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THE DEVELOPMENT AND STANDARDIZATION OF COVID-19 EXAMINATION LABORATORY: EFFECTIVITY AND CHALLENGES

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Abstract

The COVID-19 pandemic come to an end, including Indonesia. However, the laboratory examination is still on due. In terms of surveillance and detection, countermeasures are carried out by examining COVID-19 specimens by the network of COVID-19 examination laboratories. The gold standard for COVID-19 examination is to carry out an RT-PCR (Real Time Polymerase Chain Reaction) test from samples taken with nasopharyngeal and oropharyngeal swabs. Batam currently houses multiple COVID-19 testing laboratories employing RT-PCR tests. To ensure consistent high-quality testing and prompt results, it is crucial to establish standardized operational procedures for all testing facilities. This study assesses the impact of the Minister of Health of the Republic of Indonesia's Decree Number HK.01.07/MENKES/4642/2021 on the development of COVID-19 testing laboratories in Batam, managed by the Environmental Health and Disease Control Engineering Center (BTKLPP) Class I Batam. This study uses an empirical juridical method with a qualitative approach with secondary data. It was found that to get fast and valid results, the laboratory for examining COVID-19 specimens must have a standard that is a reference which refers to the Decree of the Minister of Health (Kepmenkes) RI Number HK.01.07/MENKES/4642/2021 concerning Organizing the COVID-19 Examination Laboratory and supervisory laboratory in carrying out guidance and supervision of the implementation of the examination of COVID-19 specimens in each of the laboratories for examining COVID-19 specimens in Batam.

Keywords: covid-19, examination laboratory, supervisory laboratory regulation

A. Background

After months of battling intense waves of infection, Indonesia has finally witnessed a significant decline in cases.¹ Stringent government measures, such as travel restrictions, the closure of public spaces, and mass vaccination, have contributed to the improvement of the situation. Daily case numbers have plummeted dramatically, and hospitals are no longer under the previous strain.²

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¹ CNBC Indonesia, "Kasus Positif Turun Signifikan, Terima Kasih Warga Indonesia!," CNBC Indonesia, 2021, https://www.cnbcindonesia.com/news/20210831204948-4-272712/kasus-positif-turun-signifikan-terima-kasih-warga-indonesia.

² Roxana Filip et al., "Global Challenges to Public Health Care Systems during the COVID-19 Pandemic: A Review of Pandemic Measures and Problems," *Journal of Personalized Medicine* 12, no. 8 (2022): 1295, https://doi.org/10.3390%2Fjpm12081295.





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> COVID-19 has presented a crisis in pandemic governance and policy in every country. Regardless of their economic progress, technological advancements, and high capabilities in the healthcare sector, every country has encountered uncertainty and lack of confidence in dealing with COVID-19.³ Standard crisis management systems seem to be no longer relevant in addressing COVID-19, thereby compelling governments worldwide to adopt policies that tend to be trial and error. COVID-19 has given rise to massive and global socio-economic impacts, not only stemming from the disease itself but also from policies that were expected to prevent its spread.⁴

This disease is caused by the infection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). In Indonesia, the first cases were detected on March 2, 2020, when two Indonesian citizens were confirmed positive for COVID-19 after being infected by a Japanese citizen.⁵ In the following month, April 2020, the pandemic had spread to all 34 provinces in Indonesia. The COVID-19 pandemic is not the first health crisis to hit and be faced by Indonesia. Previously, Indonesia had dealt with diseases such as SARS, H5N1 (Avian Influenza), and H1N1 (Swine Flu) in 2003.⁶ In fact, if we delve into history and consult various sources, Indonesia has faced disease outbreaks even during the colonial period when it was known as the Dutch East Indies. Some information from mass media during that time corroborates this, including articles like Algemeen Handelsblad on October 30, 1918, with the title "Spaansche Griep" (Spanish Flu); De Masbode on December 7, 1918, with the title "Kolonien Uit Onze Oost, De Spaansche Ziekte op Java" (Colonies From Our East, Spanish Disease in Java); De Telegraaf on November 22, 1918, featuring news titled "De Spaansche Griep op Java" (Spanish Flu in Java); and De Sumatra Post on December 11, 1920, with an article titled "Influenza." At that time, the population of Indonesia was approximately 35 million, with 13.3% succumbing to the Spanish Flu, which translates to over 4.6 million lives lost due to the disease.7

In the context of addressing the COVID-19 disease, President Joko Widodo subsequently issued two regulations simultaneously on March 31,

³ Ferdy Kusno, "Krisis Politik Ekonomi Global Dampak Pandemi Covid-19," *Anterior Jurnal* 19, no. 2 (2020): 94–102, https://doi.org/10.33084/anterior.v19i2.1495.

