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Pandemic response (Respiratory) — Walk-through screening station

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see <u>www.iso.org/directives</u>).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see <u>www.iso.org/</u> iso/foreword.html.

This document was prepared by ISO/TC 304, Healthcare Organization Management.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at <u>www.iso.org/members.html</u>.

Introduction

COVID-19 is the infectious disease caused by the most recently discovered coronavirus. This new virus and disease were unknown before the outbreak began in Wuhan, China, in December 2019. COVID-19 is now a pandemic affecting many countries globally. The World Health Organization declared the outbreak to be a Public Health Emergency of International Concern on 30 January 2020 and recognized it as a pandemic on 11 March 2020.

With the spread of COVID-19, the world is facing an unprecedented economic and health crisis. Many global leaders and economists view COVID-19 as "the gravest challenge since World War II." On 16 March 2020, the G7 leaders issued a joint statement "acknowledging that the COVID-19 pandemic is a human tragedy and a global health crisis, which also poses major risks for the world economy." In this extreme situation, Korea is becoming a sign of hope and a model to follow. According to major media outlets around the world, "South Korea took rapid, intrusive measures against COVID-19 and they worked" (Guardian, March 20 2). The Fortune evaluated that "South Korea has the highest rate of testing and the most comprehensive data for coronavirus in the world" (March 19).

On February 29, the number of new cases for the day surged to 909, mainly in a specific region due to a single religious group. However, on April 23, the number of new cases dropped to eight. So far, Korea is the only country with a population of over 50 million that has slowed the spread of the virus, and flattened the curve of new infections without shutting down the country nor the city at the epicenter of the outbreak, without imposing extreme personal travel or movement restrictions, and without closing airports or taking other authoritarian actions.

The Korean government is receiving many inquiries about her response against COVID19. The number of inquiries that Korea can address is certainly limited as the virus continues to spread in the country. What is Korea's secret in tackling this challenge? The swift action can be summarized as 3Ts: 1) widespread Testing, 2) contact Tracing and 3) rigorous Treating. By February, Korea made an international headline for its very first Walk-Through and Drive-Through Screening Stations for COVID-19 and the ability to test thousands of people each day. It is critical to act quickly before the situation aggravates.

A Walk-Through screening facility is a Screening Station where a test subject goes through the screening process of a medical interview, a temperature check, and specimen collection in a positive-, negative-, or adaptable-pressure booth. "K-Walk-Thru" is a collective name for the testing facilities adopted by Korea. This not only alleviates both the pressure on the hospitals and the risk of transmission by keeping potential test subjects out of hospital waiting rooms, but also reduces time by eliminating the need for disinfection required when taking samples within or outside the hospital.

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Pandemic response (Respiratory) — Walk-through screening station

1 Scope

This document describes the operation of a Walk-Through Screening Station (WTSS) for mass testing as part of pandemic response management (PRM).

NOTE COVID-19 is an exemplary disease for which such a station is developed.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at https://www.iso.org/obp
- IEC Electropedia: available at <u>https://www.electropedia.org/</u>

3.1

adaptable pressure booth

A booth with switchable directions of airflow (e.g., from negative to positive pressure or from positive to negative pressure)

3.2

air changes per hour

Volume of air changed in one hour. Air change per hour in a room, home, or building means that all the air in that environment will be replaced in one hour

[SOURCE: Miquel Porta, A dictionary of Epidemiology, Oxford university press, 2008]

3.3

confirmed case

(General) A laboratory-confirmed case[SOURCE: World Health Organization, Department of Communicable Disease Surveillance and Response, WHO Recommended Surveillance Standards. Second edition, available at https://www.who.int/csr/resources/publications/surveillance/whocdscsrisr992, <a hr

[SOURCE: Standard Operating Model of Drive-Thru Screening Station, Central Disaster and Safety Countermeasures Headquarters (CDSCHQ), South Korea]

3.4

Coronavirus

Coronaviruses are a large family of viruses which may cause illness in animals or humans. In humans, several coronaviruses are known to cause respiratory infections ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). The most recently discovered coronavirus causes coronavirus disease COVID-19**[SOURCE:WHO, Q&A on coronaviruses (COVID-19),** https://www.who.int/news-room/q-a-detail/q-a-coronaviruses.]

