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## 1. Microbiological analysis instructions for food analyses <sup>\*)</sup>

This instruction example from a real laboratory provides you with a very comprehensive overview of the possible validation steps. Naturally, this example should not be seen as a rigid requirement, which has to be complied with in every case. Especially in microbiology, the necessary validation steps have to be adjusted to the respective task. The test manager bears responsibility for the validation steps to be carried out.

### 1.1 Method selection/description

- a) official methods
- b) modified official methods
- c) literary methods

### 1.2 Training of the employees

Inspection of the test means necessary for the execution of the method

Equipment (according to equipment instructions):  
e.g. temperature-controlled equipment

Material (according to test instructions):  
e.g. growing media, reagents

### 1.3 Scope of the validation measures to be carried out

#### a) Official methods:

- ◆ specificity/selectivity (test with reference strains)
- ◆ detection limit (test with defined germ concentrations)
- ◆ traceability (test with defined germ concentrations, test of food samples with a defined number of germs)
- ◆ accuracy (participation in intralaboratory comparisons)
- ◆ precision (e.g. maximum of permissible deviation factor 10 with determination of the number of germs)

#### b) Modified official methods:

- ◆ specificity/selectivity (test with reference strains)
- ◆ detection limit (test with defined germ concentrations)
- ◆ traceability (test with defined germ concentrations, test of food samples with defined germ concentrations)
- ◆ accuracy (participation in intralaboratory comparisons)
- ◆ precision (e.g. maximum of permissible deviation factor 10 with determination of the number of germs)
- ◆ plausibility (e.g. comparison with other methods)

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<sup>\*)</sup> Translation for information purposes only. The German version is authoritative.

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**c) Literary methods:**

- ◆ specificity/selectivity (test with reference strains)
- ◆ detection limit (test with defined germ concentrations)
- ◆ traceability (test with defined germ concentrations, test of food samples with a defined number of germs)
- ◆ accuracy (participation in suitability tests/intralaboratory comparisons)
- ◆ precision (e.g. maximum of permissible deviation factor 10 with determination of the number of germs)
- ◆ plausibility (comparison with other methods. e.g. official methods)

**1.4 Preparation and release of test instructions**

The individual validation measures are documented and kept available at the test manager's. On the basis of the presented results, the test manager determines whether or not the selected method is suitable for the intended use.

The test manager approves of the method and releases it in the form of test instructions for the laboratory.

**2. Chemical analysis instructions  
(general chemical analysis of food)**

This instruction example from a real laboratory provides you with a very comprehensive overview of the possible validation steps. Naturally, also this example should also not be seen as a rigid requirement, which has to be complied with in every case. The necessary validation steps have to be adjusted to the respective task. Depending on the sample matrix, the test manager bears responsibility for the validation steps to be carried out.

**2.1 Parameter-related method selection**

Possibilities:

- a) official collection pursuant to § 35 LMBG (Law on Foodstuff and Necessaries), Swiss Food Compendium, method collections AOAC, DGF, DIN or DEV, etc.
- b) modification of an official method (e.g. on account of equipment)
- c) adoption of a method described in the literature

**2.2 Consultation with the respective colleague(s)**

**2.3 Calibration/inspection of the test means necessary for the execution of the method**

(Regulations concerning the equipment calibration can be found in the respective equipment instructions.)

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## 2.4 Scope of the validation measures to be carried out

Depending on the method selected under 2.1, different validation measures have to be carried out:

### a) Adoption of methods from official collections – determination from the respective matrix

- ◆ test of precision
- ◆ degree of precision: calculation of the absolute and relative standard deviation from the data of a multiple determination
- ◆ additional test statistic: indication of the repeatability »r« of the respective method (as far as available)
- ◆ test of the measurement uncertainty
- ◆ determination of the confidence level by means of a multiple determination
- ◆ if necessary: test of linearity
- ◆ determination of the regression coefficient, at least three-point calibration, preferably five-point calibration
- ◆ if possible: test of accuracy
- ◆ standard addition with certified pure substances: test of traceability
- ◆ test of the method with certified reference material
- ◆ participation in suitability tests, intralaboratory comparisons

### b) Modification of a method from official collections – determination from the respective matrix

- ◆ test method as described under a)
- ◆ plausibility test of the influence of the modification, if necessary calibration against certified reference material
- ◆ robustness test of the method under the selected conditions
- ◆ If the modifications are substantial, the method has to be treated as if it was adopted from the literature.