⁴ Wawan Mas'udi and Poppy S. Winanti, "COVID-19: Dari Krisis Kesehatan Ke Krisis Tata Kelola," in *Tata Kelola Penanganan COVID-19 Di Indonesia: Kajian Awal* (Yogyakarta: Gadjah Mada University Press, 2020), 3.

⁵ Teddy Tri Setio Berty, "Kasus Pertama Virus Corona Di Indonesia Jadi Sorotan Dunia," Liputan 6, 2020, https://www.liputan6.com/global/read/4191815/kasus-pertama-virus-corona-di-indonesia-jadi-sorotan-dunia.

⁶ Indra Jaya, "Penguatan Sistem Kesehatan Dalam Pengendalian COVID-19," Direktorat Jenderal Pencegahan dan Pengendalian Penyakit, 2021, http://p2p.kemkes.go.id/penguatan-sistem-kesehatan-dalam-pengendalian-covid-19/.

⁷ Egy Massadiah, "Berkaca Pada Wabah Di Masa Lalu, Doni Menengok Putaran Roda Zaman," Badan Nasional Penanggulangan Bencana, 2020, https://bnpb.go.id/berita/berkaca-pada-wabah-dimasa-lalu-doni-menengok-putaran-roda-zaman-.

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2020. These were Presidential Decree Number 11 of 2020 concerning the Declaration of a Public Health Emergency for Corona Virus Disease 2019 (COVID-19) and Government Regulation Number 21 of 2020 concerning Large-Scale Social Restrictions (PSBB), which commenced on April 1, 2020.⁸ The mechanisms for implementing PSBB at the regional level were detailed in the Ministry of Health Regulation Number 9 of 2020 on Guidelines for Large-Scale Social Restrictions in the Acceleration of the Handling of Corona Virus Disease 2019 (COVID-19), issued on April 4, 2020.⁹

The Indonesian government has made swift efforts to prevent and control COVID-19 by forming a COVID-19 disease control task force directly led by President Joko Widodo. The National Disaster Management Agency (BNPB) coordinates this task force through Presidential Decree No. 7 of 2020 regarding the COVID-19 Handling Acceleration Task Force, issued on March 13, 2020.¹⁰ By the end of March 2020, the number of confirmed COVID-19 cases in Indonesia continued to rise, reaching 1,406 people on March 27, 2020, as reported by the COVID-19 Handling Acceleration Task Force. Seven components have been the focus of pandemic control, including coordination, surveillance, detection, healthcare services, logistics, human resources, and information and communication.¹¹

In terms of surveillance and detection, efforts are made through specimen testing for COVID-19 in a network of COVID-19 testing laboratories. The gold standard for COVID-19 testing and the most accurate method currently is the RT-PCR (Real Time Polymerase Chain Reaction)¹² test performed on samples taken from nasopharyngeal and oropharyngeal swabs. Batam City has several COVID-19 specimen testing laboratories conducting RT-PCR tests.

The public expects decisive policies and actions from the government in handling the COVID-19 pandemic, as mandated by the 1945 Indonesian Constitution, Chapter XA on Human Rights, Article 28A, which states, "Everyone has the right to life and the right to live and maintain life and its livelihood," and Article 28H, paragraph 1, which states, "Everyone has the right to live in physical and spiritual well-being, to reside, and to have a

⁸ Yenny Hardiyanti, "Presiden Jokowi Keluarkan PP Dan Keppres Terkait Kedaruratan Kesehatan," SchoolMedia News, 2020, https://news.schoolmedia.id/berita/presiden-jokowi-keluarkan-pp-dan-keppres-terkait-kedaruratan-kesehatan-1847.

⁹ Tahir Saleh, "Permenkes PSBB Akhirnya Terbit, Simak Poin-Poin Krusialnya!," CNBC Indonesia, 2020, https://www.cnbcindonesia.com/news/20200405061921-4-149831/permenkes-psbb-akhirnya-terbit-simak-poin-poin-krusialnya.

