kesihatan Malaysia
Ministry of Health Malaysia
Aras 12, Blok E7, Kompleks E, Presint 1
Level 12, Block E7, Parcel E, Precint 1
Pusat Pentadbiran Kerajaan Persekutuan
Federal Government Administrative Centre
62590 PUTRAJAYA

Tel : 03-8883 2543
Faks : 03-8889 5184
Email : tkpkpst@moh.gov.my

Ruj. Kami : KKM.600-56/7/6 JLD 2(39)
Tarikh : 8 April 2020

SEPERTI SENARAI EDARAN

Datuk/Dato'/Datin/Tuan/Puan,

ARAHAN PELAKSANAAN PENGGUNAAN SISTEM INFORMASI MAKMAL KESIHATAN AWAM (SIMKA) DI SEMUA MAKMAL YANG MENGENDALIKAN SAMPEL COVID-19

Saya dengan segala hormatnya merujuk kepada perkara di atas.

3. Ketika ini, pengumpulan data ujian pengesanan COVID-19 dilakukan secara berasingan dan melibatkan proses manual yang bertindih di beberapa peringkat. Pihak Crisis Preparedness & Response Centre (CPRC) kini telah membangunkan sistem eCOVID, iaitu borang digital yang bertujuan untuk mengumpul semua data yang berkaitan dengan COVID-19. Sistem eCOVID juga telah disesuaikan dengan sistem pengumpulan data SIMKA. Disebabkan itu, penggunaan SIMKA akan menyelaraskan pengumpulan data ujian pengesanan COVID-19 bagi tujuan pengendalian kes COVID-19 diperingkat kebangsaan.

4. Oleh yang demikian, semua fasiliti kesihatan **DIWAJIBKAN** menggunakan SIMKA ini bagi pengisian data ujian pengesanan berkenaan COVID-19.

Dr Arni Binti Talib di talian 03-2697 0417 atau email arnitalib@moh.gov.my .

6. Perhatian dan kerjasama Tuan/ Puan untuk perkara ini amatlah dihargai.

Sekian, terima kasih.

"BERKHIDMAT UNTUK NEGARA"

Saya yang menjalankan amanah,

(DR HISHAMSHAH MOHD IBRAHIM) MMC27269
Timbalan Ketua Pengarah Kesihatan
Penyelidikan & Sokongan Teknikal

Figure 6.3.1: Letter of instruction of SIMKA usage to all MOH and non-MOH health facilities.

SIMKA system manages thousands of PCR data that was performed and these data were key-in by hundreds of laboratories on daily basis. In mid-year of 2020, RTK-Ag was introduced as another testing modalities for COVID-19 testing. More health facilities were involved in COVID-19 testing including the primary health services such as *Klinik Kesihatan* and private clinic. SIMKA was expanded to be able capturing all these data that was key-in by various type of health facilities.

Up to December 2021, SIMKA have captured 19,939,733 of PCR test and 18,698,545 RTK-Ag Professional tests with the average test that were captured daily was 10,000 to 40,000 test per day (Table 6.3.1).

Table 6.3.1: Total number of PCR and RTK-Ag testing nationwide that was captured by SIMKA from January 2020 to December 2021.

Year	Type of testing		Total
	PCR test	RTK-Ag Professional test	
2020	3,361,661	1,113,234	4,476,915
2021	16,578,072	17,585,311	34,165,404
Total	19,939,733	18,698,545	38,638,278

As the manager of the SIMKA system, NPHL Epidemiology Division was given the responsibility of compiling thousands of data on daily basis and cleaning the data before proceeding with the analyzing process. These processes required a good computer system in place with a strong back-up storage system and skilled personnel to complete this task. The output of the process was the reports that were submitted to Crisis Preparedness and Response Centre (CPRC) MOH on a daily basis for further action and public health measures to take place. Figure 6.3.2 below are the detailed workflow together with the key elements in the data management process.

