



**SPECIFYING ACCREDITATION
FOR COVID-19 (SARS-CoV-2)
TESTING**



RELIABLE TESTING IS A VITAL TOOL TO HELP CONTROL THE SPREAD OF CORONAVIRUS.

Increasingly economies are developing legislation or policy specifying the requirements for sampling and testing, and these may involve the acceptance of test results from other economies. There is significant activity for the testing of humans for a variety of purposes including the diagnosis and treatment of symptomatic patients, mass screening of populations, employment screening and testing to enable people to travel between countries and reduce quarantine periods. Testing is also being conducted on animals, environmental swabs, sewage and food products which is helping to prevent the spread of the virus.

The table below outlines some of the types of testing that may be performed:

| SAMPLE TYPE | ACCREDITATION STANDARD |
|------------------------|---------------------------------------|
| Human samples | ISO 15189, ISO 22870 or ISO/IEC 17025 |
| Environmental swabs | ISO/IEC 17025 |
| Veterinary samples | ISO/IEC 17025 |
| Food and feed products | ISO/IEC 17025 |
| Sewage | ISO/IEC 17025 |

SPECIFYING ACCREDITATION

Specifying accreditation for the wide range of testing that is being conducted is a vital way for regulators to ensure the reliability of tests and help reduce the impact on health, trade and the economy. Where a testing provider holds accreditation from an accreditation body that is a signatory to the ILAC Mutual Recognition Arrangement (MRA), users can have confidence that the competence of the provider is internationally recognised, and that the test results can be accepted everywhere.

Accreditation is already used by many governments to effectively support their regulatory and policy objectives in areas of national interest, including health <https://publicsectorassurance.org/topic-areas/healthcare/> and trade.

STANDARDS USED FOR ACCREDITATION

There are a number of different types of tests that are being used to help control the pandemic, and these are used for different purposes.

Testing of human samples is used to identify the presence of the virus in symptomatic patients or for mass screening the population or screening travellers prior to exiting or entering a country.

Testing is also undertaken to look for the presence of antibodies to determine if a person has immunity.

Testing of sewage and environmental samples is used to monitor the presence of the SARS-CoV-2 virus more broadly throughout the community and can be an important tool in understanding the spread of the disease in an asymptomatic population.

Testing of animals can include the testing of companion animals such as pets, and the testing of animals in agricultural settings such as those used in human food production. The potential for cross-species infection and its implications is also important to identify and understand.

There are several possibilities for the standard that is used for accreditation; this will depend on several factors such as the type of laboratory/provider and any local or national requirements:

- For human samples tested by a medical laboratory, ISO 15189 Medical laboratories – Requirements for quality and competence or ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories can be used;
- For POCT testing of human samples, ISO 22870 Point of care testing (POCT) – requirements for quality and competence can be used in conjunction with ISO 15189;
- For environmental samples, ISO/IEC 17025 may be used;
- For food and veterinary samples, ISO/IEC 17025 is used.



ILAC MUTUAL RECOGNITION ARRANGEMENT

The accreditation of a laboratory shall be issued by an accreditation body operating in accordance with ISO/IEC 17011, General requirements for accreditation bodies accrediting conformity assessment bodies and signatory to the ILAC Mutual Recognition Arrangement (MRA).

The ILAC MRA provides global acceptance of test results and covers accreditation provided under ISO 15189 (including ISO 22870 for POCT) and ISO/IEC 17025. Further information about the ILAC MRA can be found on the ILAC website www.ilac.org

SADCAS is signatory to the ILAC MRA under ISO/IEC 17025 and ISO 15189.

FINDING ACCREDITED TEST LABORATORIES

The contact details for laboratories accredited for SARS-CoV-2 testing are available from the on-line directories of the accreditation bodies that are signatories to the ILAC Mutual Recognition Arrangement for the referenced standards and accessible from <https://ilac.org/signatory-search/>.

SADCAS directory of accredited facilities: <http://www.sadcas.org/accredited-organizations>





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