3.5

COVID-19

COVID-19 is an infectious disease caused by the most recently discovered coronavirus. The new virus was unknown before its outbreak began in Wuhan, China, in December 2019

[SOURCE: WHO, Q&A on coronaviruses (COVID-19), <u>https://www.who.int/news-room/q-a-detail/q-a</u>-coronaviruses]

3.6

disinfection

Specialized cleansing techniques that destroy or prevent growth of organisms capable of causing infection[SOURCE: ISO 17966:2016(en) Assistive products for personal hygiene that support users — Requirements and test methods, <u>https://www.iso.org/obp/ui#iso:std:iso:15190:ed-2:v1:en:term:</u> 3.9]Process to reduce the number of microorganisms, but not usually of bacterial spores, without necessarily killing or removing all organisms[SOURCE: ISO 15190:2020(en) Medical laboratories — Requirements for safety, <u>https://www.iso.org/obp/ui#iso:std:iso:17966:ed-1:v1:en:term:3.7</u>]Is defined as a process of the complete elimination of vegetative forms of microorganisms, except the bacterial spores from inanimate objects. Technically, there is reduction of \geq 103 log CFU of microorganisms by this method without spores

[SOURCE: Sterilization and Disinfection, available at https://www.ncbi.nlm.nih.gov/pmc/articles/ PMC7158362/]

3.7

epidemic

Occurrence in a community or region of cases of an illness, specific health-related behaviour, or other health-related events clearly in excess of normal expectancy. The community or region and the period in which the cases occur are specified precisely. The number of cases indicating the presence of an epidemic varies according to the agent, size, and type of population exposed, previous experience or lack of exposure to the disease, and time and place of occurrence

[SOURCE: Definitions: emergencies, Humanitarian Health Action, WHO, available at https://www.who.int/hac/about/definitions/en/]

3.8

high efficiency particulate air filter HEPA

Being, using, or containing a filter usually designed to remove 99.97 % of airborne particles measuring 0.3 micrometers or greater in diameter passing through it[SOURCE: Merriam-Webster dictionary, available at https://www.merriam-webster.com/dictionary/HEPA]Retentive matrix having a minimum particle-collection efficiency of 99.97 % (that is, a maximum particle penetration of 0.03 % for 0.3 µm particles)[SOURCE: ISO 13408-1:2008(en) Aseptic processing of health care products — Part 1: General requirements, available at https://www.iso.org/obp/ui]A filter having 99.95 % efficiency at most penetrating particle sizes (class H13 in accordance with EN 1822), or 99.97 % (or higher) fractional efficiency at 0,3 µm using dispersed oil particulate (DOP) aerosol as defined by IEST RP-CC001 recommended practice[SOURCE: ISO 17536-1:2015(en) Road vehicles — Aerosol separator performance test for internal combustion engines — Part 1: General]High-efficiency filter used for removing aerosol particles from an air stream

[SOURCE: SOURCEISO 2889:2010, ISO 12749-2:2013(en)]

Note 1 to entry: A HEPA filter usually collects aerosol particles at the most penetrating particle size (between 0,1 μ m and 0,3 μ m diameter) with high efficiency and is designed to collect greater fractions of aerosol particles with diameters either larger or smaller. The minimum efficiency of a HEPA filter is not defined in an International Standard

3.9

K-Walk-Thru

A collective name for the testing facilities adopted by Korea for the first time in the world to collect samples quickly and safely for a respiratory pandemic [The Government of the Republic of Korea, How Korea responded to a pandemic using ICT, Flattening the curve on COVID-19, Apr 15]

3.10

negative pressure

Pressure that is less than existing atmospheric pressure

[SOURCE: Merriam-Webster, https://www.merriam-webster.com/medical/negative%20pressure]

3.11

negative pressure room

A room in which the air pressure differential between the room and the adjacent indoor airspace directs the air flowing into the room (i.e. room air is prevented from leaking out of the room and into adjacent areas such as the corridor)

[SOURCE: WHO Interim Guideline, Infection prevention and control of epidemic- and pandemic-prone acute respiratory diseases in health care, available at <u>https://apps.who.int/iris/bitstream/handle/10665/69707/WHO_CDS_EPR_2007.6_eng.pdf?sequence=1]</u>

