

ILAC covid19 brochure

Erik Øhlenschläger, International Manager DANAK
8. og 9. juni 2021

Fra ILAC covid 19 brochure udgivet primo 2020:

Many regulators are already using accreditation effectively to support their regulatory and policy objectives in areas of national interest including health <https://publicsectorassurance.org/topic-areas/healthcare/> and trade and are therefore familiar with specifying accreditation. For those not previously involved in this process, the following are some key points that should be considered to ensure the testing is carried out in a laboratory that has been assessed and found to be competent to carry out SARS-CoV-2 testing.

1. The laboratory shall be accredited in accordance with the requirements of ISO 15189 *Medical laboratories – Particular requirements for quality and competence*
2. The laboratory's scope of accreditation to ISO 15189 *Medical laboratories – Particular requirements for quality and competence* shall include SARS-CoV-2 testing.
3. The accreditation of a [laboratory](#) shall be issued by an accreditation body (AB), operating in accordance with ISO/IEC 17011, *General requirements for accreditation bodies accrediting conformity assessment bodies* and signatory to the ILAC Mutual Recognition Arrangement.

Hvad så?

- Henvendelser fra kolleger i Kina og Irland
- Senere henvendelser fra rejsende til Hong Kong og Singapore.
- Sagen taget op på møde i ILAC EX. Hvem kunne vide at brochuren var udarbejdet af sekretariatet og NATA repræsentanter (fra Australien) og godkendt af Chair og vice Chair?
- Mindre revision blev omsat til helt ny udarbejdelse af brochuren.
- Ny brochure endeligt udgivet i marts 2021.



Why become an accredited reference material producer?

ISO 20387: Accreditation for Biobanking Facilities



Specifying Accreditation



Specifying Accreditation for COVID-19 Testing



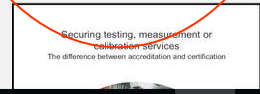
Factsheet - Specifying accreditation in Regulation



Why use an Accredited Laboratory?



How does using an Accredited Laboratory benefit Government and Regulators?



Securing testing, measurement or calibration services



Recommended guide for engaging with Government & Regulators



Why use an Accredited Inspection Body?



How does accredited inspection benefit Government and Regulators?

Brug for support?

Support@ilac.org

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

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.