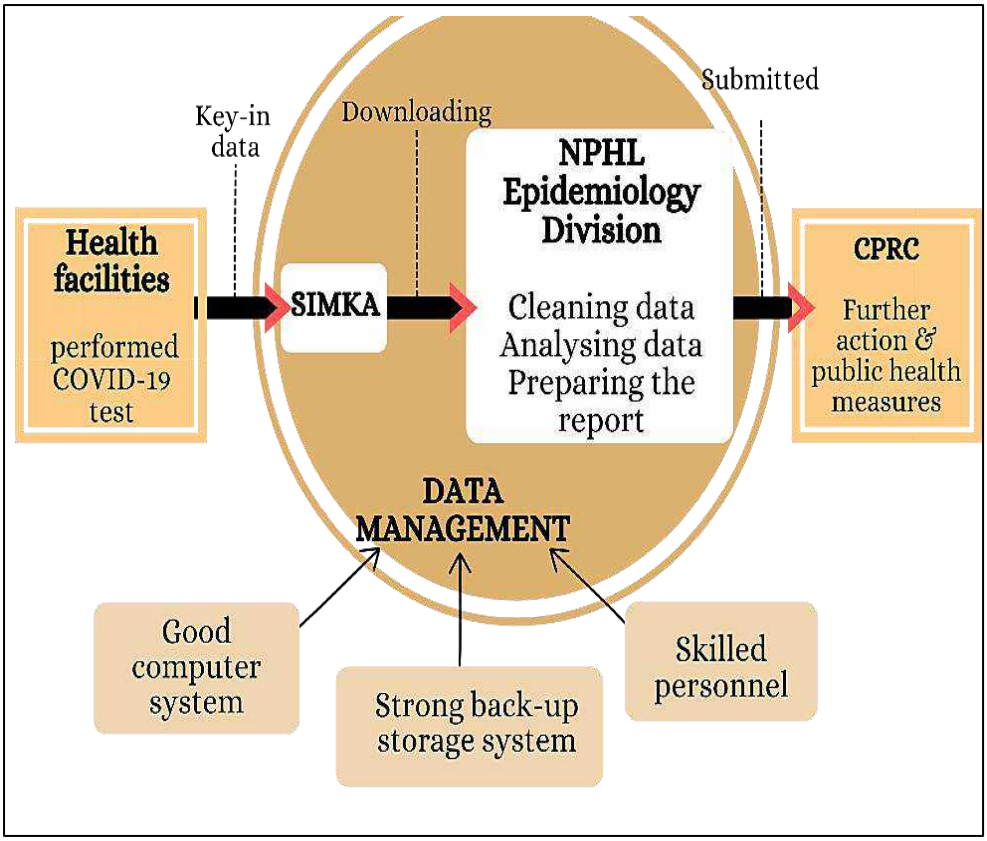
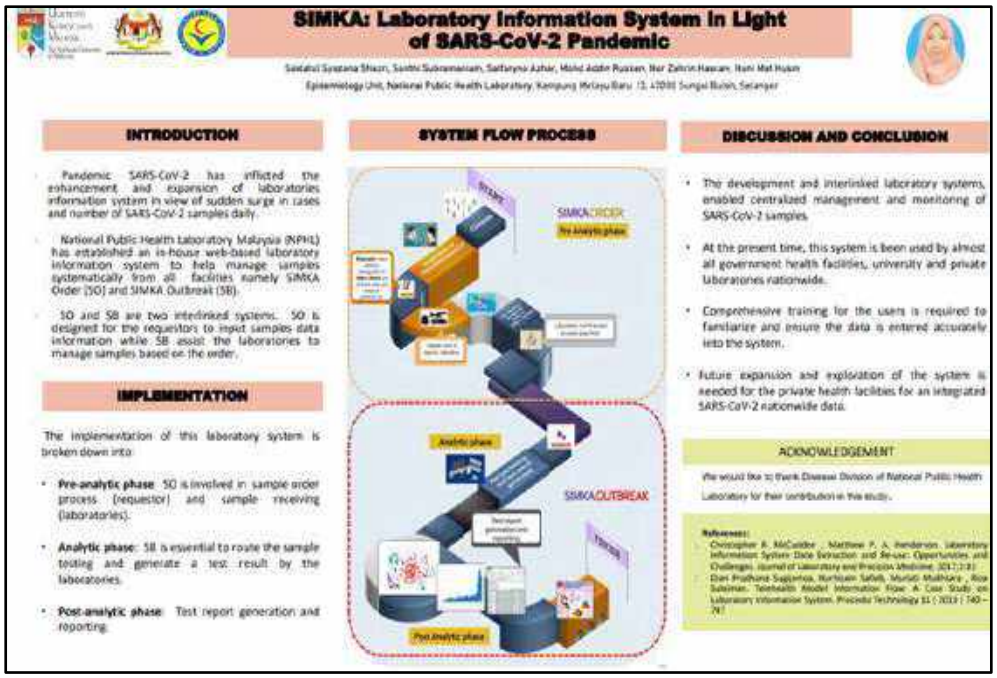


Figure 6.3.2: Workflow of data management and the key elements.

The role of SIMKA as the data management system in SARS-CoV-2 pandemic of Malaysia has been well established and recognised. Several papers has been produced to document this achievement (Figure 6.3.3).