¹⁰ Riyanti Djalante et al., "Review and Analysis of Current Responses to COVID-19 in Indonesia: Period of January to March 2020," *Progress in Disaster Science* 6 (2020), https://doi.org/https://doi.org/10.1016%2Fj.pdisas.2020.100091.

¹¹ Jaya, "Penguatan Sistem Kesehatan Dalam Pengendalian COVID-19."

¹² Julia Martin, Noelia Tena, and Agustin G. Asuero, "Current State of Diagnostic, Screening and Surveilance Testing Methods for COVID-19 from an Analytical Chemistry Point of View," *Microchemical Journal* 167 (2021), https://doi.org/https://doi.org/10.1016/j.microc.2021.106305.

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good and healthy environment, as well as the right to obtain health services."

Minister of Health Regulation (Permenkes) of the Republic of Indonesia No. HK.01.07/MENKES/4642/2021 plays a pivotal role as a guiding standard for the Technical Implementation Units (UPT) in the Field of Environmental Health and Disease Control when operating COVID-19 testing laboratories in Batam City during the period of 2021-2023. This regulation provides a detailed and comprehensive framework for the operation of COVID-19 testing laboratories, encompassing technical procedures, operational requirements, sanitation standards, and other operational guidelines that must be adhered to by the UPTs managing these laboratories.¹³

Moreover, this Permenkes establishes quality standards and COVID-19 testing methods to be followed by the laboratories, particularly in the examination of specimens using the RT-PCR (Real Time Polymerase Chain Reaction) test, which is currently considered the most accurate method. Consequently, this Permenkes offers clear guidance to UPTs in the Field of Environmental Health and Disease Control to ensure that the operation of COVID-19 testing laboratories in Batam City complies with the established standards and maintains consistent service quality throughout the 2021-2023 period.

Beyond serving as a technical standard, this Permenkes also aims to ensure uniformity in the implementation of COVID-19 testing across various laboratories, thereby rendering test results more reliable and accountable. With these clear guidelines and standards stipulated by this Permenkes, the UPTs in the Field of Environmental Health and Disease Control can play a crucial role in ensuring that COVID-19 testing laboratories in Batam City operate effectively and in accordance with the established standards, thereby optimizing their contributions to the management of the COVID-19 pandemic.

One of the issues arising in relation to COVID-19 testing laboratories in Batam City is the uneven sanitation problem.¹⁴ Although some laboratories have conducted COVID-19 specimen examinations using the RT-PCR test, the level of sanitation within these laboratories may vary. Differences in sanitation standards, layout, equipment maintenance, and adherence to hygiene protocols can pose serious issues.

The disparity in sanitation levels in COVID-19 testing laboratories can result in the risk of disease transmission, both to laboratory staff and to patients who come for testing. Poor cleanliness can lead to cross-

¹³ Intan Umbari Prihatin, "Menkes Budi Gunadi Tetapkan Jenis Lab Pemeriksaan Covid-19," Liputan 6, 2021, https://www.liputan6.com/news/read/4561880/menkes-budi-gunadi-tetapkan-jenis-lab-pemeriksaan-covid-19?page=2.

¹⁴ I Nyoman Mastika, Ida Bagus Putu Adnyana, and I Gusti Agung Nyoman Setiawan, "Analisis Standarisasi Laboratorium Biologi Dalam Proses Pembelajaran Di SMA Negeri Kota Denpasar," *Jurnal Pendidikan Dan Pembelajaran IPA Indonesia* 4, no. 1 (2014).



contamination, test result errors, and even disease transmission if the laboratories do not maintain sanitation protocols effectively.¹⁵

Furthermore, the inconsistency in sanitation levels can also disrupt the credibility of COVID-19 test results issued by laboratories. Patients receiving positive test results from one laboratory and negative results from another may doubt the accuracy of the tests, leading to confusion.¹⁶

Therefore, the issue of uneven sanitation levels in COVID-19 testing laboratories in Batam City demands serious attention. Improvement efforts in this regard include stricter monitoring and supervision of laboratory compliance with the sanitation guidelines established in the Minister of Health Regulation (Permenkes) of the Republic of Indonesia No. HK.01.07/MENKES/4642/2021. These measures are crucial to ensure that all laboratories maintain the same sanitation standards, thereby enabling reliable test results and minimizing disease transmission in the efforts to manage the COVID-19 pandemic in Batam City.