3.12

negative pressurized medical container NPMC

A portable screening/testing facility that ensures the safety of the healthcare workers and testees by maximizing ventilation with HEPA filters, negative pressure, and managing the direction of airflow to prevent cross infection during disease testing

[SOURCE: Kyunggido Screening Station, South Korea, Introduction to large-scale screening centers for COVID-19. 2020]

3.13 pandemic

The worldwide spread of a new disease

[SOURCE: Emergencies preparedness, response, WHO, available at https://www.who.int/csr/disease/ https://www.who.int/csr/disease/

3.14

parts per million

Volumetric concentration of the component i in 106 volume parts of gas mixture

[SOURCE: ISO 11042-1:1996(en) Gas turbines — Exhaust gas emission — Part 1: Measurement and evaluation, available at <u>https://www.iso.org/obp/ui#iso:std:iso:11042:-1:ed-1:v1:en:term:3.8</u>]

3.15

pascal

A metric unit of measurement for pressure based on air velocity; 250 Pa equals 1.0-inch water gauge

[SOURCE: https://www.cdc.gov/infectioncontrol/guidelines/environmental/background/air.html]

3.16 personal protect equipment PPE

equipment that can include, but is not limited to, clothing, gloves, helmets, footwear and face protection

[SOURCE: ISO/TR 21808:2009, 2.1]

3.17

positive pressure room

A room in which a higher pressure inside the treated area is maintained than that of the surrounding environment. This means air can leave the room without circulating back in. In this way, any airborne particle that originates in the room will be filtered out. Germs, particles, and other potential contaminants in the surrounding environment will not enter the room. In medical settings, a positive pressure room allows staff to keep vulnerable test subjects safe from infections and disease

[SOURCE: NEGATIVE AND POSITIVE PRESSURE ROOMS 101 | HOSPITAL INFECTION CONTROL, available at https://airinnovations.com/negative-positive-pressure-rooms-hospital-infection-control/]

3.18

mobile WTSS

A disinfected single mobile booth, which requires minimized consumption of personal protection equipment and is targeted to provide rapid testing for early detection of viruses and mitigates cross-infection between healthcare workers and test subjects in a pandemic [The Government of the Republic of Korea, How Korea responded to a pandemic using ICT, Flattening the curve on COVID-19, Apr 15]

3.19

suspected case

A case that is compatible with the clinical description and has an epidemiological link to confirmed or suspected

[SOURCE: World Health Organization, Department of Communicable Disease Surveillance and Response, WHO Recommended Surveillance Standards. Second edition, available at https://www.who.int/csr/ resources/publications/surveillance/whocdscsrisr992.pdf?ua=1]

3.20 Walk-Through Screening Station WTSS

A WTSS consists of disinfected, single or multiple, mobile or fixed booths with negative, positive or an adaptable pressure which enables minimized consumption of personal protection equipment. It is targeted to provide rapid testing for early detection of viruses and mitigates cross-infection between healthcare workers and test subjects in a pandemic. It not only alleviates the pressure imposed on the hospitals and the risk of transmission by minimizing the chance of virus spreading, but also reduces the need for disinfection when taking samples [The Government of the Republic of Korea, How Korea responded to a pandemic using ICT, Flattening the curve on COVID-19, Apr 15]

4 Background of WTSS

4.1 Fundamental concept

Rapid and safe testing capabilities are an integral part of the fight against an endemic or pandemic. An infectious agent may be transmitted by direct contact, droplet spread, or airborne. Therefore, effective ways to minimize contact between test subjects and testers are critical.

Wall-through Screen Stations (WTSSs) have received attention as demand for screening tests has soared while test resources such as negative pressure tents are limited, and reduction time for disinfection and ventilation after specimen collection is much sought-after.

Healthcare workers in the WTSS do not have to wear PPE, as it takes only one or two minutes for each sampling, especially in a positive-pressure booth.

