Second expression of Interest for reference laboratories of the CoronaVirus Network (CoViNet)

Deadline for submission: 11 July 2025

Date of publication: 9 June 2025

The World Health Organization Health (WHO), acting through its Emergencies Programme within its Department of Epidemic and Pandemic Threat Management is pleased to announce a second expression of interest (hereinafter, this "EOI") for laboratories to become reference laboratories within the WHO Coronavirus Network (CoViNet), whose Terms of Reference are set forth in Annex 1 to this EOI. This follows a first open call that was published on 28 August 2023.

Laboratories who are interested in becoming reference laboratories of CoViNet must complete and submit an online application form, available at https://extranet.who.int/dataformv6/index.php/891523?lang=en. The application form must be received by WHO no later than **11 July 2025 23:00 CET.**

A laboratory's submission of an application form by the deadline stated above does not automatically mean that such laboratory will be selected for participation in, or will participate as a reference laboratory, in the WHO Coronavirus Network.

For the avoidance of doubt, a laboratory's selection as reference laboratory and participation in the WHO Coronavirus Network will be subject to and contingent upon such laboratory first meeting all relevant criteria and requirements therefor which include, but are not limited to: (1) such laboratory meeting all essential criteria set out in section 4 below; (2) such laboratory first duly and fully completing, signing and returning to WHO an original of the Terms of Reference for the reference laboratories of WHO Coronavirus Network, a copy of which is set forth in Annex 1 hereto.

Background and overall goal of CoViNet

The first WHO reference laboratory network for SARS-CoV-2 (the "WHO SARS-CoV-2 Reference Laboratory Network") was established in January 2020, with the initial objective to provide confirmatory testing to countries with no or little testing capacity for SARS-CoV-2. Since then, the needs for SARS-CoV-2 have evolved and monitoring the evolution of the virus, spread of variants and assessing the impact of variants on public health remains essential. In the 4th year of the COVID-19 pandemic, WHO broadened and revised the scope, objectives and terms of reference of WHO SARS-CoV-2 Reference Laboratory Network to also include, among other things: (i) expertise in animal health and environmental surveillance, (ii) other coronaviruses, including MERS-CoV, and (iii) enhance capacities for the identification of novel coronaviruses that could negatively affect human health. It was also decided that the WHO SARS-CoV-2 Reference Laboratory Network, with its expanded and revised scope, objectives and terms of reference, would be renamed and thereafter referred to as the "WHO Coronavirus Network".

The overall goal of the WHO Coronavirus Network (CoViNet) is to facilitate global expertise and capacity for early and accurate detection as well as monitoring and genotypic and phenotypic assessment of -SARS-CoV-2, MERS-CoV and novel coronaviruses of public health importance, The work of CoViNet will be essential to support the ongoing risk assessments conducted by the WHO Technical Advisory Group for Virus Evolution (TAG-VE) and the ongoing independent assessments of the Technical Advisory Group for COVID-19 vaccine composition (TAG-COVAC) on the implications of emerging SARS-CoV-2 variants on COVID-19 vaccine composition.

CoViNet will operate through enhanced collaborations and integration with relevant existing and planned regional and national laboratory networks such as the COVID-19 Genomic Surveillance Regional Network (COVIGEN), the SEARO regional reference laboratory network, and alliances such as Global Laboratories Alliance for the Diagnosis of High Threat Pathogens (GLAD-HP), Global Influenza Surveillance and Response System (GISRS) and the International Pathogen Surveillance Network (IPSN) and through linkages with existing global and regional initiatives including the WHO Hub for Pandemic and Epidemic Intelligence.

Furthermore, because coronaviruses are zoonotic, it is critical that CoViNet be comprehensive and promote strong engagement of animal and environmental laboratories using a One Health approach. These labs will be considered for selection by WHO in coordination with the Food and Agriculture Organization, the World Organisation for Animal Health and/or through consultation with WHO Collaborating Centers for Water Quality, Sanitation and Hygiene.