Based on the previous description, the author aims to analyze and gain further insight into the operation of COVID-19 testing laboratories based on the Minister of Health's Decision (Kepmenkes) No. HK.01.07/MENKES/4642/2021 regarding the Organization of Corona Virus Disease 2019 (COVID-19) Testing Laboratories, particularly focusing on the implementation of these laboratories in Batam City.

B. Identified Problems

The research issues addressed in this study are as follows:

- 1. What are the obstacles in implementing the Minister of Health Decision regarding Organization of Coronavirus Disease 2019 (COVID-19) Testing Laboratories in Batam City in 2021-2022?
- 2. What are the solutions to the obstacles in implementing The Decision of the Minister of Health of the Republic of Indonesia Regarding the Organization of Coronavirus Disease 2019 (COVID-19) Testing Laboratories especially in Sanitation issues?

C. Research Methods

This research aims to analyze and gain further insight into addressing the issues formulated above. This study is categorized as empirical legal research or juridical-empirical research.¹⁷ Juridical-empirical research is

¹⁵ Jamie E. Ehrenpreis and Eli D. Ehrenpreis, "A Historical Perspective of Healthcare Disparity and Infectious Disease in the Native American Population," *The American Journal of the Medical Sciences* 363, no. 4 (2022): 288–94, https://doi.org/https://doi.org/10.1016%2Fj.amjms.2022.01.005.

¹⁶ Sri Wahyuningsih Nugraheni, Erna Zakiyah, and Nur Rohmah, "Analisis Kualitatif Dokumen Rekam Medis Rawat Inap Penyakit Covid-19 Di Rumah Sakit PKU Muhammadiyah Sura karta," in *Strategi Dan Kolaborasi Dalam Membangun Kemandirian Kesehatan Di Indonesia* (Surakarta: Universitas Duta Bangsa Surakarta, 2022), 449–57, https://doi.org/https://doi.org/10.47701/sikenas.vi.2094.

¹⁷ Soerjono Soekanto and Sri Mamudji, *Penelitian Hukum Normatif: Suatu Tinjauan Singkat* (Jakarta: Rajawali Press, 2018).

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conducted to delve deeper into understanding how the law operates within society (social). Therefore, the approach used by the author is Juridical-Sociological. Juridical-Sociological research is a form of legal research that employs secondary data as initial data and then proceeds with primary data or field data, investigating the application of legal regulations while seeking relationships between various variables. The data collection methods consist of document studies, observations, and interviews.¹⁸

Since both primary and secondary data are utilized in this research, the Juridical-Sociological method is employed. The results of observations and interviews constitute the primary data, while primary legal materials and other secondary documents serve as secondary data.¹⁹

To ensure objectivity in this research, the study employs Soerjono Soekanto's Legal Effectiveness Theory²⁰ as its analytical framework. This theory posits that the effectiveness of a law is influenced by various factors, including the law itself, law enforcement, supporting infrastructure, societal factors, and cultural factors. These factors are considered neutral, meaning their impact can be either positive or negative, depending on their contents. These five factors are closely interconnected and form the essence of law enforcement and the yardstick for evaluating the effectiveness of legal enforcement.

D. Research Finding and Discussion

1. Covid-19 Pandemic in Batam City and Policies

According to Law No. 24 of 2007 concerning Disaster Management, a disaster is an event or a series of events that threaten and disrupt the lives and livelihoods of the community caused by natural and/or non-natural factors as well as human factors resulting in loss of life, environmental damage, property loss, and psychological impacts. Disasters caused by non-natural factors are disasters resulting from non-natural events or a series of non-natural events, such as technological failures, modernization failures, epidemics, and disease outbreaks. The Covid-19 pandemic can be considered an example of a disaster caused by non-natural factors, falling into the category of a disease epidemic.²¹

Covid-19, which affected the Riau Islands Province, particularly Batam City, resulted in a significant number of casualties, leading to the city being categorized as a "black zone" in July 2021. The Covid-19 pandemic necessitated swift and precise measures. The Batam City Government introduced various policies and regulations in handling Covid-19 to regain

¹⁸ Amiruddin and Zainal Asikin, *Pengantar Metode Penelitian Hukum* (Jakarta: Raja Grafindo Persada, 2012).

¹⁹ Rina Shahriyani Shahrullah and Henry Hadinata Cokro, "Penegakan Hukum Bagi Pedagang Usaha Mikro, Kecil Dan Menengah Terhadap Para Pelaku Usaha Monopoli," *Journal of Law and Policy Transformation* 5, no. 2 (December 10, 2020): 113–27, https://doi.org/10.37253/jlpt.v5i2.1391.