### c) Method adoption from the literature

- ◆ test of the described specificity and selectivity of the method
- ◆ initial determination with pure substances or standards, subsequently determination from the matrix
- ◆ specification of the measurement range – determination from the matrix: determination of the concentration range, for which quantitative statements can be made
- ◆ test parameters as described under a)
- ◆ as far as possible: test with a second independent method
- ◆ as far as necessary: determination of the detection and quantification limit – determination from the matrix
- ◆ robustness test of the method under the selected conditions

### d) Development of an in-house method

- ◆ test of the described specificity and selectivity of the method
- ◆ initial determination with pure substances or standards, subsequently determination from the matrix
- ◆ determination of the detection and quantification limit from the matrix
- ◆ specification of the measurement range – determination from the matrix

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- ◆ determination of the concentration range, for which quantitative statements can be made
- ◆ test parameters as described under a)
- ◆ as far as possible: test with a second independent method
- ◆ robustness test of the method under the selected conditions

## **2.5 For qualitative determinations, the validation complexity is normally reduced to the following factors:**

- ◆ test of the specificity and selectivity, if it does not concern a method from official collections
- ◆ determination of the detection limit of the determination system
- ◆ determination of the detection limit in the sample matrix
- ◆ robustness test of the selected determination method for the specification of particular test instructions

## **2.6 Preparation and release of test instructions**

The individual validation measures are documented and kept available at the test manager's. On the basis of the presented results, the test manager determines whether or not the selected method is suitable for the intended use.

The test manager approves of the method and releases it in the form of test instructions for the laboratory.

## **3. Methods for the detection of pathogens (including detection of pathogen-specific antigens and nucleic acids)**

This instruction example provides you with a very comprehensive overview of the possible validation steps. Naturally, this example should not be seen as a rigid requirement, which has to be complied with in every case. Rather, the necessary validation steps should be adjusted to the respective task, so that in some cases not all of the listed steps are required or other steps may be possible. The test manager bears responsibility for the validation steps to be carried out. Each method that has produced results, which are transferred to the customer, must be validated. However, there can be an imbalance in the validation complexity, which is to be estimated relatively high with in-house methods and relatively low with approved standard methods.

Official methods or methods of national/international standardisation organisations do not necessarily require a complete validation (EA 10/4 or EAL G18, 8.2). The use of commercial reagent sets (officially approved test kits) do not require further validation, if the validation data can be obtained from alternative sources. Laboratories should demand the delivery of the validation data from the manufacturers and documentation that the validation has been carried out in compliance with the norms (see also EA 10/4 or EAL G18, 8.3). An ISO 9000 certificate does not guarantee the validation of the test kits in compliance with the norms. In either case, the test manager bears responsibility that the used methods are suitable for the intended purpose of the laboratory.

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### **3.1 Method selection/description**

- a) standard methods (official and approved methods: for instance according to EU regulations, national legislation, federal catalogue of measures Zoonoses)
- b) modified standard methods
- c) literary and in-house methods

### **3.2 Training of the employees**

### **3.3 Inspection of the test means necessary for the execution of the method**

- a) equipment (according to equipment instructions): e.g. temperature-controlled equipment, pipettes
- b) material (according to test instructions): e.g. growing media, reagents, test kits (e.g. result of the batch test; internal batch test, for example with the help of reference serums, if necessary; comparison of the used batches)

### **3.4 Scope of the validation measures to be carried out (cf. EN ISOIEC 17025)**

#### **a) Standard methods:**

- ◆ accuracy (e.g. participation in intralaboratory comparisons, comparison with reference material)
- ◆ precision (e.g. test of aliquots of the same sample 20 days in a row and subsequent determination of the mean value and variation coefficient)
- ◆ detection limit (e.g. test with defined pathogen/germ concentrations)
- ◆ specificity (e.g. test with reference strains), if necessary

#### **b) Modified Standard methods:**

- ◆ accuracy (e.g. participation in intralaboratory comparisons, comparison with reference material)
- ◆ detection limit (e.g. test with defined pathogen/germ concentrations)
- ◆ precision (e.g. test of aliquots of the same sample 20 days in a row and subsequent determination of the mean value and variation coefficient)
- ◆ specificity (e.g. test with reference strains), if necessary
- ◆ plausibility (e.g. comparison with the unmodified method, demonstration of the scientific experience and knowledge of the method), if necessary

#### **c) Literary and in-house methods:**

- ◆ accuracy (e.g. participation in intralaboratory comparisons, comparison with reference material)
- ◆ detection limit (e.g. test with defined pathogen/germ concentrations)
- ◆ precision (e.g. test of aliquots of the same sample 20 days in a row and subsequent determination of the mean value and variation coefficient)
- ◆ specificity (e.g. test with reference strains), if necessary
- ◆ plausibility (e.g. comparison with the unmodified method, demonstration of the scientific experience and knowledge of the method)

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### **3.5 Preparation and release of test instructions**

The individual validation measures are documented and kept available at the test manager's. On the basis of the presented results, the test manager determines whether or not the selected method is suitable for the intended use.

