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# Veterinary Laboratory Support to the Public Health Response for COVID-19

## TESTING OF HUMAN DIAGNOSTIC SPECIMENS IN VETERINARY LABORATORIES

The COVID-19 pandemic is creating unprecedented pressure on Public Health services world-wide. A multidisciplinary collaborative approach is required to minimise the impact of this rapidly spreading virus. Veterinary Services can support Public Health services to meet the extraordinary surge in demand for diagnostic testing of human samples for SARS-CoV-2 by making available appropriately equipped and competent veterinary laboratories. In some countries human laboratory diagnostic services are at maximum capacity and, as an alternative, veterinary laboratories are being asked to provide support. Veterinary laboratories are well positioned because they have experience in quality assurance, biosafety and biosecurity, and high throughput testing for the surveillance and control of infectious diseases in animals, some of which are zoonotic. Additionally, Veterinary Services can provide expertise in the fields of epidemiology, risk assessment, training and risk communication.

Testing of human specimens in veterinary laboratories should be part of a coordinated government-led Public Health response and laboratories performing COVID-19 diagnostics should ensure they comply with regulations regarding the laboratory testing of human specimens.

## Purpose

*The following non-prescriptive high-level guidance aims to support Public Health services by providing a list of key considerations for testing human specimens for SARS-CoV-2 virus (the causative agent of COVID-19) in veterinary laboratories.*

*This document does not cover research activities.*

## Considerations

### 1. Regulatory affairs (national level)

Veterinary laboratory support to the public health response should respect national regulatory and emergency response frameworks. These frameworks and specific requirements vary between countries.

During a crisis or state of emergency the government often has powers, if needed, to circumvent existing regulations to make resources available. This may extend to circumventing regulations in order to allow veterinary laboratories to receive and test human specimens.

When considering the deferment of samples from human laboratories to veterinary laboratories a risk assessment should be conducted, considering factors such as business continuity and prioritization, the types of test performed and testing requirements, scalability while maintaining quality standards, quality assurance, biosafety (including sample transport) and biosecurity, data management and reporting, personnel and logistics, and lastly training needs of personnel. Risk management strategies should aim to reduce identified risks. This process will support the development of the framework for coordination between veterinary laboratories and the Public Health services.

## 2. Business continuity and prioritisation

To respond to the emergency, SARS-CoV-2 diagnostic testing in the veterinary laboratory may need to be prioritized over existing laboratory services. A rapid prioritization assessment, adapted to each situation, is needed. This assessment would include determining essential and non-essential services. Non-essential work could be discontinued or postponed until the crisis is over or arrangements may be made for other laboratories with equivalent standards, to support this work.

The veterinary laboratory should consider the impact of additional work on business continuity; on animal health and welfare, veterinary public health, trade, food safety, food security (downstream effects); and on its human and financial resources. The outcome of the prioritization will depend on the animal and public health situation and resources available in each country.

## 3. Types of test and testing requirements

Ideally, testing protocols should be harmonized between public health and veterinary laboratories and should follow standard operating procedures.

Nucleic acid detection methods, such as real time RT-PCR, are the methods of choice for detecting SARS-CoV-2 in humans. Substitution of normal RNA extraction processes using heat inactivation of specimens is not recommended because this may result in loss of sensitivity.

Antibody tests are not useful for early detection of SARS-CoV-2 (although they may be useful to estimate potential protective immunity in individuals, and in surveillance studies to estimate population prevalence and immunity). The sensitivity of antigen tests is not yet fully demonstrated, and they are currently not recommended for routine diagnosis.

To mitigate against risks of supply chain interruptions, laboratories may source reagents from multiple suppliers and countries (although this can create challenges in test validation). Testing of reagents on receipt by the laboratory should be done to check for contamination.

Only validated diagnostic tests should be used. If the test has been validated elsewhere it should still undergo verification in the veterinary laboratory performing the tests. Numerous commercial RT-PCR kits are available but not all have been validated. Commercial kits should be subject to verification prior to use and should be backed up by in house assays in case of supply chain problems.

Primer and probe sequences for the detection of SARS-CoV-2 are available on the WHO website and several studies on assay performance with published primers and probes have been published. Due to viral mutations, primers and probes should be regularly assessed for their suitability to detect circulating strains. All newly purchased primers and probes should be tested for their performances before using in routine testing.

Appropriate controls should be used to identify any amplification inhibition associated with samples.

## 4. Scalability

Veterinary laboratories often have experience with high throughput of samples from animal populations and in dealing with surges in demand.

To manage expectations, the veterinary laboratory should clearly communicate its capacity for sample processing, testing, and reporting of results for COVID-19 specimens. This capacity may change over time.

A laboratory information management system (LIMS) will reduce errors and should be used if available. Automated data transfer between veterinary and public health laboratories systems can also save time in sample information registration and reporting results.