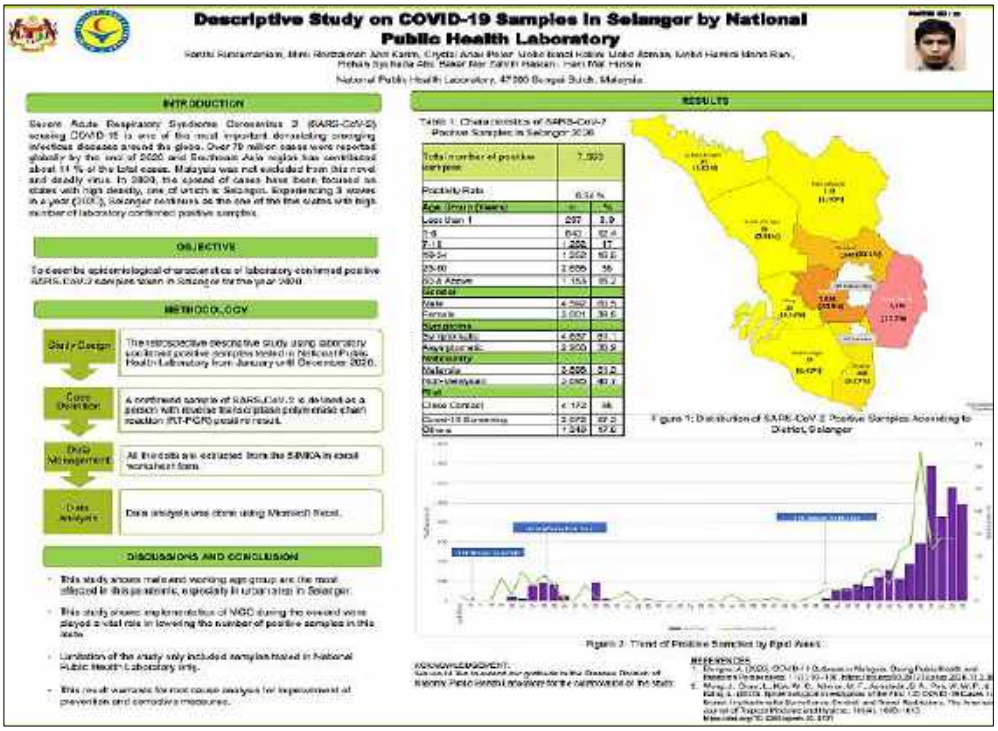


Figure 6.3.3: Examples of how data from SIMKA analyzed and presented for research purpose.

During the high volume of samples handled both in MOH and non MOH laboratories, the urge to provide function of handling bulk records challenged the IT Section of NPHL to study the variables intensely and worked on the function in SIMKA. NPHL expert team have managed to offer the bulk upload function in the SIMKA System which allowed the facilities to upload their records even if they used their internal Laboratory Information System (LIS), thus the SIMKA has eased the burden for the private facilities.

For patient (public) notification of results, SIMKA has provided the CPRC Team the data that was needed. NPHL team has been uploading SIMKA line listing in text format into a specific platform which CPRC MySejahtera Team provides in which they configured it to be automatically pushed on daily basis and specifically before 12noon. The workflow of SIMKA data sharing (Figure 6.3.4).

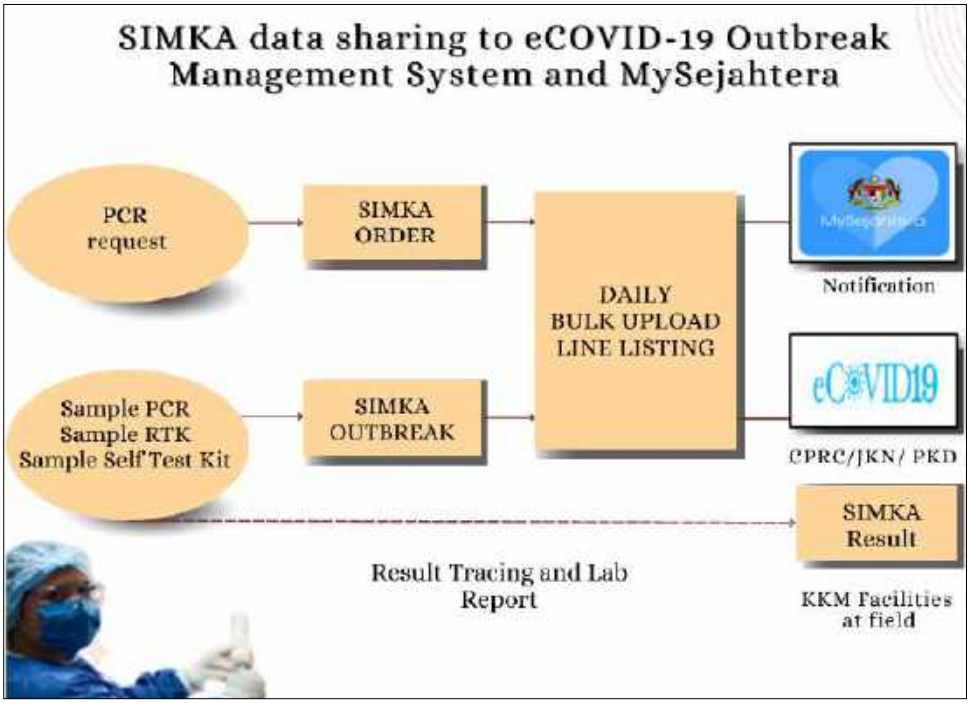


Figure 6.3.4: SIMKA data sharing to eCOVID-19 Outbreak Management System and MySejahtera.