The test manager releases the method for the laboratory.

## **4. Methods for the detection of a pathogen-specific immune response (antibody determination, serology)**

This instruction example provides you with a very comprehensive overview of the possible validation steps. Naturally, this example should not be seen as a rigid requirement, which has to be complied with in every case. Rather, the necessary validation steps should be adjusted to the respective task, so that in some cases not all of the listed steps are required or other steps may be possible. The test manager bears responsibility for the validation steps to be carried out. Each method that has produced results, which are transferred to the customer, must be validated. However, there can be an imbalance in the validation complexity, which is to be estimated relatively high with in-house methods and relatively low with approved standard methods.

Official methods or methods of national/international standardisation organisations do not necessarily require a complete validation (EAL G18, 8.2). The use of commercial reagent sets (officially approved test kits) do not require further validation, if the validation data can be obtained from alternative sources. Laboratories should demand the delivery of the validation data from the manufacturers and documentation that the validation has been carried out in compliance with the norms (see also EAL G18, 8.3). An ISO 9000 certificate does not guarantee the validation of the test kits in compliance with the norms. In either case, the test manager bears responsibility that the used methods are suitable for the intended purpose of the laboratory.

### **4.1 Method selection/description**

- a) standard methods (official and approved methods: for instance according to EU regulations, national legislation, federal catalogue of measures Zoonoses)
- b) modified standard methods
- c) literary and in-house methods

### **4.2 Training of the employees**

### **4.3 Inspection of the test means necessary for the execution of the method**

equipment (according to equipment instructions): e.g. temperature-controlled equipment, pipettes

material (according to test instructions): e.g. growing media, reagents, test kits (e.g. result of the batch test; internal batch test, for example with the help of reference serums, if necessary; comparison of the used batches)

#### 4.4 Scope of the validation measures to be carried out

(see also ISO 17025):

Depending on the method selected under 4.1, different validation measures have to be carried out:

##### a) Standard methods:

- ◆ accuracy (e.g. participation in intralaboratory comparisons, comparison with reference material)
- ◆ precision (e.g. test of aliquots of the same sample 20 days in a row and subsequent determination of the mean value and variation coefficient)
- ◆ statistical spread with multiple determinations (variation, standard deviation)
- ◆ detection limit (test with defined concentration of an analyte or with reference serums)
- ◆ determination of the diagnostic sensitivity (share of the test positives in the number of correct or “golden standard” positives), if not otherwise available
- ◆ determination of the diagnostic specificity (share of the test negatives in the number of correct or “golden standard” negatives), if not otherwise available

##### b) Modified standard methods:

- ◆ accuracy (e.g. participation in intralaboratory comparisons, comparison with reference material)
- ◆ precision (e.g. test of aliquots of the same sample 20 days in a row and subsequent determination of the mean value and variation coefficient)
- ◆ statistical spread with multiple determinations (variation, standard deviation)
- ◆ detection limit (test with defined concentration of an analyte or with reference serums)
- ◆ determination of the diagnostic sensitivity (share of the test positives in the number of correct or “golden standard” positives), if not otherwise available
- ◆ determination of the diagnostic specificity (share of the test negatives in the number of correct or “golden standard” negatives), if not otherwise available
- ◆ plausibility (e.g. comparison with the unmodified method, demonstration of the scientific experience and knowledge of the method), if necessary

##### c) Literary and in-house methods:

- ◆ accuracy (e.g. participation in intralaboratory comparisons, comparison with reference material)
- ◆ precision (e.g. test of aliquots of the same sample 20 days in a row and subsequent determination of the mean value and variation coefficient)
- ◆ statistical spread with multiple determinations (variation, standard deviation)
- ◆ detection limit (test with defined concentration of an analyte or with reference serums)
- ◆ determination of the diagnostic sensitivity (share of the test positives in the number of correct or “golden standard” positives)
- ◆ determination of the diagnostic specificity (share of the test negatives in the number of correct or “golden standard” negatives)
- ◆ plausibility (e.g. comparison with another method, e.g. a standard method, demonstration of the scientific experience and knowledge of the method)

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#### **4.5 Preparation and release of test instructions**

The individual validation measures are documented and kept available at the test manager's. On the basis of the presented results, the test manager determines whether or not the selected method is suitable for the intended use.

The test manager releases the method for the laboratory.