Formalizing CoViNet will also serve to continue strengthening health emergency prevention, preparedness, response, and resilience (HEPR), building on gains made during the COVID-19 pandemic. The information generated through the CoViNet will be central to the work of the WHO technical and scientific Advisory Groups, including TAG-VE, TAG-CO-VAC, SAGE, and the R&D Blueprint for Epidemics working groups. CoViNet activities will be carried out at national and international levels to inform global policy decision making. The table below provides an overview of CoViNet functions **for SARS-CoV-2, MERS-CoV and novel coronaviruses of public health importance:**

Who ?	**CoViNet Function**	**CoViNet Activities**
WHO Technical advisory groups (TAG-VE, TAG-CO-VAC) CoViNet core OneHealth group ; WHO Secretariat	-Support development of public health policy related to prevention, preparedness and response -shape research agenda	-Policy based on outputs of WHO variant risk evaluation framework and other evidence - identification of research/knowledge gaps;
Reference laboratories with relevant expertise in functions required for variant tracking and risk evaluation	-Receive identify and track variants through genome sequence analysis -Characterize variants according to comprehensive WHO variant risk evaluation framework	- provide confirmatory testing of virus materials -according to strict biosafety and ethical standards, conduct components of risk evaluation of variants of interest or concern eg. growth advantage, immune escape,

	-capacity building in lab methods to support and enhance national surveillance and regional expertise -	antigenic characterization, therapeutic susceptibility, diagnostic accuracy - development and/or revision of relevant methods, recommendations and other documents - research at human-animal interface
i) National reference centers supporting needs of integrated surveillance for respiratory viruses/respiratory pathogens) ii) Coronavirus-specific reference lab where i) is not established or where existing labs handling respiratory viruses would require major revisions to accommodate needs.	- Technical resource - Focal point for WHO and for national surveillance activities reliant on specialized diagnostic and laboratory services for coronaviruses - Maintenance of high biosafety standards and technical proficiency	- Laboratory confirmation from clinical samples, wastewater by molecular _+/- serology (antigen, antibody) - Virus culture - Genomic sequencing - Participation in and coordination of subnational external quality assessments - Safe data and sample sharing to support variant tracking and risk evaluation.

This Call for EOI is exclusively to select reference laboratories for assessment by WHO which has entire discretion to decide if the applicant laboratories meet all the criteria and requirements (as described in this Call for EOI) to become member of the CoViNet.

1. Objectives of the CoViNet Reference Laboratories

The CoViNet reference laboratories shall support both overarching goals of CoVINet as well as specific objectives including:

Core objectives:

1. Early and accurate detection of SARS-CoV-2, MERS-CoV and novel coronaviruses of public health importance

2. Surveillance and monitoring of the global circulation and evolution of SARS-CoV, MERS-CoV and novel coronaviruses of public health importance recognizing the need for a “One Health” approach

Specific to reference laboratories:

3. Timely risk assessment for SARS-CoV-2, MERS-CoV and novel coronaviruses of public health importance, to inform WHO policy related to a range of public health and medical countermeasures.
4. Support capacity building[1] of laboratories relevant to needs of WHO and CoViNet, particularly those in low and middle-income countries, for SARS-CoV-2. MERS-CoV and novel coronaviruses of public health importance.

Key achievements and expected activities of CoViNet reference laboratories

The first CoViNet newsletter, published on 25 March 2025 and can be found here, and provides an overview of the 2024 activities undertaken within the network.
In support of the CoViNet objectives, reference laboratories will be expected to carry out a range of activities and also interface with laboratories conducting national coronavirus surveillance activities.
In order to be eligible to participate as a in CoViNet, each applicant laboratory must demonstrate, to WHO's satisfaction, that it meets **the** criteria essential criteria and meet **at least one or more** of the desirable criteria set forth below.