²⁰ Soerjono Soekanto, Efektivitas Hukum Dan Peranan Sanksi (Bandung: Remaja Karya, 1988).

²¹ Badan Nasional Penanggulangan Bencana, "Definisi Bencana," Badan Nasional Penanggulangan Bencana, 2023, https://www.bnpb.go.id/definisi-bencana.

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> control, such as the Mayor's Regulation of Batam City No. 49 of 2020 on the Implementation of Discipline and Law Enforcement of Health Protocols as Efforts for Prevention and Control of Corona Virus Disease 2019 in Batam City, along with other regulations related to budget allocations focusing on healthcare activities deemed capable of reducing the impact of the Covid-19 pandemic, particularly in treating Covid-19-positive individuals and patients, thereby reducing the number of cases and deaths due to Covid-19.²²

> Quoting from the official website of the Batam City Government at lawancorona.batam.go.id, daily data related to the Covid-19 pandemic shows that the pandemic is ongoing. As of October 27, 2022, the data reveals a total of 224,419 suspected cases, with 31,436 confirmed cases of Covid-19 and 937 deaths.²³

Various efforts have been made to control the spread of Covid-19 cases in Batam City, including contact tracing (a minimum of 15 close contacts per confirmed case), increasing and enhancing testing (Rapid Diagnostic Testing - Antigen for close contacts followed by PCR testing), evacuating and treating cases in makeshift homes designated as referral centers. Batam City has 15 Covid-19 Referral Hospitals and 1 National Referral Hospital: RSKI Covid-19 Galang. Furthermore, both national and local government regulations and policies have emphasized Covid-19 vaccination as an effective intervention to break the chain of transmission. In the implementation of Covid-19 vaccination, the concept of herd immunity can be achieved with high and even immunization coverage throughout the region, with a minimum of 70% coverage, indirectly providing protection for other age groups as per WHO and Indonesian Technical Advisory Group on Immunization (ITAGI) recommendations. Batam City's high vaccination coverage has played a role in reducing Covid-19 cases, as evident from the daily Covid-19 data. The achievement of complete vaccination doses (received two doses) is currently at 91.31%, indicating successful Covid-19 control in Batam City.

In 2022, Batam City continued to grapple with the challenges posed by the Covid-19 pandemic. The city had experienced fluctuations in Covid-19 cases over the past year, with periods of surges followed by relative declines. The local government, in close coordination with national health authorities, had implemented a range of measures to combat the spread of the virus. These measures included strict health protocols, increased testing and contact tracing efforts, and an aggressive vaccination campaign. By the beginning of 2023, Batam City had made significant progress in vaccinating its population, with a high percentage of residents having received both doses of the Covid-19 vaccine. This contributed to a noticeable reduction in the number of daily cases and, most importantly, a decline in severe cases and fatalities.

²² Syakila Verolia, "Efektivitas Realokasi Anggaran Dalam Penanganan Covid-19 Di Kota Batam Provinsi Kepulauan Riau" (Institut Pemerintahan Dalam Negeri, 2022).

²³ https://lawancorona.batam.go.id/2022/10/31/data-harian-Covid-19-31-oktober-2022/



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As Indonesia as a whole made substantial strides in managing the pandemic, there were discussions at the national level regarding the possibility of repealing the pandemic status of Covid-19. The decision to repeal the pandemic status was contingent on several factors, including the overall Covid-19 situation, vaccination coverage, and the capacity of healthcare systems to manage cases effectively. The repeal of the pandemic status would mark a significant milestone in Indonesia's battle against Covid-19, signaling a transition from a pandemic phase to an endemic phase where the virus would be more controlled, and life could return to a semblance of normalcy. However, such a decision required careful consideration of the potential risks and the need to maintain vigilance in monitoring the virus's behavior to prevent any resurgence.

The International Health Regulations (IHR) 2005 is an international legal instrument that currently binds 194 countries worldwide, including all member states of the World Health Organization (WHO). Its purpose and scope encompass the prevention, protection, and response to international disease spread, with the principle of not impeding international trade and travel. The IHR 2005 not only defines new diseases as threats to health but also mobilizes member countries to consider control from various aspects, such as chemical and radioactive pollution, to safeguard public health, prevent disease spread, and address transboundary health issues that may affect the majority of the global population.