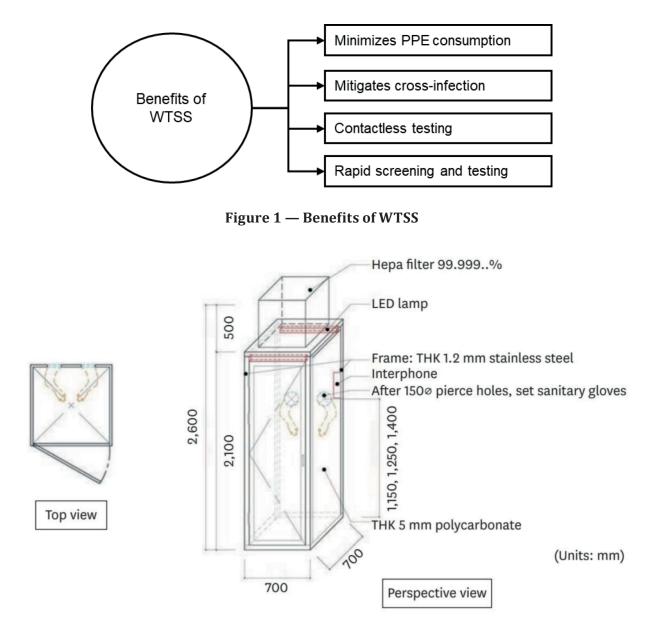


Figure 2 — Schematic blueprint of Walk-Through booth (Negative pressure booth example)

4.2 Four types of WTSS

The key principle is to improve the way in which people are tested. There are four types of Walk-Throughs: 1) open Walk-Through, applicable to inspection of entrants at any open areas, 2) negative pressure, 3) positive pressure, and 4) adaptable pressure. The next section provides details on each type.

5 Open WTSS

5.1 Operational principle

For an asymptomatic case, a diagnostic test is performed in an open-space screening clinic. For a symptomatic case, a test can be performed in a separate space (i.e. quarantine laboratory, quarantine facility/room). This type of station uses natural ventilation, so the risk of environmental disinfection is low. However, it requires sufficient outdoor space, and inspections may be subject to the weather conditions.



Figure 3 — Open Walk-Through

5.2 Screening process

5.2.1 Registration

- 1) A test subject shall provide information (name, passport number, contact information, etc.) in the application form during registration.
- 2) A staff member should guide them to fill in the form in the dedicated waiting area in the arrival hall to reduce the time required for registration.
- 3) A guide (a staff member) should guide the test subject to the medical staff for examination.

5.2.2 Examination

- 1) The medical staff should check ID, a history of contact with confirmed cases, symptoms, and other relevant data.
- 2) When necessary, additional checks should be performed, including checks on body temperature and respiratory symptoms.
- 3) The guide should guide the test subject to an available booth.

5.2.3 Specimen collection

Specimen collection procedures should follow the general guidelines according to the instructions from the manufacturers or to the public health guidance on sample collection and storage.

5.2.4 Notification of test result

The laboratory notifies the test result to the Screening Station.

6 Negative Pressurized WTSS

6.1 Operational principles

The negative pressure type uses lower air pressure to allow the outside air into the segregated environment. It keeps potentially harmful particles within the negative pressure booth by preventing the internal air from leaving the booth. The booth isolates suspected cases, protecting the people outside from exposure.

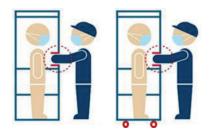


Figure 4 — Fixed (Left) and mobile (Right) Negative pressure booth

In a WTSS with negative pressure booth, a test subject goes inside the booth while the healthcare workers remain outside, effectively cutting off direct contact and enabling a quick sample collection. The station generally requires a smaller area for testing booths and a shorter time for testing. This setup gives people quick access to screening and at the same time adequately protects healthcare workers and reduces personal protective equipment consumption. A multiple fold increase in testing capacity can be easily achieved.

6.2 Screening process

The usual flow of processes is as follows: Registration and Questionnaire – Wait –Examination and Specimen Collection – Education – Payment - Exit. From the entrance to the exit, all test subjects should keep their masks on.

6.2.1 Registration and questionnaire

A test subject can register and fill out a questionnaire through a kiosk or on his/her mobile phone. In absence of such means, healthcare workers help the person to fill out the questionnaire.

- 1) The questionnaire should include:
 - A. Demographics: Name, Age, Social Security Number or Passport Number, Mobile Phone Number, Address, Reason for consultation
 - B. Epidemiologic information: travel history, association with an outbreak
 - C. Clinical information: Symptoms, Body temperature measured by a healthcare worker, Intake of antipyretic drugs, and other symptoms

In case of using a kiosk or mobile phone, after the questionnaire has been filled out, a text message with a registration number and the number of people waiting can be sent to the test subject. In the waiting area, the test subject shall wear a mask and keep a distance of at least two meters from others.