Essential criteria

1. Demonstrated expertise, experience capacity and capabilities to conduct experiments according to internationally recognized biosafety and biosecurity standards (minimum BSL3)

2. Demonstrated capacity, expertise, experience and capabilities to perform:

    a. confirmatory testing of virus materials and other clinical samples from suspected cases of SARS-CoV-2, MERS-CoV and / or novel coronaviruses of public health importance;

    b. whole genome sequencing and provision of such sequence data to a publicly-accessible database

AND

<u>One or more</u> of the following activities:

i. Support the identification of causative agent(s) for respiratory illness(es) of **unknown origin** in collaboration with other relevant institutions;

ii. Assess viral fitness/transmissibility and pathogenicity of emerging viruses/variants *in silico*, *in vitro* and/or *in vivo*;

[1] e.g. advanced genomic and phenotypic analysis, enabling enhanced surveillance and monitoring functionality

iii. Evaluate immune escape potential of emerging viruses/variants *in silico*, *in vitro* and/or *in vivo*;
iv. Monitor resistance of available and newly developed therapeutics *in silico, in vitro* and/or *in vivo*;
v. Support the development and evaluation of laboratory diagnostic reagents for coronaviruses, including, without limitation, through:
    a) development or refinement of molecular assays;
    b) development of protocols for antiviral resistance testing;
    c) antigenic characterization;
    d) development/assessment of specific tests for diagnostic humoral immune responses; and
    e) support with structured validation of the developed and commercial assays

Desirable criteria

In order to be eligible to participate as a reference laboratory in the CoViNet, each applicant laboratory must demonstrate, to WHO's satisfaction, that it meets **at least one or more** of the following desirable criteria:

1. Experience with coronavirus surveillance in animals
2. Experience with environmental surveillance of coronaviruses e.g. in wastewater:
3. Access to onsite sequencing facility and experience with bioinformatic analysis;
4. Access to specimens to support CoViNet anticipated deliverables through an established network of clinical sites from which acquiring specimens (animal, human, environmental)
5. Possession of or access to a biobank with coronavirus strains and sera from humans or animals infected with coronaviruses
6. Access to regular funding to support domestic and international surveillance, and risk assessments of pathogenic coronaviruses of public health importance;
7. Experience with working for WHO or another international or regional public health organization or WHO networks (e.g., GISRS, COVIGEN, etc);
8. WHO Collaborating Centre designation with planned or ongoing workplan that includes activities related to SARS-CoV-2, MERS-CoV or novel coronaviruses preparedness and response activities;

9. Experience with handling live coronaviruses;
10. Experience in integration of laboratory clinical and epidemiological data to guide public health response and willingness to support capacity-building activities in this area;
11. Experience in training and capacity strengthening activities

The shortlisting of the CoViNet reference laboratories will be done in consultation with regional representation and it will be based on an overall assessment of:

- Compliance with essential and desirable criteria
- Geography to ensure balanced distribution of laboratories in WHO regions
- Access to regular co-funding

2. Expected Deliverables of reference laboratories Participating in CoViNet

In furtherance of CoViNet's core objectives, the reference laboratories of the WHO Coronavirus Network will contribute to a range of activities linked to specific deliverables.

The following deliverables are important pieces to inform the overall assessment of the risk posed by coronaviruses to public health, as well as impact on performance of countermeasures, and they may be further revised or refined by WHO as and when needed.

CoViNet objective	**Activities**	**Anticipated deliverable**
1. Early and accurate detection of SARS-CoV-2, MERS-CoV and novel coronaviruses of public health importance; 2. Surveillance and Monitoring of the global circulation and evolution or SARS-CoV-2, MERS-CoV and novel coronaviruses of public health importance;	Capacity building across all levels of CoViNet	Expansion of genomic and/or phenotypic characterization of SARS-CoV-2 VOC/VOI/VUM and MERS-CoV clades in countries selected by WHO
3. Timely risk assessment to inform WHO policy related to a range of public health and medical countermeasures	Immune escape assessment of coronaviruses	Up to biannual assessment of the immune escape of SARS-CoV-2 VOC/VOI/VUM circulating in various WHO regions.

1. Early and accurate detection of SARS-CoV-2, MERS-CoV and novel coronaviruses of public health importance;	Assessment of diagnostics capacity to detect a novel zoonotic coronavirus	Annual EQA programme for zoonotic coronavirus for CoViNet reference laboratories
3. Timely risk assessment to inform WHO policy related to a range of public health and medical countermeasures	Laboratory assessment of the pathogenicity of coronaviruses	Annual assessment of the overall pathogenicity profile of SARS-CoV-2 VOC/VOI/VUM circulating in various WHO regions
3. Timely risk assessment to inform WHO policy related to a range of public health and medical countermeasures	One Health*	Characterization of circulating MERS-CoV clades in animal reservoirs and animal surveillance of SARS-CoV-2 to inform assessment of public health risk for humans Implementation of wastewater surveillance for SARS-CoV-2 in countries selected by WHO.

