BBMRI.at
Biobanking and BioMolecular resources Research Infrastructure Austria

Fully booked webinar on SARS-CoV-2 diagnostics & CE-certification

BBMRI.at, en.co.tec and LISAvienna jointly organized a webinar on the question of whether the CE marking can be understood as a sufficient seal of quality for in-vitro diagnostics (IVDs). The question of the quality assessment of in-house or research use-only tests was also addressed. The event on June 5, 2020 was fully booked, and 100 people from enterprices, universities and regulatory bodies all over Austria were able to attend.

Presentations are available for download

- Programmübersicht
- Begrüßung, Peter Halwachs, LISAvienna
- Coronavirus Kontamination weltweit, Irina Korschineck, ingenetix
- Das CE-Zeichen auf einem IVD. Erfüllung allgemeiner Sicherheits- und Leistungsanforderungen oder Gütesiegel?, Martin Schmid, en.co.tec
- Anforderungen an Präanalytik und Biosafety für COVID-19-Diagnostik, Kurt Zatloukal, Med Uni Graz, BBMRI.at
- Erfahrungen und Problemstellungen aus der Anwenderpraxis, Gregor Hörmann, MedUni Wien, Tirol Kliniken, ÖGLMKC
- Konformitätsbewertung (CE Kennzeichnung) von IVD – Anforderungen aus Sicht einer Benannten Stelle, Sabine Ohse, mdc

Details:

IVDs with CE mark

According to the current regulations, every laboratory test – also Sars-CoV-2 tests - used for diagnostic purposes on human samples must be checked in advance in the laboratory for its suitability. Tests used in accordance with the manufacturer's instructions require verification of the performance characteristics as specified by the manufacturer. The laboratories must document that these performance characteristics for the described application area are actually achieved in their own laboratory.

In practice, however, SARS-CoV-2 tests with CE marking occasionally experience problems with the manufacturer's information, which make this verification difficult. Other problems are related to the quality of the performance data of the manufacturers or to the quality of the samples used. Particularly sample pre-analytics can have an impact on the sample quality.

For the user it is difficult to assess whether the IVD manufacturer was developed according to the required scientific standards or whether the required specificity and sensitivity is met and was determined using a sufficiently large and suitable cohort and with samples of appropriate quality.

In-house and research use-only tests

For in-house or research use-only tests, as well as for the use of CE-certified tests outside of the area of application or in a modified form, the test laboratories themselves must carry out the validation. The corresponding evaluation and the performance characteristics must be documented and justified - this is a great challenge in practice.

External quality controls

Currently (under the In Vitro Diagnostic Directive, IVDD), external quality controls are not mandatory for IVD manufacturers, but are be beneficial to evaluate the diagnostic quality of the tests (specificity, sensitivity). Test laboratories can take part in round robin tests to have external quality control. A system for this is currently under construction in Austria.

Bundesministerium Bildung, Wissenschaft und Forschung

Funded by
GZ 10.470/0016-II/3/2013 (2013-2018)
BMBWF-10.470/0010-V/3c/2018 (2018-2023)