6.2.2 Examination

The completed questionnaire is delivered to the healthcare worker. The doctor examines the questionnaire and if a medical exam or sample collection is warranted, the doctor calls the test subject in.

6.2.3 Specimen collection

The doctor verifies ID, conducts a physical exam, and collects upper and lower respiratory tract specimens through the glove wall.

The test subject wears his/her mask back on once the specimen is collected, and stays in the booth for some time (i.e. one minute) before exit to remove 99.9 % of the virus in the air (Ventilation phase 1). With his specimen stored in a specimen bottle and/or a sputum cup, the test subject can exit the booth.

6.2.4 Ventilation

There are three phases of ventilation in negative pressure booths. Ventilation Phase 1 prevents virus leakage from the booth when a person leaves it. After the departure of the person, the booth stays empty for 5 min to remove the remaining viral particles (Phase 2). Then the healthcare worker should enter the booth to perform environmental disinfection, after which the booth remains empty for 5 min to inactivate the virus and to remove the potential toxic effect of the disinfectant (Phase 3). For further details, refer to Table 1.

Specimon collection	Ventilation	Ventilation	Ventilation
Specimen collection	Phase 1	Phase 2	Phase 3
The test subject wears his/her mask again after specimen collection	The subject stays in the booth for 1 min	After the subject leaves the booth, it remains empty for 5 min	After disinfection, the booth remains empty for 5 min
	Remove 99.9 % of the virus in the air of the booth	Remove the remaining virus in the air of the booth	Allow sufficient contact time to inactive the virus Remove potential toxic effect of the disinfectant

Table 1 — Ventilation phases after specimen collection

6.2.5 Disinfection

- 1) Principle
 - A. Disinfectant: Only proved virus disinfectants shall be used
 - B. Disinfection method: Wipe the inside of the booth with a mop sufficiently moistened with disinfectant so that the disinfectant remains on the surface for the contact time specified in the manufacturer's instructions. Since disinfection must be started from the less contaminated surface, disinfect in order of door, both walls, and glove-wall.
 - C. Personal Protective Equipment: The disinfection staff should wear proper PPE according to the public health guidance. It is recommended to wear PPE, preferably of Level D or N95 respirator, a waterproof gown, a goggle or face shield, and gloves. Use of disposable plastic gowns or gloves is also recommended to save PPE.
 - D. The staff should not wear the same mask for too long.
 - E. Used mops are to be disinfected prior to being disposed. Mops are allowed to be reused when they are adequately disinfected.
- 2) The protocol of disinfection
 - A. Conduct ventilation Phase 2 after each test subject.
 - B. After Phase 2 is completed, the cleaning staff member starts disinfecting the inner surface of the booth from the door to the glove-wall. The surface of a ledge inside the booth should be disinfected as well.
 - C. In cleaning the glove-wall surface, remove the outer gloves and disinfect the inner gloves. If any flaws are found, the staff must replace the inner gloves. Disinfect the stethoscope if the stethoscope is installed.

- D. Conduct ventilation Phase 3.
- E. Place new outer gloves on the inner gloves and put the COVID-19 diagnostic kit on the ledge.
- F. The booth is ready for the next test subject.

6.2.6 Storage of the collected specimen

The specimen from the test subject should be properly packed and immediately refrigerated (4 $^{\circ}$ C) in accordance to the public health guidance.

6.2.7 Notifying of the test result

The test subject receives a message/notification of the test result. If possible, the test subject may be notified of the possible time by which the result will be available to him/her.

7 Positive pressurized WTSS

The mobile WTSS using positive pressure offers extensive testing capabilities. It makes it possible to economize on PPE consumption and to crease tests multiple folds. The testing booth allows for safe environment that removes the risk of cross-infection between test subjects and healthcare workers.