Since October 2021 when eCOVID-19 Outbreak Management System (OMS) was ready, NPHL has started developing the Application Programming Interface (API) to enable direct integration for both eCOVID-19, OMS and MySejahtera. All parties involved have worked hand in hand to strive the aim for direct integration in which ultimately, to able real time notification of confirmed case to patient (public). Below is the overall Malaysia COVID-19 of Outbreak Management System (OMS).

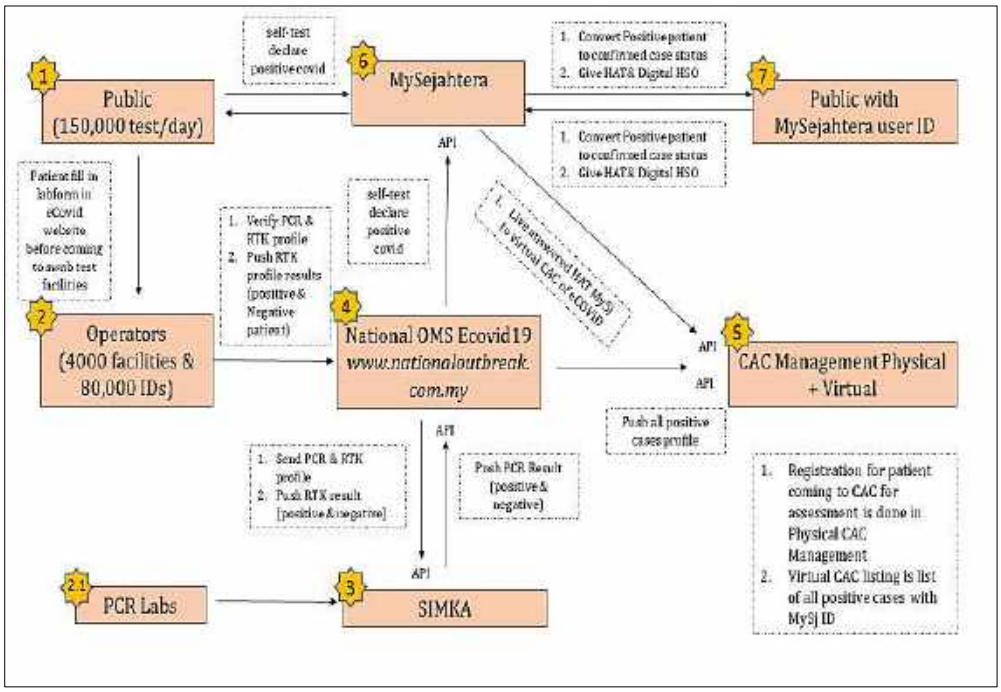


Figure 6.3.5: Malaysia COVID-19 of OMS.

Epidemiology Division of NPHL was given the huge responsibility to share the report analysis of the laboratory data of COVID-19 to the stakeholders. These include the Laboratory Based Surveillance data of COVID-19 and the daily testing results to CPRC MOH on daily basis (Figure 6.3.6).

