Summary of the findings during training Valitest Performance Characteristics
January 26, 2021

Every diagnostic test has its performance characteristics. The choice to use a certain test for a certain intended use is largely made on basis of these characteristics. This implies that the importance of different performance criteria is dependent on the scope of a diagnostic test. The purpose of this interactive meeting was to explore the importance of the scope of a diagnostic test and to find out which performance criteria are important in different testing situations and why. During the first part of the meeting, different characteristics were explained as well as their importance in validation. The participants in the meeting presented a mixture of a practical, legal, scientific and managing scope, thus entering different views into the discussions.

For the second part of the workshop the group was divided into 6 smaller breakout groups. In these groups different fictional practical cases were discussed. Each group discussed at least two of the five cases (see table 1, page 2) provided. During the discussions the focus was on how to work with or interpret a certain characteristic and how to decide which criteria would be important under which circumstances.

During the third part of the meeting all participants gathered again to share the findings and conclusions they collected during the discussions. In short these were:

- The context, what you want or need to achieve with a test, is always the first question to ask because it determines the importance of a characteristic and what you need from a criteria. As an example: if you want to detect a pathogen in symptomless material you definitely need a high sensitivity.
- The use of validated tests is important because it is the best way to determine and compare the value of the result of an test.
- It is not possible to get “the best of all worlds” and sometimes you need to or can tradeoff between characteristics. E.g. sensitivity can become less important when an test is so fast that you can perform many tests in a short time and thus monitor your crop continuously.
- Use type strains as a reference and control to be sure that you truly detect the target organism.
- Finding relevant control material is a challenge particularly when it comes to determination of the influence of selectivity on an test. Not all organisms are available or can be “grown” and not all relevant host material can be obtained.

Table 1: Overview of the cases discussed in the breakout groups

	Topic of the case	Questions to help discussion
1	You are working in the laboratory of a seed company and detection of Tomato Leaf Curl New Delhi Virus in tomato is one of your targets. For this you use a validated test with a high analytical specificity and high limit of detection (LOD); you find 1% or your samples positive. The lots where these positive samples originate from are destroyed which is an acceptable loss for the company. However, you worry about the low sensitivity and would like to introduce a new ELISA test which claims a LOD which is 100x lower.	• What would you focus on when performing the comparison? • Which performance criteria would you assume to be important as well?
2	You are lab manager of a diagnostic service laboratory. You get word that a devastating fungal disease is spreading rapidly through Europe. Your customers ask you to start testing for this new emerging pathogen.	• What should this new test be able to do and why? • Which tests would you consider? • Which performance criteria do you consider to be important and why?
3	You are a scientist working in a propagation-company and use IF for the detection of a bacterial disease. However; you need to test an increasing number of samples and would like to start using TaqMan or PCR instead of the IF. The bacterial disease is not a quarantine organism.	• Will it be possible to switch? • What should you take into account when it comes to performance criteria?
4	You are looking for a test with a very high analytical specificity, very high analytical selectivity and 100% reproducibility.	• Would this be possible at all? • How would you test for this? • What would you need as testing material and/or controls? • What could this implicate for other performance criteria?
5	You received a number of samples from your colleague of the breeding department. He tested samples of lettuce plants in different growth stages with a PCR for detection of LMV. He found that the signal varied between the growth stages; negative in seed, positive in seedling and plantlet, negative in full grown plants. He asked you what to do.	• What would you test to find out what is happening? • Which performance criteria would you focus on and why? • Would you consider another type of test?