The primary national requirements under the International Health Regulations (IHR) 2005 that a country must possess in preventing, protecting, and responding to public health in the face of disease spread include regulations and policies, coordination, surveillance, response, preparedness, risk communication, human resources, and laboratory capacity. The implementation of these requirements should be structured hierarchically, from the national level to regional (provincial/district/city) and directly to the community. Laboratories play a fundamental and vital role in supporting activities and programs related to disease and vector detection.

The Indonesian government has formulated policies regarding laboratories in disease control through the Minister of Health Regulation Number 658/MENKES/PER/VIII/2009, taking into consideration the need for laboratory testing of clinical specimens from suspected cases in response to new emerging and re-emerging infectious diseases. This ensures the rapid, accurate, and tiered diagnosis of the causative agents of these diseases. Covid-19 can be categorized as a new-emerging infectious disease, making laboratories essential for accurate diagnosis.

In the implementation of the Covid-19 response, Indonesia has issued various policies, including Minister of Health Regulation Number HK.01.07/MENKES/4641/2021 on Guidelines for the Implementation of Testing, Tracing, Quarantine, and Isolation in Accelerating the Prevention and Control of Coronavirus Disease 2019 (Covid-19). Additionally, Minister of Health Regulation Number HK.01.07/MENKES/4642/2021

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specifically addresses the organization of Covid-19 testing laboratories. Therefore, it can be stated that Indonesia's Covid-19 testing policies have effectively accommodated the support needed for Covid-19 management.

2. Standardization of COVID-19 Testing Laboratories in Batam City

According to the World Health Organization (WHO), a laboratory quality management system consists of 12 essential elements. A quality management system is defined as a coordinated activity to direct and control an organization regarding its quality. All operational aspects of the laboratory, including organizational structure, processes, and procedures, need to be addressed to ensure good quality, leading to accurate and reliable test results. The 12 essential elements of a laboratory quality management system are as follows: organization; personnel; equipment; procurement and inventory; process control; documents and records; information management; occurrence management; assessment; process improvement; customer service; and facilities and safety.

An assessment instrument for Covid-19 laboratories has been developed to evaluate the capacity or capability of existing laboratories, whether they have already conducted or intend to conduct RT-PCR Covid-19 testing. Laboratory assessments can be conducted by national health authorities, multilateral agencies, non-governmental organizations (NGOs), and laboratory managers. The assessment tools include the following: organization and management; documentation; specimen collection, handling, and transportation; data and information management; management of consumables and reagents; equipment management; facilities; community resources; biosafety management; public health functions; Covid-19 testing capacity and capability; and gap analysis.

The role of public health laboratories is quite extensive and encompasses laboratory services for disease surveillance, diagnosis, prevention, treatment, and health promotion. Other roles include providing training standards for human resources to be placed in laboratories; standardizing equipment, reagents, and consumables; and quality control of testing procedures and results.

Regarding the Standardization of Laboratory, this research is based on the report of the Class I BTKLPP Batam, which serves as a Technical Implementation Unit (UPTD) under the Directorate General of Disease Prevention and Control. The report plays a significant role in enhancing disease control and strengthening health security in the service area in 2022. Therefore, Class I BTKLPP Batam has identified strategic issues that need to be considered or prioritized in the health development planning within the service area.²⁴

3. BTKLPP Class I Batam: Challenges and the Solutions

²⁴ Balai Teknik Kesehatan Lingkungan dan Pengendalian Penyakit, "Laporan Kinerja BTKLPP Kelas I Batam Tahun 2022" (Batam, 2023).





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During 2021, based on the General report of Class I BTKLPP Batam,²⁵ during the COVID-19 pandemic, the Disease Laboratory Installation emerged as the central reference for PCR testing of COVID-19 samples in the service area. BTKLPP Class I Batam also provided support to several hospitals in the Riau Islands Province to enable their laboratories to serve as references for PCR testing of COVID-19 samples. In addition to being a central COVID-19 reference, the Disease Laboratory Installation also conducted examinations for TCM-TB and PCR confirmation for Dengue. This included reference microscopic TB examinations in the Riau Islands Province and reference microscopic Malaria examinations.

The COVID-19 pandemic resulted in a shortage of human resources, and the addition of COVID-19 volunteers, particularly laboratory analysts, could not handle all the increased workload of COVID-19 sample processing, which rose by over 100% in May, June, July. Nearly 50% of employees contracted COVID-19, causing disruptions in the environmental laboratory activities.