*these activities are coordinated with members of the quadripartite, which includes FAO, and WOAH

3. Opportunities arising from participation

Laboratories that are selected to, and that meet all applicable criteria and requirements to, participate in the WHO Coronavirus Network may have the following opportunities in connection with such participation

1. Opportunity and expectation to collaborate, as and where appropriate, with institutions and experts around the world to conduct research and contribute to innovation in the field of coronavirology;
2. Depending on country income level, reference labs may have access to funding opportunities, including from WHO, and partnerships with other institutions and organizations, providing additional resources and support for their work;
3. Opportunities to contribute, as and where appropriate, to global health priorities and initiatives, including research, policy development, and implementation efforts; and
4. Enhanced capacity-building and training opportunities which may potentially include, as and where appropriate opportunities to train and mentor professionals from other institutions and countries, and to help build capacity and strengthen health systems around the world.

4. Application and selection process

Submission of Application Materials

WHO welcomes applications from laboratories that are interested to participate as reference laboratory in the WHO Coronavirus Network, subject to and in accordance with the provisions, criteria and requirements set out in this EOI and in the Term of Reference of CoViNet reference laboratories (see annex 1 hereto).

To express your laboratory's interest to participate in CoViNet, please duly complete and submit an online application form, available at https://extranet.who.int/dataformv6/index.php/891523?lang=en. by no later than **11 July 2025 23:00 CET** (the "Deadline"):

Evaluation of Application Materials and Short-Listing

Assuming that your laboratory's Application Materials (as defined above) are received by WHO by no later than the Deadline (as defined above), your Application Materials will be reviewed and assessed by the WHO CoViNet Secretariat.

As soon as possible following the Deadline, the WHO CoViNet Secretariat will prepare a shortlist that is comprised of laboratories: (1) whose Application Materials were received by the Deadline, and (2) who meet all of the Essential Criteria set out in Section 4 of this EOI; and (3) who meet at least one of the Desirable Criteria set out in Section 4 of this EOI.

The laboratories that are included in the abovementioned shortlist (hereinafter referred to as "Shortlisted Laboratories") will be informed by WHO in writing of their status as such and may be asked to provide additional information concerning their application.

Next steps : Selection and Invitation to Participate as CoViNet reference laboratory; Approval of the CoViNet Terms of Reference

The final selection of Shortlisted Laboratories will be primarily based on consideration of capacities, expertise, geography and availability of co-funding for CoViNet related activities. The selected laboratories will be invited by WHO to participate in the WHO Coronavirus Network. As part of such invitation, WHO will formally request selected laboratories to complete, sign, date and return to WHO an original of the Terms of Reference for Reference Laboratories of the WHO Coronavirus Network.

For the avoidance of doubt, a laboratory's participation in CoViNet shall be subject to and conditioned upon such laboratory having first returned to WHO—by the applicable deadline to be specified by WHO

in writing—an original of the Terms of Reference for Reference Laboratories of the WHO Coronavirus Network (Annex 1 hereto) which has been fully completed, signed and dated by a duly authorized representative of such laboratory. In the event that WHO does not receive, by the applicable deadline, the aforementioned Terms of Reference duly and fully completed, signed and dated by the laboratory, then: (1) the participation and work of such laboratory in the WHO Coronavirus Network shall not commence; (2) such laboratory shall not be considered as a laboratory participating in the WHO Coronavirus Network; and (2) WHO shall have the right to withhold, suspend and/or terminate (as determined by WHO in its sole discretion) the invitation for such laboratory to participate as a reference laboratory in the WHO Coronavirus Network.

Information on Outcomes

All laboratories who submit Application Materials by the Deadline will be informed by WHO, in writing, on the outcome of this EOI as soon as possible following the completion of the entire process.

As WHO is responsible for administering the WHO Coronavirus Network, all decisions regarding the assessment, selection and participation of laboratories in CoViNet shall be taken solely by WHO, in its discretion (with due regard to this EOI and the Terms of Reference for CoViNet reference laboratories), and shall not be subject to appeal.