Figure 5 — Positive pressurized booth

7.1 Operational principles

A positive-pressure booth is designed to afford the health workers an effective means to collect specimens. It facilitates comparatively large sample collections, for example, possibly 10 sample collections per hour, compared to, on average, one sample collection per hour in a regular screening centre. The whole processing time of a test subject can take minutes from "registration – examination – specimen collection – booth disinfection-education." Healthcare workers in the booth do not necessarily have to wear PPE, and each sampling takes a minute or so.

7.2 Screening process

7.2.1 Reservation

A reservation system should be implemented in order to reduce waiting time. When available, the review of health conditions and travel history can be carried out when arranging a visit, and such information is provided by the health centres and healthcare organizations in advance.

Confirmation for reservation is desirable, which includes at least the subject name, visit date/time, location to visit.

7.2.2 Registration

The registration process is the same as the one in the Open WTSS. For details, please refer to <u>5.2.1</u>.

7.2.3 Medical examination

The medical examination process is the same as the one in the Open WTSS. For details, please refer to 5.2.2.

7.2.4 Specimen collection

A specimen from the test subject is collected as instructed in the specimen collection kit. The test subject receives further information on contamination prevention.

7.2.5 After specimen collection

After a specimen is collected, a doctor or healthcare worker bends the top of the cotton swab so that it can be contained in the sample VTM. The test subject then puts the cap back on the sample VTM (the doctor can put the cap back on but with a resistance of their latex gloves, the cap may not be closed properly.) The test subject puts the sample VTM on the rack and disinfects his/her hands.

Disinfection

- 1) Wipe with disinfectant
- 2) Environmental disinfection

Fumigation disinfection and disinfection by wiping (CDC's recommendation)

7.2.6 Notification of the test result

The test subject receives a message/notification of the test result. If possible, the test subject may be notified of the possible time by which the result will be available to him/her.

8 Adaptable pressure

An adaptable-pressure booth switches airflow direction from time to time (negative pressure- > positive pressure, positive pressure- > negative pressure). Transition from positive to negative can be done without a filter change; however, the opposite transition requires a filter change.

When both negative- and positive- pressure booths are in use, the majority of examinations can be conducted in the positive pressure booth, and the negative pressure booth can be reserved for testing test subjects with a positive symptom or who require collection of lower respiratory tract specimen, in order to prevent contamination of the surrounding environment.

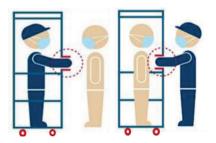


Figure 6 — Positive(left) and Negative pressure (Right) booth

Annex A (informative)

Examples of WTSS

A.1 Open Walk-Through



Figure A.1 — Example of Open Walk-Through at Incheon International Airport, South Korea

A.2 Global examples of WTSS

Country	Headline	URL
South Korea(1)	Example of Fixed WTSS (Negative pressure booth, H Plus Yangji Hospital)	https://biz.chosun.com/site/ data/html_dir/2020/09/23/ 2020092301580.html?utm _source=naver&utm_medium= original&utm_campaign=biz
South Korea(2)	Example of M-WTSS at Busan Nam-gu community healthcare centre, Korea	https://news.naver.com/ main/read.nhn?oid=044&aid= 0000216967
Germany	Lufthansa opens walk-in COVID-19 testing facilities at FRA and MUC	https://www.futuretravel experience.com/2020/06/ lufthansa-opens-walk-in-covid -19-testing-facilities-at-fra-and -muc/