In terms of laboratory standardization, BTKLPP Class I Batam conducted assessments of several COVID-19 testing laboratories in the Riau Islands Province,²⁶ including the COVID-19 Laboratory of RS Budi Kemuliaan in Batam City, Medilab in Batam City, the Laboratory of Bhayangkara Hospital in Batam City, and RUMKITBAN Hospital in Batam City.

In 2022, COVID-19 testing laboratories face a new challenge in the management of the new emerging disease COVID-19, particularly in Whole Genome Sequencing (WGS) or SGTF. To monitor the spread of the SARS-COV-2 virus variants, some confirmed COVID-19 cases require WGS testing. WGS examinations are sent to genomic surveillance network laboratories, and the number of WGS examinations is conducted based on predefined case targets and criteria in various regions, COVID-19 referral hospitals, and entry points to the country. The criteria for WGS specimen testing are also determined in accordance with WHO guidelines.

The standardization of COVID-19 testing laboratories in Batam between 2021 and 2022 has already met equipment and resource-related standards. However, continuous improvement is necessary due to Ministry of Health regulations governing the organization of COVID-19 testing laboratories. One critical aspect highlighted in the annual report is the recommendation for examiners to separate specimen preparation and testing processes, if possible, to avoid cross-contamination during the examination. This recommendation underscores the need to address the high transmission risk among examiners, as reported in the findings.

²⁵ Balai Teknik Kesehatan Lingkungan dan Pengendalian Penyakit Kelas I Batam Kelurahan Sei Binti Kecamatan Sagulung Kota Batam, "Laporan Kinerja Tahun 2021" (Batam, 2022).

²⁶ Balai Teknik Kesehatan Lingkungan dan Pengendalian Penyakit Kelas I Batam, "Standar Pelayanan Balai Teknik Kesehatan Lingkungan Dan Pengendalian Penyakit (BTKLPP) Kelas I Batam" (Batam, 2021).

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The COVID-19 laboratory supervision conducted by BTKLPP Kelas I

Batam identified several areas for improvement in the laboratories. These include implementing one-way direction workflow, ensuring proper decontamination of equipment, considering separate personnel for sample preparation and testing, and having appropriate facilities and equipment.²⁷ These recommendations aim to enhance the safety and efficiency of the laboratories.

Based on the findings of the supervision, it is evident that there are certain issues that need attention from the Ministry of Health in the future. These issues include the need for proper infrastructure and facilities in some laboratories, such as meeting the standards for conducting COVID-19 testing and ensuring the availability of necessary equipment.²⁸ Additionally, there is a need for adequate training and resources to support biosafety and biosecurity practices, as well as the implementation of Good Laboratory Practice.²⁹ Addressing these issues will be crucial to ensure the effectiveness and reliability of COVID-19 testing in the future. The Ministry of Health should consider providing support and guidance to the laboratories to improve their infrastructure, equipment, and personnel training, thereby enhancing the overall quality of COVID-19 testing services.

Е. Conclusions

Covid-19 pandemic brought about significant challenges. A shortage of human resources and a surge in COVID-19 cases necessitated the addition of volunteers, notably laboratory analysts. Despite their efforts, there were disruptions in environmental laboratory activities. As the establishment of KEPMENKES HK.01.07/MENKES/4642/2021 regarding the Organization of Corona Virus Disease 2019 (COVID-19). The standardization of laboratories in the region became a priority, with assessments conducted on various COVID-19 testing facilities. The report highlights the need for improvement, with suggestions such as one-way workflow implementation, proper decontamination of equipment, separation of personnel for sample preparation and testing, and ensuring suitable facilities and equipment.

Moving into 2022, the emergence of new variants necessitates Whole Genome Sequencing (WGS) for monitoring. This poses another challenge for COVID-19 testing laboratories. Consequently, it is evident that the Ministry of Health should address key issues in the near future. This includes the provision of proper infrastructure, equipment, training, and resources to support biosafety, biosecurity, and Good Laboratory Practice, ensuring the reliability and effectiveness of COVID-19 testing services. The support and guidance from the Ministry of Health will be pivotal in achieving these objectives.

²⁷ Balai Teknik Kesehatan Lingkungan dan Pengendalian Penyakit, "Laporan Tahunan 2021 BTKLPP Kelas I Batam" (Batam, 2021).

²⁸ Ibid.

²⁹ Ibid.

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