Quality standards should be maintained during transition to large scale testing. Procedures should be put in place to minimize any increased risk of cross contamination. Additional resource needs (including budget, staff, equipment, consumables, and infrastructure) should be carefully considered when scaling up.

## 5. Quality Assurance

Ideally, laboratories should meet quality standards e.g. ISO/IEC 17025 or equivalent. However, many veterinary laboratories which could support the response are not accredited to ISO/IEC 17025 and would not be able to become accredited during a crisis. Such laboratories should perform their work in accordance with the principles of ISO/IEC 17025. Proficiency testing and inter-laboratory comparisons with public health laboratories may be used to demonstrate competency.

Veterinary laboratories performing COVID-19 diagnostics should assure they comply with regulations regarding human laboratory testing.

## 6. Biosafety

In veterinary laboratories biosafety and biosecurity procedures should be implemented according to OIE Standards for Biological Risks in Veterinary Laboratories and Animal Facilities[1]. Good Microbiological Practices and Procedures (GMPP) should be implemented whenever handling specimens.

In accordance with WHO guidelines, diagnostic testing which does not involve culture or isolation of virus can be done in a BSL2 Laboratory (as a minimum requirement). It is highly encouraged to start with a local risk assessment[2]. Specimen handling and addition of a validated extraction buffer should be done by trained competent staff wearing appropriate personal protective equipment (PPE) and preferably in a certified Class II or Class III biosafety cabinet. When extracting manually, special attention should be given to any activity which can generate aerosols including centrifugation, closing/opening Eppendorf tubes, pipetting etc.

Diagnostic work for SARS-CoV-2 should be separated from work with other pathogens. Biological amplification of SARS-CoV-2 (virus isolation or animal inoculation) is strongly discouraged owing to the considerably higher risks of laboratory associated infection and potential risk of recombination between human and animal coronaviruses, in addition to the requirement for well-established biosafety systems together with BSL3 facilities to culture virus.

## 7. Biosecurity

Access to laboratories should be restricted. Waste disposal procedures should be the same as for other types of biohazardous waste. Sample storage areas should be secured, including those outside the main laboratory spaces. A list of the authorized staff involved in COVID-19 sample registration, processing and archive should be maintained and shared with relevant authorities (for biosecurity and health purposes). Access to datasets on testing (including storage locations and details) should be restricted to only necessary personnel.

Policy for retention of the tested samples should be established in advance and implemented. Ideally, specimens should be safely discarded (autoclaved) upon completion of the test with confirmation from the Public Health services that no repeat tests are required.

## 8. Data management and reporting

Considering clinical aspects and accountability, interpretation of test results should be supervised by the Public Health services. Test results should be reported to the Public Health service, which is responsible for communicating with health care facilities and patients. Confidentiality issues can be managed by anonymizing

[1] https://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/1.01.04_BIOSAFETY_BIOSECURITY.pdf

[2] https://apps.who.int/iris/bitstream/handle/10665/331138/WHO-WPE-GIH-2020.1-eng.pdf?sequence=1&isAllowed=y

patient information using bar codes or number codes. If veterinary laboratories have access to any patient information they should comply with the clinical and general data protection regulations.

Veterinary laboratories can be engaged as service providers under the main Public Health laboratory. Veterinary laboratories should ensure sample traceability by using electronic data recording systems that would facilitate daily reports to Public Health services and data back-ups.

Data transfer protocols including identifying the type of information to be transferred and mechanisms to transfer data between organisations can be time consuming to establish and should be considered early when planning to take on any COVID-19 testing.

Communication and Intellectual Property issues should be agreed between veterinary laboratories and Public Health services.

## 9. Personnel and logistics

Guidance for groups at high-risk from COVID-19 and their exclusion from the laboratory should be sought from the medical authority, in consultation with laboratory managers. Keeping the staff mentally and physically healthy is the priority. Dividing the staff into several teams with alternate schedules may ensure that the laboratory remains well staffed and running even in the event that a member of one of the teams is under suspicion of COVID-19 infection. Staff health status should be assessed daily, and staff may be tested for SARS-CoV-2 considering guidelines and recommendations issued by the relevant Public Health services. A clear plan for when a staff member is suspected or tests positive should be developed in advance, addressing how both staff wellbeing and business continuity will be assured. It is important to educate staff and manage risk perception through regular meetings.

Staff working with either human serum or blood samples should be vaccinated against Hepatitis B virus.

## 10. Training needs

For laboratory staff used to working with infectious agents and to using the adequate level of PPE, “just-in-time” training should emphasize the specificities of testing human specimens for SARS-CoV-2, including handling of human specimens and testing procedures for SARS-CoV-2 (based on risk assessment for biological materials). Training should also address wellbeing. All staff should demonstrate proven competency in the diagnostic techniques that will be used in the laboratory. Although risk is lower when compared to some other front-line staff, considering that laboratory staff may eventually become unwell with COVID-19, succession training is recommended.

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