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Challenges in ISO17025 test validation

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Challenges in ISO17025 test validation
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Introduction
The characteristics of diagnostic tests are determined by validation. The ISO17025 is the quality standard for veterinary diagnostic laboratories, and OIE documents describe how validation should be performed1. However, in practice validation can be challenging, due to lack of materials or when there is no gold standard or when it is a typing test. During the last few years we have done a number of validations at our laboratory all with their own challenges and I want to share what we have done to tackle these challenges.
Methods
Limited positive material available
For the detection limit one positive sample can be sufficient. This can be material from our own collection, our network, a reference lab, a testkit, or from the kit manufacturer. For molecular tests synthetic RNA/DNA can be used.
For herd sensitivity a large number of positive animals is needed. When there is one or a few antigens available, spiking of a matrix (blood, organs, swabs) from a number of negative animals was used. By spiking a number of negative animals part of the host variation, including inhibiting factors, is included. However, individual reactions to an infection are not mimicked.
In case of herd sensitivity for a serological test a dilution in negative serum from a number of negative animals was used, provided that enough positive serum with high titre was available.
A positive control is needed in every test, ideally that control is already used during the validation. Here, also one representative positive sample can be enough.
No gold standard test available
Determining the detection level of a serological test when there is no gold standard is a problem. We cannot quantify the number of antibodies to determine the detection level, and it is not clear how this would relate to the result of the test. If there is no gold standard test, alternative options are: the first day an animal can be tested positive after a confirmed infection (infection experiment), or if this was not available a dilution series of a positive serum was used as a rough indication of the detection level.
Typing tests
A complete validation for a typing test was not performed, for example herd sensitivity is not important since only the positive samples from the initial detection test are tested.
Results
For most situations a solution could be found. Sometimes the validation was limited, due to lack of positive material, but at our laboratory validation is an ongoing process. Results of proficiency tests are added to the initial validation report as well as reproducibility data from the Shewart charts. So even in the case of a limited initial validation it builds up afterwards. Typing tests were preferably validated in connection with the detection test.

Conclusions
Different solutions can be used when an ideal validation cannot be performed. It would be valuable to discuss these challenges and solutions with colleagues to improve the quality and to standardise this process.