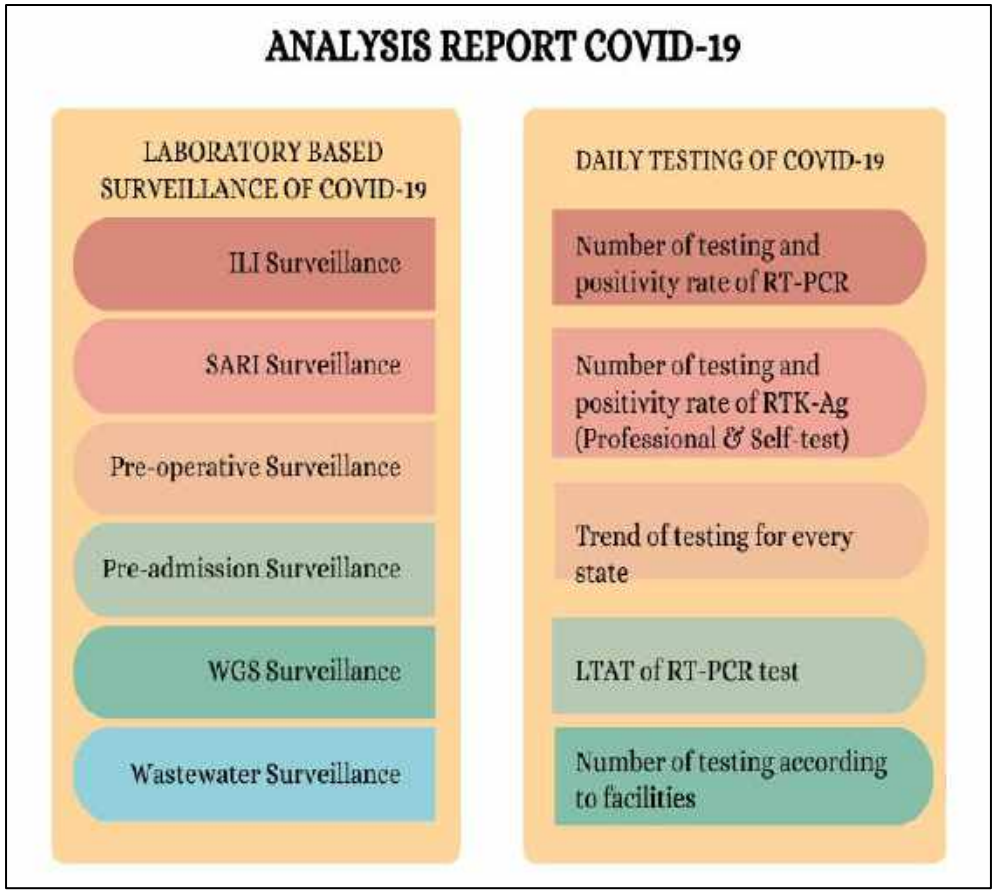


Figure 6.3.6: Analysis report COVID-19 data that were shared to CPRC MOH.

Besides the CPRC MOH, NPHL also provides the input of laboratory data that was required by other agencies such as the Ministry of Finance (Data LAKSANA) and PERKESO. The data were shared with them via the MOH CPRC as the focal point between the agencies and MOH. For the WGS data, the NPHL team has also been contributing to giving the genomic data sequences of SARS-CoV-2 in the GISAID database which is an international public domain that is open for all to view.

Figure 6.3.7: Discussion on COVID-19 Pandemic Data involving the key personnels.

CHAPTER 7
SUCCESS STORIES

WRITERS

CHAPTER	NAME
7.1	Dr Nor Zahrin binti Hasran
	Dr Mimi Rodzaimah binti Abdul Karim
	Pn Salfaryna binti Alzahari
	Pn Siti Fairuz binti Mar Ramli
	En Mohd Hamidi bin Mohd Rani
7.2	Cik Zirwatul Adilah binti Aziz
	Pn Nurul Aina Murni binti Che Azid
	Pn Hannah Phoon Yik Phing
7.3	En Selvanesan A/L Sengol

7.1 The Untold Story of SIMKA

Development of SIMKA Outbreak and SIMKA Order

No one would have thought that our in-house application system would been chosen as the main platform to collect laboratory results in beginning of the pandemic. With the strength of only two (2) programmers, the team has put their heart and soul trying hard to fulfil every single needs of the stakeholders. The SIMKA Outbreak was introduced when Virology lab and Specimen Receiving Counter found that current workflow in using SIMKA version 3.0 was no longer helping them fasten the registration process.

Thus, from the seven (7) steps of registration using SIMKA v3, the team simplified the steps and set all variables specifically of what COVID-19 data analysis need. With the new version of SIMKA, the registration can be expedited. Later in May 2020, another milestone makes a huge success where end to end took place. Laboratory only accepted online request with complete demographic patients which has been registered by the ground users at PKD, hospitals, CAC and *Klinik Kesihatan* prior sending the samples to the respective labs. The rationale of introduction online request (SIMKA Order) is to minimize typo during registration in bulk, sample misplaced and ease the high volume of records at labs. Only PCR and Rapid Mol (PCR) tests were made available in SIMKA Order as the RTK test could be done and verified directly at the facilities. The cumulative number of registered users of SIMKA (Table 7.1.1).

Table 7.1.1: Total SIMKA registered users by category facilities.

Facilities	Cumulative Numbers of Registered Users (both SIMKA Outbreak & Order
Klinik Kesihatan	**4,120**
Hospital	**1,965**
Institusi Kerajaan	**2,030**
Jabatan Kesihatan Negeri	**8,520**
Pejabat Kesihatan Daerah	**28**
Non MOH Agency (MINDEF, MOSTI, Universities)	**793**
General Practitioners	**392**
Private health centre	**3,468**
Private laboratories	**641**
Multinational companies (with OSH division)	**46**
Total numbers as of 31 August 2022	**22,003**

Responsive Helpdesk Support Centre

Not only the development of the system has taken so much of their time, the set up centralized of Helpdesk Support Centre is one of the success created by the NPHL IT team. The efficient and responsive support centre played a major help to users at the ground to ensure they use the system correctly. Internal KPI was set to three (3) days for every request or data correction received thru official email/ WhatsApp. The requests were varied from application of SIMKA usernames, patients' data correction (typo). The total numbers of requests by category up to 30 September 2022 (Table 7.1.2).

Table 7.1.2: Total numbers of requests by category up to 30 September 2022.