Country	Headline	URL
United Kingdom	COVID-19 testing booth developed and named after Boris Johnson	https://www.med-technews .com/news/covid-19-testing -booth-developed-and-named -after-boris-johns/
India	India's 'booth' jugaad to counter corona	https://economictimes .indiatimes.com/news/politics -and-nation/indias-booth -jugaad-to-counter-corona/ what-is-booth-testing-system/ slideshow/75060882.cms
Israel	Israel launches new 'contactless' roadside covid-19 testing booths which have zero contact between nurse and patient	https://www.dailymail.co.uk/ news/article-8226793/Israel -launches-new-contactless -roadside-covid-19-testing -booths.html
Japan (1)	New corona PCR test is easy "walk-through method" booth Developed in prefectures, etc. No internal pressure adjustment required, low price / Niigata	https://mainichi.jp/articles/ 20200523/ddl/k15/040/ 122000c
Japan(2)	Walkthrough PCR test Kobe city to introduce	https://www.kobe-np.co .jp/news/iryou/202005/ 0013347565.shtml
Japan(3)	Transportable "PCR test box" test operation started Fukuroi Hospital	https://www.at-s.com/news/ article/health/shizuoka/774189 .html
Japan(4)	Walk-through PCR test "finished in 10 minutes", specialized facility in Yokosuka	https://www.yomiuri.co .jp/medical/20200423 -OYT1T50258/
Japan(5)	"Walk-through method" PCR outpatient facility installed in Yamato City Hall	https://www.kanaloco.jp/news/ social/entry-341456.html
Japan(6)	"PCR test center" opened in Aomori City about 40 tests can be performed a day	https://www.daily-tohoku.news/ archives/37865
Japan(7)	PCR inspection centre released Hamamatsu City, trailer house utilization	https://www.at-s.com/news/ article/health/shizuoka/770072 .html
Japan(8)	Hakodate City Medical Association to open PCR test centre within the month	https://digital.hakoshin.jp/ health/medical/62148
Japan(9)	PCR sample collection by appointment Shibukawa District Medical Association is the centre	https://www.jomo-news.co.jp/ news/gunma/society/216505
Japan(10)	PCR Center opened on 22nd Ashikaga Medical As- sociation, 5th place in the prefecture	https://www.shimotsuke.co.jp/ articles/-/325107
Nigeria	'Flying Doctors' boost Nigeria's COVID-19 testing	https://www.afro.who.int/news/ flying-doctors-boost-nigerias -covid-19-testing

Table A.1 (continued)

A.3 Negative Pressurized Medical container (NPMC)

A pandemic is a crisis that undermines the sustainability of not only the healthcare system of a country, but also its society. In the case of a newly discovered infectious disease that is easily spread in particular by high-density contact, an effective infection control strategy would be to quickly identify, isolate, and treat patients through rapid examination, given that there is no vaccine or treatment available. A Negative Pressurized Medical Container (NPMC), one that completely separates the path between the healthcare worker and the patient, prevents cross-infection by directing airflow from the healthcare worker to the patient. Examination/diagnosis can be done using a microphone/amplifier, without direct

contact with the patient. In addition, since sputum collection rooms have a greater risk of exposure, the NPMC can be operated as an isolated negative pressure room, so that the safety of the healthcare worker and the patient can be ensured.

Since the air that passes through the HEPA (High Efficiency Particulate Air) filters, designed to exhaust the polluted air completely from the inside in about 30 min, goes outside, the outflow of pathogens is prevented. Each NPMC allows for an increased number of patients in a shorter period of time than in a screening station. In addition, a reservation system is in place in order to prevent cross-infection in portable screening stations. With reservation and questionnaire carried out in advance, test subjects are exposed to less chance of contamination at the testing site.

In addition, testing can be performed with fewer medical healthcare workers. In other settings, it may take on average three members per container: one medical staff member, one disinfecting member, and one assistant. Since the NPMC can be mobile with a multiple number of screening rooms in it, it is possible to examine a relatively large number of suspected patients.

Indoor spaces

Spaces occupied by the healthcare workers and the patients must be completely separated - one NPMC can be divided into one resting room and one changing room for healthcare workers, two sample collection rooms, and three medical examination rooms.

It is necessary to adjust the pressure of the indoor air in such a way that the air always flows from low to high pollution. That is, the air should flow from the non-pressurized zone to the pressurized treatment room to the pressurized sputum examination room. The rooms for sample collection and sputum testing must maintain a negative pressure of 2.5 pa or greater. At the room exits, a pressure indicator should be installed and it is recommended to display the pressure to the tenths (0.1 Pa) for monitoring. The NPMC proposed in this Annex complies with the negative pressure room standard by the US Centers for Disease Control and Prevention (US CDC). NPMCs can be deployed rapidly in case of a large-scale outbreak of an infectious disease.

Outdoor spaces

Clean zones and Contaminated zones should be separated. A separate space (i.e. waiting room) must be reserved for visitors to wait. The waiting room should be an outdoor facility with proper ventilation. Depending on the outside temperature, a thermal insulation or shade-creating mechanism can be installed. A visitor must wear a surgical mask while waiting and maintain a distance of 2 m (at least 1m or more. An independent space may be in place for the operating staff to rest in.

