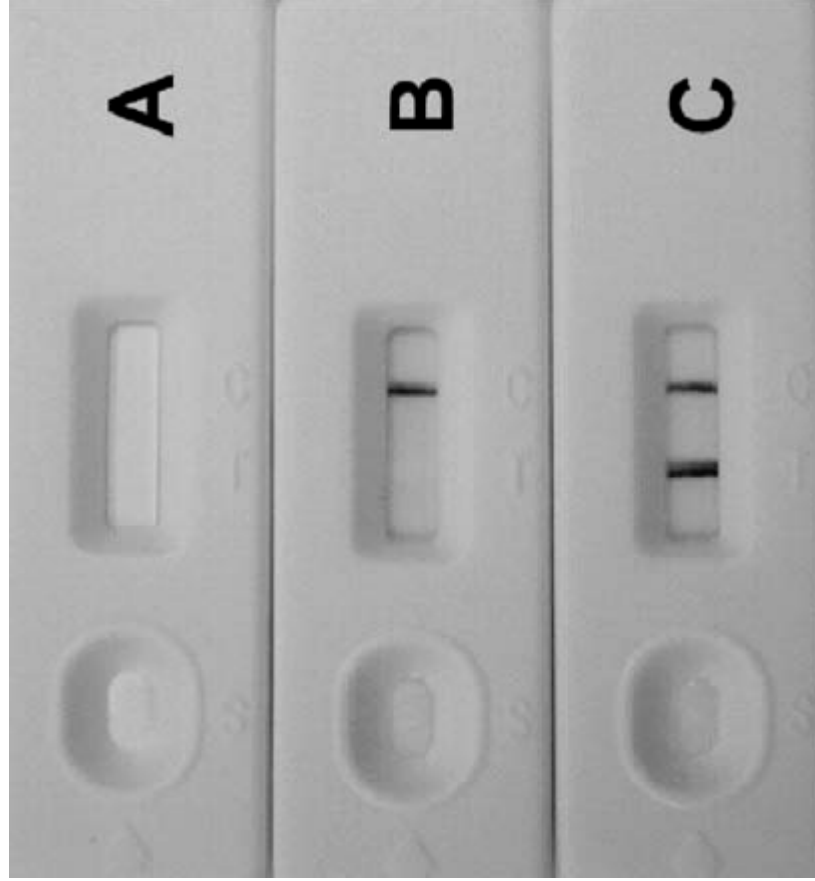
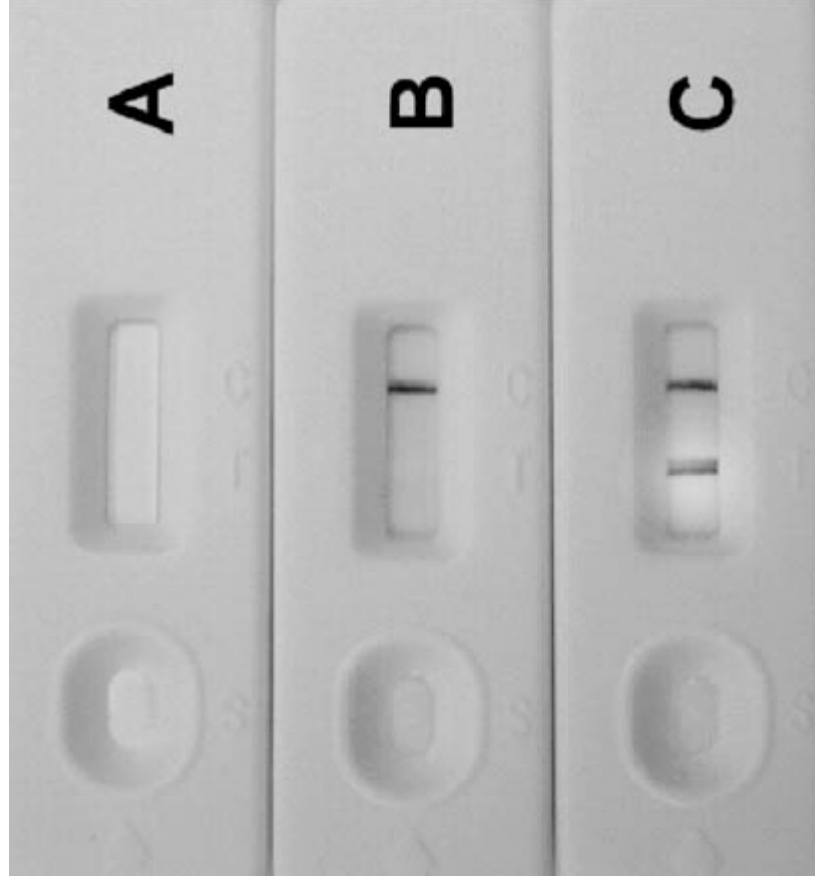
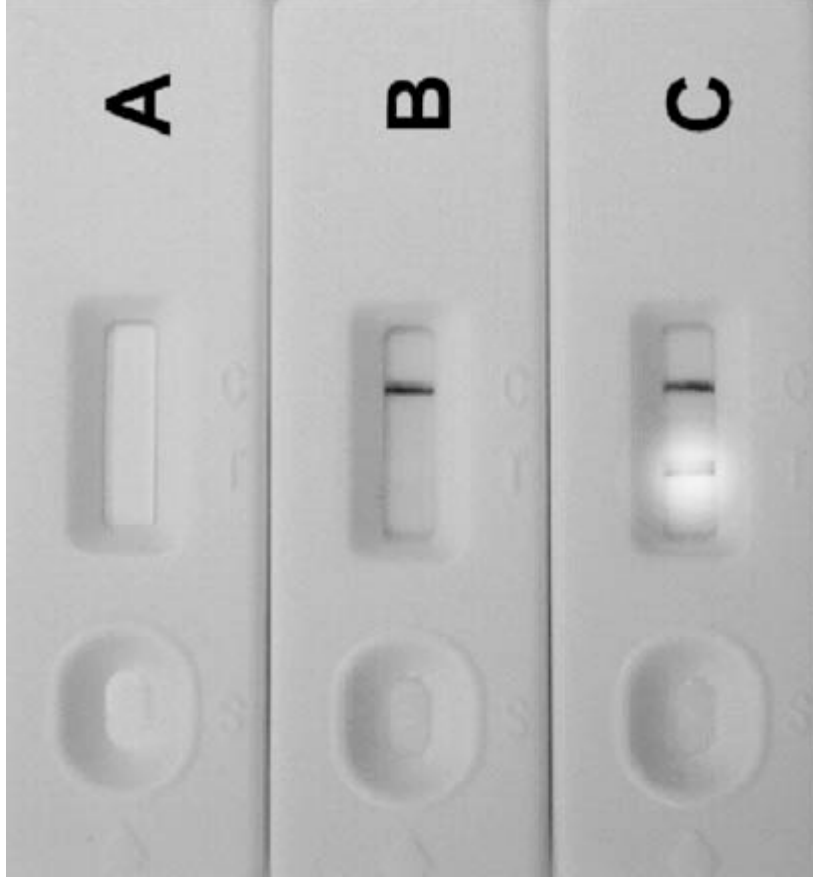