Deadline

The deadline for submission of your laboratory's Application Materials is **11 July 2025 23:00 CET.**

5. Annexes and Related documents

- Conditions for Applicants (Annex 1 hereto) (which apply to laboratories wishing to submit an application as part of this Call for EOI);
- Terms of Reference of CoViNet (Annex 2) (which apply to laboratories only if and when an applicant laboratory becomes a Selected Laboratory); and
- Online application form and associated documents, available at https://extranet.who.int/dataformv6/index.php/891523?lang=en.

6. Questions

Should you have any questions about this EOI or the WHO Coronavirus Network, please send an email *to: covid19@who.int*.

Annex 1: Conditions for Applicants to become possible reference laboratories of the WHO Coronavirus Laboratory Network

Each of the reference laboratories participating in the WHO Coronavirus Laboratory Network (the "CoViNet") shall support the core objectives of such Network; as well as the specific objective namely to enable:

1. Early and accurate detection of SARS-CoV-2, MERS-CoV and novel coronaviruses of public health importance;

2. Surveillance and monitoring of the global circulation and evolution of SARS-CoV, MERSCoV and novel coronaviruses of public health importance recognizing the need for a "One Health" approach;

Specific to reference laboratories:

3. Timely risk assessment to inform WHO policy related to a range of public health and medical countermeasures; and

4. Support capacity building of laboratories relevant to needs of WHO and CoViNet, particularly those in low and middle-income countries, for SARS-CoV-2. MERS-CoV and novel coronaviruses of public health importance.

In addition to the foregoing, each of the reference laboratories participating in the CoViNet shall carry out points 1 and 2 and at least one, but preferably more, of the activities listed in points 3 to 18 below in order to contribute to achieving the CoViNet objectives:

1. Confirmatory testing of virus materials and other clinical samples from suspected cases of SARSCoV-2, MERS-CoV and or novel coronaviruses of public health;

2. Whole genome sequencing and provision of such sequence data to a publicly accessible database and upon request, provide well-characterized viral strains, sequences and other relevant material to the WHO BioHub;

3. Support the identification of causative agent(s) for respiratory illness(es) of unknown origin/virus discovery in collaboration with other relevant collaborators;

4. Assess viral fitness/transmissibility and pathogenicity of emerging viruses/variants in silico, in vitro and/or in vivo;

5. Evaluate immune escape potential of emerging viruses/variants in silico, in vitro and/or in vivo;

6. Monitor resistance of available and newly developed therapeutics in silico, in vitro and/or in vivo;

7. Support the development, monitoring and evaluation of laboratory diagnostic reagents (and assays) for coronaviruses, including, without limitation, through:

    a. development or refinement of molecular assays;

    b. development of protocols for antiviral resistance testing;

    c. antigenic characterization

d. development/assessment of specific tests for diagnostic humoral immune responses;

e. support with structured validation of developed and commercial assays; and

f. monitoring of genetic changes that may affect diagnostic performance

8. At the request of WHO, promptly provide WHO with the technical details of diagnostic reagents and/or molecular assays developed and/or evaluated by the participating laboratory pursuant to point 7 above;

9. Monitor the efficacy of diagnostics with emerging novel coronaviruses and their variants;

10. Support the implementation of a One Health surveillance approach that includes human disease surveillance as well as linking with, supporting and/or conducting animal and environmental coronavirus surveillance;

11. Inform WHO to develop and evaluate its strategy and recommended methods for the global surveillance and diagnosis of SARS-CoV-2, MERS-CoV and other coronaviruses of public health importance , including by assisting WHO in the development and/or revision of relevant methods, and other documents. For the avoidance of doubt, however, notwithstanding the laboratory's assistance as described herein, it is hereby expressly acknowledged and understood that WHO will retain final discretion and control as to the content of any such WHO recommended methods, or other documents; Furthermore, each laboratory participating in the CoviNet must comply with the following terms and conditions:

12. Share anonymized information (stripped of all personal identifiers) generated on viral evolution of relevant coronaviruses, including SARS-CoV-2, MERS-CoV and novel coronaviruses of public health importance and identify genetic changes that may be relevant to diagnostic tests, vaccine development and/or antiviral treatment;