A.3.1 External Structure



Figure A.2 — Reference photo of NPMC in Kyunggido, South Korea

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A.3.2 Testing room and announcement



Table A.2 — Examples of Testing room and announcement

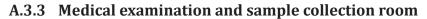


Table A.3 — Examples of Medical examination and sample collection room



A.3.4 Safety equipment container and wash basin



Table A.4 — Examples of Safety equipment container and wash basin

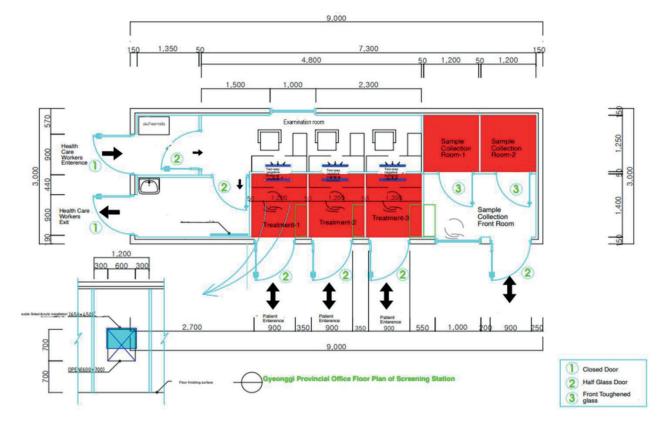


Figure A.3 — Reference layout of NPMC

Bibliography

- [1] ISO 20658:2017, Medical laboratories-Requirements for collection, transport, receipt, and handling of samples
- [2] ISO 22583:2019, Guidance for supervisors and operators of point-of-care testing (POCT) devices
- [3] ISO 35001:2019, Biorisk management for laboratories and other related organisations
- [4] World Health Organization, Global Surveillance for human infection with coronavirus disease (COVID-19): interim guidance, 2020
- [5] WORLD HEALTH ORGANIZATION, DEPARTMENT OF COMMUNICABLE DISEASE SURVEILLANCE AND RESPONSE, WHO RECOMMENDED SURVEILLANCE STANDARDS. Second edition, available at <u>https://www.who.int/csr/resources/publications/surveillance/whocdscsrisr992.pdf?ua=1</u>
- [6] YEOHYUN AHN, Standard procedure for Walk-through Screening Station, 2020
- [7] KIM S.I., LEE J.Y., Walk-through Screening Center for COVID-19: an Accessible and Efficient Screening System in a Pandemic Situation. J. Korean Med. Sci. 2020
- [8] H Plus Yangji Hospital, Standard procedure for Walk-through Screening Station, 2020
- [9] DISASTER Central, HEADQUARTERS Safety Countermeasures, KOREA South, Standard operation model for COVID-19 Drive-through Screening Station, Mar 2020.
- [10] The Government of the Republic of Korea, How Korea responded to a pandemic using ICT, Flattening the curve on COVID-19, Apr 15, 2020
- [11] JENSEN P.A., LAMBERT L.A., IADEMARCO M.F., RIDZON R., Cdc. Guidelines for preventing the transmission of Mycobacterium tuberculosis in health-care settings, 2005. MMWR Recomm. Rep. 2005, 54 (RR-17) pp. 1–141
- [12] MUTCHLER J.E., Principles of ventilation. In: NIOSH. The industrial environment its evaluation and control. Washington DC: U.S. Department of Health E, and Welfare, Public Health Service, NIOSH; 1973. Publication #74-117. <u>https://www.cdc.gov/niosh/pdfs/74-177-v.pdf?id=10.26616/ NIOSHPUB74117</u>
- [13] UNITED STATES ENVIRONMENTAL PROTECTION AGENCY. List N: Disinfectants for Use Against SARS-CoV-2. March 19, 2020 2020. <u>https://www.epa.gov/pesticide-registration/list-n-disinfectants</u> <u>-use-against-sars-cov-2</u> (accessed March 24 2020).
- [14] Ahn, Sunju-Park, Haepum-Song, Seungyoug-Ryu, Jiyoung-Kim, Suhwa, Non-pharmaceutical Standard Models for Managing Pandemic, JOURNAL OF STANDARDS, CERTIFICATION AND SAFETY, 2021