Method of Request	***CUMULATIVE (2022)***		***AUGUST 2022***		***SEPTEMBER 2022***	
	n	**%**	**n**	**%**	**n**	**%**
Form (only at NPHL)	**269**	**1.83**	50	**11.31**	43	**7.11**
Email	**12693**	**86.31**	349	**78.96**	515	**85.12**
Phone calls through call centre	**1406**	**9.56**	39	**8.82**	42	**6.94**
WhatsApp	**337**	**2.29**	4	**0.90**	5	**0.83**
Total	**14705**	**100**	**442**	**100**	**605**	**100**

Bulk Upload – The Impossible Make Possible

With the increasing of samples during third wave of COVID-19 in Malaysia, the need to enhance SIMKA to meet all the major need. Thus, the developer team of SIMKA studied on all variables in SIMKA Outbreak and with assistance by the Epidemiology team, SIMKA excellently met the needs to cater upload records in bulk and with other format. The bulk upload function templates of every variables that compulsory to be inserted into SIMKA Outbreak were shared with all the private laboratories and a few general practitioners (GP) that has other LIS in place and has dedicated technical officer to take charge on the bulk upload (Figure 7.1.1).

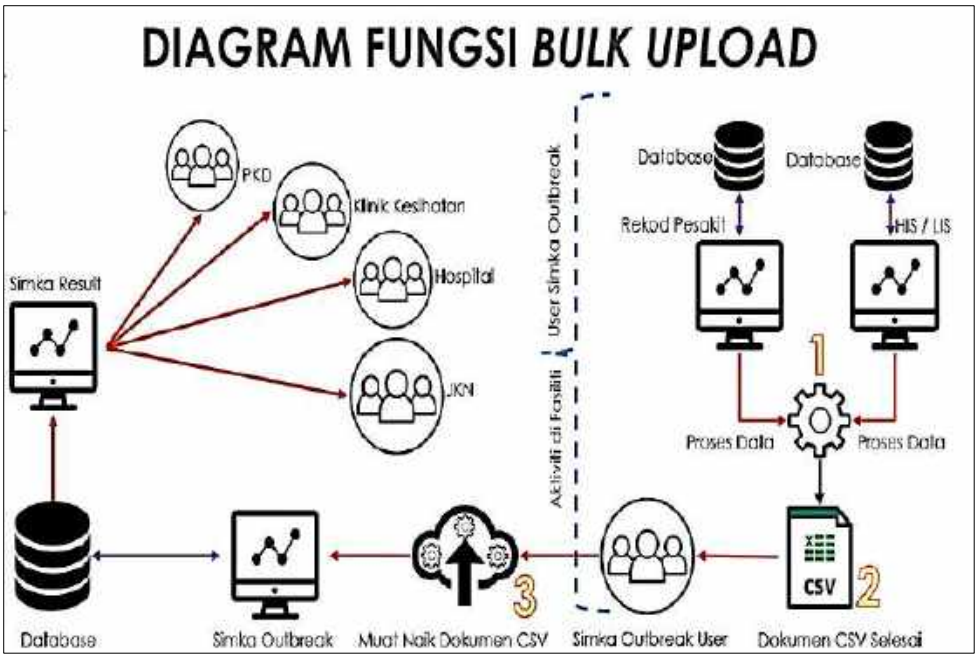


Figure 7.1.1: The template for bulk upload purpose.

The upload would be failed if any of the compulsory variables not be included in the csv file. Virtual training and guides have been given to them from time to time to ensure they can benefit from the function. The function later being offered to District Education Department to assist Ministry of Education (MOE) during the period of students COVID-19 check where the schools reopened.

Integration Fasten the Notifications

As the needs for the public to get faster notification and not to wait for the PKD to update them, notifications were pushed to their MySejahtera profile every next day from the date their tests being verified in SIMKA. NPHL IT team has uploaded the daily line listing consisted of three (3) main files which were PCR records, RTK records and those from the Bulk Upload functions. But due to some occasion, notifications not

being pushed on reasonable time, both CPRC and SIMKA was challenged to explore direct integration to enable real time data sharing faster.

Both CPRC eCOVID19 and SIMKA team conducted various discussions and testing until the API can be used where PCR results will automatically be updated and sent notifications to MySejahtera on real time basis.

SIMKA Recognition during *Anugerah Inovasi Peringkat Kementerian Kesihatan Malaysia* Year 2020

NPHL has joined the competition hosted by Committee of *Anugerah Inovasi Kementerian Kesihatan Malaysia* on SIMKA which enrolled for Process Category. This annual competition offered four (4) categories which are Product, Process, Service and Technology.

For pandemic COVID-19, NPHL has innovated the process of registration samples by simplifying the process of registration and introduced the innovated processed via SIMKA Outbreak.

The competition was held during pandemic in which along the stages of this competition country have been under Restriction Movement Order (RMCO). During preliminary level on 25 September 2020 where took place at headquarters, the team leader – NPHL Head IT Section, Puan Salfaryna Binti Alzahari partner with Lab Officer, Mr Selvanesan A/L Sengol has presented the system to the panellists. The participation has been chosen to go the final level along with other participation from various divisions.

NPHL team which led by Puan Salfaryna consists of seven (7) members who were Mr Selvanesan, the lab officer which uncharged on Covid-19 samples management, Dr Nor Zahrin Binti Hasran., Dr Mimi Rodzaimah Binti Abdul Karim and Mr Mohd Hamidi Bin Mohd Rani who in charged on data analysis and collaboration with eCOVID-19 OMS and

the system development and support team, Mr Mohd Addin@ Rusken Bin Ruslan and Puan Siti Fairuz Binti Mar Ramli.