# AOAC Qualitative Chemistry Validation Guideline WG

What is „qualitative“?







- how we define Qual Chem as opposed to quant methods.
- The difficulty is that all qual methods have an LoD which is a quantitative value.
- Definition: In the field of analysis of samples for the presence of target analytes, a qualitative method provides you with a "positive" or "negative" result - without giving information about the corresponding concentration.

- are we looking at multiparameter methods or single parameter methods (e.g. diptick) only?

- : is a method that has the potential to be used quantitatively in the scope of the Qual Chem WG?
- Example is real-time PCR where you can give a yes/no answer but also give copy numbers which would be a quantitative statement.

# CvH

- Most methods are based on the principle that the probability of getting a positive response depends on the unknown concentration of the target analyte in the sample. Furthermore we can assume that this probability is getting higher with increasing concentrations. That's why we need to know at which concentration the probability of having a positive response is above a predefined level (e.g. 95 %) and this concentration level is the LOD. So, if we get a positive response on an unknown sample, the target analyte could be present in the sample below, at or above the LOD. However, if the sample contains the target analyte at LOD level, we can be sure that with a probability of 95 % we will get a positive response. So LOD is very important to check for fitness of purpose of the method

# CvH

- Furthermore we need to differentiate between the method's response - which could be just based on a visual inspection (e.g. dip stick) or a number (e.g. from reader of dip stick or ct-value) - and the final interpretation (positive or negative) . Therefore I would define two sub-groups of qualitative methods. In the first group we just get positive and negative results on a bunch of samples, whereas in the second group there are numbers beyond the interpretation (positive or negative). For instance often the method contains a cut-off value against a measurement is compared to decide whether a sample is positive or not

# CvH

- The guideline that Roy and myself propose deal with the validation of methods based on positive and negative results (dealing with binary information).
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- 4.) When using the numbers measured with methods of the second group, we could apply a different approach, because even if the numbers do not have a direct physico-chemical meaning they contain more information compared to a binary information (positive or negative). But this is not addressed in the current discussion.