13. Meet all applicable deadlines and timeframes for the conduct of the laboratory's obligations and activities as part of the CoViNet;

14. Maintain and demonstrate a high level of technical proficiency, capacity and ability in all matters pertaining to the CoViNet including, but not limited to, through proficiency testing where applicable for the used methods;

15. Treat all virus materials and clinical samples, together with all data and information relating thereto, which are obtained by the laboratory through its participation in this CoViNet (collectively, the "materials") as confidential and proprietary to the providing country, and ensure that materials are not transferred or provided to any third party unless: (i) the recipient third party is a participating laboratory under the CoviNet; and (ii) WHO has expressly requested in writing that the transferring laboratory provide the materials to such recipient laboratory; and (iii) the recipient laboratory uses the materials solely for the Purpose (as defined in paragraph 19 below), and no other purpose. In connection with all of the foregoing, the laboratory must implement and maintain appropriate technical and organizational measures to protect the confidentiality and security of the materials, and to protect the materials from unauthorized access, theft, damage, loss, destruction or misuse;

16. Ensure that the participating laboratory only uses the materials for the following purposes (which are hereinafter collectively referred to as the "Purpose"): (1) detection, identification, and characterization (including through whole genome sequencing) of the SARS-CoV-2, MERSCoV, and novel coronaviruses of public health importance, including the inclusion of resulting sequence data in a publicly accessible database, (2) non-commercial assay development, (3) commercial assay development, provided always however that the participating laboratory shall have first entered into an agreement with WHO concerning such commercial assay development which shall include, without limitation, provisions to the effect that the commercial exploitation of any intellectual property rights, including the ownership of knowhow, arising from any such commercial assay and/or its development shall be designed to achieve the general availability of the product(s) and the availability of the product(s) to the public health sector of developing countries on preferential terms (including as to price) and in sufficient quantities to meet demand; (4) validation of assays, and (5) the performance of any other work as explicitly foreseen in these Conditions for Applicants;

17. Ensure that, except as may explicitly otherwise be provided in these Conditions for Applicants, the participating laboratory does not use, and does not provide and permit others to use, the materials for any purpose other than the Purpose, unless a separate written agreement has first been established with the Provider (as defined in paragraph 18 below) covering such other use. Any such separate agreement will be promptly provided by the participating laboratory to WHO;

18. Ensure that results of the use of the materials for the Purpose are only be reported to the national laboratory or governmental agency that provided the materials (hereinafter, the "Provider"), except (a) that the participating laboratory will, subject to agreement with WHO and/or Provider, as applicable, be entitled to publish the results of the use of the materials for the Purpose; and (b) as otherwise set forth in paragraph 19 below;

19. Adhere to and comply with: (i) all applicable laws, statutes, rules, regulations and other legal or ethical requirements; (ii) all relevant national biosafety standards for work with high-threat pathogens; and (iii) all national and/or international regulations relating to the receipt of dangerous goods;

20. Obtain and maintain in effect any applicable licenses, permits, authorizations, consents, approvals, accreditations, documentation and/or other recognition which are necessary or required (whether at the national, regional and/or international level(s)) for the laboratory to perform its tasks in connection with the CoViNet;

21. At the request of WHO, make available to WHO (under confidential cover where required) all relevant anonymized (i.e., stripped of all personal identifiers) data and information, as well as all results of work performed by the participating laboratory pursuant to these Conditions for Applicants, for the purposes of guiding WHO in the development of WHO's strategy, recommended methods, recommendations, guidelines and/or other documents referred to in paragraph 11 above;

22. Ensure that any agreements entered into by the participating laboratory with any Provider in connection with the CoViNet are consistent with these Conditions for Applicants; and

23. Agree that nothing contained in or relating to these Conditions for Applicants and/or the CoViNet will be construed as a waiver of any privileges and immunities enjoyed by WHO, and/or as submitting WHO to any national court jurisdiction

IN WITNESS WHEREOF, the undersigned laboratory has caused its duly authorized representative to sign, as of the date ser forth below, this document in two (2) originals in the English language, in order to evidence such laboratory's agreement with, acceptance of and commitment to comply with these Conditions for Applicants. Signed for and on behalf of the applicant laboratory:

Signature: _____

Name of Entity: _____

Name of Authorized Representative: _____

Title of Authorized Representative: _____

Date: _____ Mailing Address: _____

Email Address: _____

Telephone Number: _____

Annex 2: Terms of Reference for the references laboratories of the WHO Coronavirus Laboratory Network

Each of the reference laboratories participating in the WHO Coronavirus Laboratory Network (CoViNet) shall support the core objectives of such Network; as well as the specific objective namely to enable:

1. Early and accurate detection of SARS-CoV-2, MERS-CoV and novel coronaviruses of public health importance
2. Surveillance and monitoring of the global circulation and evolution of SARS-CoV, MERS-CoV and novel coronaviruses of public health importance recognizing the need for a "One Health" approach

Specific to reference laboratories:

3. Timely risk assessment to inform WHO policy related to a range of public health and medical countermeasures.
4. Support capacity building of laboratories relevant to needs of WHO and CoViNet, particularly those in low and middle-income countries, for SARS-CoV-2. MERS-CoV and novel coronaviruses of public health importance.

In addition to the foregoing, each of the reference laboratories participating in the WHO Coronavirus Network (the "Network") shall carry out points 1 and 2 and at least one, but preferably more, of the activities listed in points 3 to 18 below in order to contribute to achieving the Network objectives:

1. Confirmatory testing of virus materials and other clinical samples from suspected cases of SARS-CoV-2, MERS-CoV and / or novel coronaviruses of public health importance;
2. Whole genome sequencing and provision of such sequence data to a publicly-accessible database and upon request, provide well-characterized viral strains, sequences and other relevant material to the WHO BioHub;
3. Support the identification of causative agent(s) for respiratory illness(es) of unknown origin in collaboration with other relevant institutions;
4. Assess viral fitness/transmissibility and pathogenicity of emerging viruses/variants *in silico*, *in vitro* and/or *in vivo*;
5. Evaluate immune escape potential of emerging viruses/variants *in silico*, *in vitro* and/or *in vivo*;
6. Monitor resistance of available and newly developed therapeutics *in silico, in vitro* and/or *in vivo*;
7. Support the development, monitoring and evaluation of laboratory diagnostic reagents (and assays) for coronaviruses, including, without limitation, through:
    a. development or refinement of molecular assays;
    b. development of protocols for antiviral resistance testing;
    c. antigenic characterization;
    d. development/assessment of specific tests for diagnostic humoral immune responses; and
    e. support with structured validation of developed and commercial assays;

f. monitoring of genetic changes that may affect diagnostic performance

8. At the request of WHO, promptly provide WHO with the technical details of diagnostic reagents and/or molecular assays developed and/or evaluated by the participating laboratory pursuant to point 7 above;
9. Monitor the efficacy of diagnostics with emerging novel coronaviruses and their variants;
10. Support the implementation of a One Health surveillance approach that includes human disease surveillance as well as linking with, supporting and/or conducting animal and environmental coronavirus surveillance;
11. Inform WHO to develop and evaluate its strategy and recommended methods for the global surveillance and diagnosis of SARS-CoV-2, MERS-CoV and other coronaviruses of public health importance , including by assisting WHO in the development and/or revision of relevant methods, and t other documents. For the avoidance of doubt, however, notwithstanding the laboratory's assistance as described herein, it is hereby expressly acknowledged and understood that WHO will retain final discretion and control as to the content of any such WHO recommended methods, or other documents;

Furthermore, each laboratory participating in the reference laboratory network must comply with the following terms and conditions:

12. Share anonymized information (stripped of all personal identifiers) generated on viral evolution of relevant coronaviruses, including SARS-CoV-2, MERS-CoV and novel coronaviruses of public health importance and identify genetic changes that may be relevant to diagnostic tests, vaccine development and/or antiviral treatment;
13. Meet all applicable deadlines and timeframes for the conduct of the laboratory's obligations and activities as part of the Network;
14. Maintain and demonstrate a high level of technical proficiency, capacity and ability in all matters pertaining to the Network including, but not limited to, through proficiency testing where applicable for the used methods;
15. Treat all virus materials and clinical samples, together with all data and information relating thereto, which are obtained by the laboratory through its participation in this Network (collectively, the "materials") as confidential and proprietary to the providing country, and ensure that materials are not transferred or provided to any third party unless: (i) the recipient third party is a participating laboratory under the Network; and (ii) WHO has expressly requested in writing that the transferring laboratory provide the materials to such recipient laboratory; and (iii) the recipient laboratory uses the materials solely for the Purpose (as defined in paragraph 19 below), and no other purpose. In connection with all of the foregoing, the laboratory must implement and maintain appropriate technical and organizational measures to protect the confidentiality and security of the materials, and to protect the materials from unauthorized access, theft, damage, loss, destruction or misuse;
16. Ensure that the participating laboratory only uses the materials for the following purposes (which are hereinafter collectively referred to as the "Purpose"): (1) detection, identification, and characterization (including through whole genome sequencing) of the SARS-CoV-2, MERS-CoV, and novel coronaviruses of public health importance, including the inclusion of resulting sequence data in a publicly accessible database, (2) non-commercial assay development, (3) commercial assay development*, provided always however that* the participating laboratory shall

have first entered into an agreement with WHO concerning such commercial assay development which shall include, without limitation, provisions to the effect that the commercial exploitation of any intellectual property rights, including the ownership of know-how, arising from any such commercial assay and/or its development shall be designed to achieve the general availability of the product(s) and the availability of the product(s) to the public health sector of developing countries on preferential terms (including as to price) and in sufficient quantities to meet demand; (4) validation of assays, and (5) the performance of any other work as explicitly foreseen in these Amended and Restated Terms of Reference;

17. Ensure that, except as may explicitly otherwise be provided in these Amended and Restated Terms of Reference, the participating laboratory does not use, and does not provide and permit others to use, the materials for any purpose other than the Purpose, unless a separate written agreement has first been established with the Provider (as defined in paragraph 18 below) covering such other use. Any such separate agreement will be promptly provided by the participating laboratory to WHO;
18. Ensure that results of the use of the materials for the Purpose are only be reported to the national laboratory or governmental agency that provided the materials (hereinafter, the "Provider"), except (a) that the participating laboratory will, subject to agreement with WHO and/or Provider, as applicable, be entitled to publish the results of the use of the materials for the Purpose; and (b) as otherwise set forth in paragraph 19 below;
19. Adhere to and comply with: (i) all applicable laws, statutes, rules, regulations and other legal or ethical requirements; (ii) all relevant national biosafety standards for work with high-threat pathogens; and (iii) all national and/or international regulations relating to the receipt of dangerous goods;
20. Obtain and maintain in effect any applicable licenses, permits, authorizations, consents, approvals, accreditations, documentation and/or other recognition which are necessary or required (whether at the national, regional and/or international level(s)) for the laboratory to perform its tasks in connection with the Network;
21. At the request of WHO, make available to WHO (under confidential cover where required) all relevant anonymized (i.e., stripped of all personal identifiers) data and information, as well as all results of work performed by the participating laboratory pursuant to these Amended and Restated Terms of Reference, for the purposes of guiding WHO in the development of WHO's strategy, recommended methods, recommendations, guidelines and/or other documents referred to in paragraph 11 above;
22. Ensure that any agreements entered into by the participating laboratory with any Provider in connection with the Network are consistent with these Amended and Restated Terms of Reference; and
23. Agree that nothing contained in or relating to these Terms of Reference and/or the Network will be construed as a waiver of any privileges and immunities enjoyed by WHO, and/or as submitting WHO to any national court jurisdiction.

IN WITNESS WHEREOF, the undersigned laboratory has caused its duly authorized representative to sign, as of the date ser forth below, this document in two (2) originals in the English language, in order

to evidence such laboratory's agreement with, acceptance of and commitment to comply with these Amended and Restated Terms of Reference.

S**igned for and on behalf of the participating laboratory:**

Signature: _____

Name of Entity: _____

Name of Authorized Representative: _____

Title of Authorized Representative: _____

Date: _____

Mailing Address: _____

Email Address: _____

Telephone Number: _____