The final level was held via virtual platform on 7 November 2020 in which all participant was instructed to present to the panellist according to their turn. NPHL has been numbered as the first presentation and the team has presented very well from NPHL meeting room. The question and answer sessions has been conducted very precise and closed completely at stipulated time. All the hard work paid off when SIMKA Outbreak has won *Anugerah Khas Juri* and two other award (Figure 7.1.2 (a, b and b) and Figure 7.1.3).

Sijil Penghargaan

KEMENTERIAN KESIHATAN MALAYSIA

PROJEK SISTEM PENGURUSAN DATA BERSEPADU MAKMAL COVID-19

(MAKMAL KESIHATAN AWAM KEBANGSAAN)

Anugerah Khas Juri

ANUGERAH INOVASI
KEMENTERIAN KESIHATAN MALAYSIA 2020
(KATEGORI PROSES)

Figure 7.1.2 (a): Certificate of Anugerah Khas Juri


KEMENTERIAN KESIHATAN MALAYSIA

Sijil Penghargaan

PROJEK INOVASI :
SISTEM PENGURUSAN DATA
BERSEPADU MAKMAL COVID - 19
(KATEGORI : PROSES)

ANUGERAH INOVASI
KEMENTERIAN KESIHATAN MALAYSIA
2020

25 September 2020

Bahagian Dasar & Hubungan Antarabangsa
Kementerian Kesihatan Malaysia

Figure 7.1.2 (a): Certificate of Preliminary Level.


MINISTRY OF HEALTH MALAYSIA

WITSA GLOBAL EXCELLENCE ICT AWARDS

MAKMAL KESIHATAN AWAM BUNGAI BULOH
(MMKA)

Figure 7.1.2 (b): Certificate of WITSA Global Excellent ICT Awards

Figure 7.1.3: The team lead presentation during the final level via online.

7.2 COVID-19 Bio-Genomics for ASEAN Countries

SARS-CoV-2 Whole Genome Sequencing (WGS) technologies are invaluable tools for improvement of surveillance testing, development of vaccines, diagnostics kits, therapeutics and investigation of disease. Laboratory personnel must acquire the skills to perform WGS of the SARS-CoV-2 virus and phylogenetic network analysis of the viral genomes. This information with the epidemiological data were analysed together for public health decision makings. Therefore, NPHL as the reference laboratory, the need to have the right technology at the right time operated by competent laboratory personnel is crucial and non-negotiable. NPHL personnel were among the key persons that were involved in making this event a success (Figure 7.2.1).

Figure 7.2.1: The key persons who has been involved in the event.

The former Director of the National Public Health Laboratory (NPHL) Malaysia, Dr. Noorliza Mohamad Noordin led the idea and initiated the Strengthening Laboratory Capacity on SARS-CoV-2 Genomics Training project for knowledge sharing and enhanced communication among ASEAN Countries. A series of discussions was held since 2021 with

the ASEAN Secretariat for the planning and execution stages. The project was funded by GIZ (German Corporation for International Cooperation).

The project was successfully conducted by NPHL, Malaysia for 20 weeks (07 April 2022 – 07 September 2022), commencing with the Official Launch on the 7th of April 2022. The highlight of the event was during the plenary session whom Dr Joshua Quick, a molecular biologist specializing in the next-gene sequencing presented his hour-long engaging talk entitled, "The ARTIC Sequencing Protocol for SARS-CoV-2".

Figure 7.2.2: The summary of the workshop.

The training was attended by six (6) ASEAN Member States; Brunei, Cambodia, Indonesia, Malaysia, Thailand and Vietnam (2 institutions), with at least 20 participants per session. The training included 20 weeks of interactive presentations, hands-on and discussions aimed at improving participants' knowledge about the basic principles of biosafety and the Whole Genome Sequencing (WGS) workflow;

encompassing sample selection to genome analysis. A total of 124 sequences were successful shared by the six (6) ASEAN Member States (AMS) and the publication of the analyzed sequences in a high-impact journal is highly anticipated at the end of 2022 (Figure 7.2.2). The training sessions were efficiently handled by two experts namely, Dr Tan Joon Liang and Mr. Muhd Khairul Luqman Muhd Sakaff with the enthusiastic support of the NPHL Secretariat team.

Despite the many challenges and difficulties faced during the COVID-19 pandemic, the virtual platform made the opportunity for learning possible despite the COVID-19 restrictions, regardless of geographical locations. It was ultimately, the great teamwork and collaborative effort from all parties which made the training successful, effective and impactful for future endeavors.

