



Nordic Committee on Food Analysis

www.nmkl.org – located at the Norwegian Veterinary Institute



NordVal – an organisation under NMKL, certifying alternative methods (microbiological and chemical)

www.nmkl.org

Working Group on Qualitative Chemistry Guidelines for Alternative Methods

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NMKL – Nordic Committee on Food Analysis

- elaborating methods for food analysis
- elaborating guidelines
- arranging courses/seminars
- Nordic influence internationally, coordination within CEN
- facilitating networking



NordVal is a committee of NMKL, validating and certifying proprietary/alternative methods

a proprietary method is one in where a party, or proprietor, exercises private ownership of the method. It is generally extended to a method with a registered trademark/brand name and which is owned and generally marketed by a commercial company



3 Guides on Qualitative Analysis:

- 1) Evaluation of Results from Qualitative Methods
(NMKL Procedure No. 20, 2007 incl. Excel Spreadsheet)
- 2) Guide in Validation of Alternative Proprietary Chemical Methods
(NordVal Protocol 2, 2010)
- 3) Protocol for the validation of alternative microbiological methods
(NordVal Protocol 1, updated 2009)



1) Evaluation of Results from Qualitative Methods (NMKL Procedure No. 20, 2007 incl. Excel Spreadsheet)

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Whereof 6 are statisticians.



1) Evaluation of Results from Qualitative Methods (NMKL Procedure No. 20, 2007 incl. Excel Spreadsheet)

The procedure describes how to evaluate valid results from qualitative and semi-quantitative methods.

- results from a comparison of two qualitative methods (one of the methods could be an alternative method (test-kit))
- evaluation of a method against expected/“true results” carried out in an in-house, an intermediate or in a full collaborative method performance study.

A practical guide, a procedure that can be used by everyone, without requiring profound statistical knowledge.

It was needed and elaborated for NMKL validation of qualitative methods. An Excel spreadsheet is made available at www.nmkl.org for the calculations described in this procedure.



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1) Evaluation of Results from Qualitative Methods (NMKL Procedure No. 20, 2007 incl. Excel Spreadsheet)

Performance characteristics:

- sensitivity, SE
- accuracy, RA
- specificity, SP
- false positives, FP
- false negatives, FN
- limit of detection, LOD
- the agreement between methods/replicates, κ



Cross table – used for evaluating the results

Method 2		Obtained		
		+	-	Sum
Expected	+	43	17	60
	-	2	28	30
Sum		45	45	90
Sensitivity, RT(%)		72 %		
False Negative, FN(%)		28 %		
Specificity, SP(%)		93 %		
False Positive, FP(%)		7 %		
$p_o = \frac{N_{11}}{N} + \frac{N_{22}}{N}$		0,79		
$p_e = \frac{(N_{1-} \cdot N_{-1}) + (N_{2-} \cdot N_{-2})}{N \cdot N}$		0,50		
$\kappa_o = \frac{p_o - p_e}{1 - p_e}$		0,58		
Interpretation of Kappa: If $\kappa > 0.61$ the agreement is good				



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All values lie on the diagonal of the cross table → perfect agreement
More values placed outside the table diagonal → less agreement

To get an estimate of the agreement between the methods, Cohen's kappa may be calculated as follows:

The observed proportion of agreement, the accuracy, is:

$$RA = p_o = \frac{N_{11} + N_{22}}{N}$$

The expected frequency of agreement, the expected accuracy, or repeatability by chance is:

$$p_e = \frac{(N_{1-} \cdot N_{-1}) + (N_{2-} \cdot N_{-2})}{N^2}$$

To measure the agreement between the methods, Cohen's κ (kappa) can be applied:

$$\kappa = \frac{p_o - p_e}{1 - p_e}$$

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In general, the following κ values are used in the interpretation of kappa:

$\kappa \leq 0.20 \rightarrow$ Poor agreement

$\kappa \in \{0.21 - 0.40\} \rightarrow$ Fair agreement

$\kappa \in \{0.41 - 0.60\} \rightarrow$ Moderate agreement

$\kappa \in \{0.61 - 0.80\} \rightarrow$ Good agreement

$\kappa > 0.80 \rightarrow$ Very good agreement

For method validation, considering the overall agreement “very good agreement” is often required, i.e. $\kappa > 0.80$



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2) Guide in Validation of Alternative Proprietary Chemical Methods (NordVal Protocol 2, 2010)

SCOPE

This NordVal Protocol describes validation of proprietary chemical methods (test kits). The objective is to guide expert laboratories, NordVal technical committees and the NordVal steering group in the validation, evaluation and certification of test kits.

This protocol consists of the following two parts, describing

- validation and evaluation of qualitative proprietary methods
- validation and evaluation of quantitative proprietary methods

Preferably, the alternative method should be validated against a reference method. However, when no such method is available the validation can be carried out using certified reference materials, control materials and/or spiked samples at different levels in various matrixes.



www.nmkl.org

2) Guide in Validation of Alternative Proprietary Chemical Methods (NordVal Protocol 2, 2010)

Extensive study at expert laboratory

Intermediate study – results are confirmed by at least one additional laboratory

The study design are described

The evaluation of results carried out very much similar to NMKL Procedure No. 20

In addition to LOD, Detection Capability CC_{β} is included (harmonisation to Codex and EU directive)

Acceptance criteria are given