7.3 Be Trained and Training Others in Handling Specimen

Packaging and transportation of clinical samples are one of the crucial requirements to be fulfilled in every single laboratory that performs test. Initially in early day of COVID-19 pandemic, NPHL received various type of sample packaging, many requesters from district health office were unaware of the requirements of triple packaging. Example of inappropriate packing was samples packed with rubber band and gauze. It was a great disaster for laboratory staffs to unpack the sample as they were exposed to hazardous materials. Sharp cutting tools need to be used to unpack the sample wrapping. Some requester even snuck the sample containers into narrow opening containers, which was very challenging for laboratory staff to remove the samples from the containers. Following that, NPHL took the initiative to teach the right triple packaging and sample transportation method to all District Health Officers throughout the country.

Prior to this, NPHL technical officers have attended the workshop by ASEAN Regional Public Health Laboratory entitled the Webinar Series

on Infectious Substances Shipping for Local Sample Transport of COVID-19 Specimens which was held from 2nd to the 11th June 2020 (Cohort 1) - 50 lab experts from Brunei Darussalam, Cambodia, Malaysia, Myanmar, Indonesia, and Thailand attended this workshop. The Cohort 2 was held on 23rd, 25th, 30th June & 2nd July 2020 (Cohort 2) attended by 100 of participants including 58 lab experts representing both public health and animal health laboratories from Brunei Darussalam, Lao PDR, Malaysia, Myanmar, Indonesia, Philippines, Singapore, Viet Nam and Thailand attended. The workshop includes training on package receiving, preparation and shipping for laboratory biosafety/biosecurity officers, trainers and others responsible for shipping programs at own facilities (Figure 7.3.1).

Malaysia was represented by 8 participants from NPHL, 2 Observers & 1 Evaluator for Cohort 1 and 14 participants from NPHL, 10 participants Ipoh PHL & 1 Evaluator for Cohort 2. In total, Malaysia was represented by 38 participants. Subsequently, NPHL conducted an in-house Training of Trainer (TOT) for Triple Packaging and Transportation Infectious Specimen Course on 21st September 2020 to train additional trainers from the NPHL (Figure 7.3.2 and Figure 7.3.3).

Figure 7.3.1 Among the participants that attend the ASEAN Regional Public Health Laboratory Webinar Series on Infectious Substances Shipping for Local Sample Transport of COVID-19 Specimens

Figure 7.3.2: Among the participants that attend in-house Training of Trainer (TOT) for Triple Packaging and Transportation Infectious Specimen Course virtually.

Figure 7.3.3: Among the participants in NPHL that attend in-house Training of Trainer (TOT) for Triple Packaging and Transportation Infectious Specimen Course.

Some of slide presentation that was used during the training were shown in Figure 7.3.4 (a) and (b) below.

Figure 7.3.4 (a)

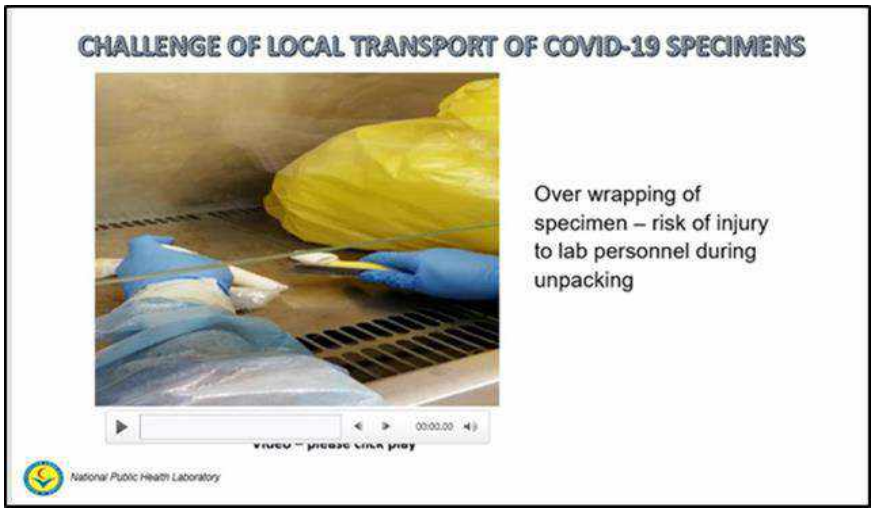


Figure 7.3.4 (b)

Figures 7.3.4 (a) and 7.3.4 (b) were part of the points highlighted during the training

Beside the virtual workshop, the training was also done via hands on training at NPHL (Figure 7.3.5).

Figure 7.3.5: Hands-on training on Specimen handling conducted at NPHL.

COVID -19 MEMORABILIA

TRIBUTES TO OUR NPHL WARRIOR !!

TRIBUTES TO OUR NPHL WARRIOR !!

TRIBUTES TO OUR NPHL WARRIOR !!








TRIBUTES TO OUR NPHL WARRIOR !!








TRIBUTES TO OUR NPHL WARRIOR !!








TRIBUTES TO OUR NPHL WARRIOR !!

TRIBUTES TO OUR NPHL WARRIOR !!

TRIBUTES TO OUR NPHL WARRIOR !!

TRIBUTES TO OUR NPHL WARRIOR !!

Appreciation

&

Acknowledgement

Lab Warriors