



NMKL

Nordic Committee on Food Analysis
www.nmkl.org

Understanding Codex's, and the Standard Development Organisations' problems, with the adoption of proprietary methods of analysis

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- What is a proprietary method
- The need for proprietary methods
- The availability of proprietary methods
- "Problems" with including references to proprietary methods in standards
- How proprietary methods are dealt with in SDOs
- The importance of having an independent party reviewing the performance of proprietary methods
- Who validates/ reviews proprietary methods

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- Proprietary methods
- Rapid methods
- Black box methods
- Alternative methods
- Test-kits
- Screening methods

Definitions

1) A proprietary method means that a party, or proprietor, exercises private ownership of the method.

[NordVal Protocol]

2) Method with a registered trademark/brand name, which is owned and generally marketed by a commercial company.

NOTE:

Generally, some of the components of the method are undisclosed.

Example: ELISA or PCR test kits supplied in various formats by companies

[ISO N077 – PG1 16140PG1 - Terminology]



The need for proprietary methods

For allergen testing proprietary methods are the only available methods.

Use of proprietary methods often means:

- increased effectiveness
- faster and less expensive analyses – less costly and simpler instrumentation
- ready-to-use methods, simpler preparation steps
- less time consuming
- the methods descriptions are easy to follow

Availability

Microbiology:

- ✓ *Salmonella*,
- ✓ *Listeria*,
- ✓ *E.coli*,
- ✓ Aerobic bacteria,
- ✓ Coliforms,
- ✓ *Staphylococcus*,
- ✓ *Campylobacters*
- ✓ Yeast and mould

Toxins:

- ✓ Aflatoxins
- ✓ Deoxynivalenol (DON)
- ✓ T-2 Toxins

Antibiotics:

- ✓ Penicillin G,
- ✓ Amoxicillin, Ampicillin, cephalosporins

Biochemical:

Food allergens:

- ✓ Peanut
- ✓ Gliadin, secalins, hordeins
- ✓ Folic acid
- ✓ Vitamins
- ✓ Histamine
- ✓ Muscle proteins

Performance tested by AOAC RI, see www.aoac.org

Availability of proprietary methods

Abkem Iberia
 Abraxis inc
 Biocontrol inc
 Biosense Laboratories
 Charm Sciences inc
 Chrystal Chem (Morinaga allergen)
 Diagnostix
 ELISA Systems
 ELISA Technologies
 EuroProxima
 Hallmark Analytical Ventures Ltd
 Helica biosystems inc
 Neogen Corp
 Oxoid Ltd
 r-Biopharm
 Romer Labs
 Strategic Diagnostics inc
 Tecna srl
 Tecra
 Tepnel
 Vicam

There are a number of manufacturers of proprietary methods, both for microbiological and chemical methods.

They have good marketing programs and hence proprietary methods are easily available.

Codex's "problems" with referring to proprietary methods

Pros

- Easy to enforce
- No frequent changes in the method.

.. referring to proprietary methods

Cons

- No freedom of choice in method; a method which a laboratory might not use in their daily routine and hence not trained to perform, might have to be taken into use in case of dispute situations

Similar argumentation for taking method performance criteria into use in Codex for type II and type III methods

.. referring to proprietary methods

Cons

- Preventing further development: new and better techniques are not taken into use.

A manufacturer that has their method referred to might not want to revise the method in fear of losing its reference. Further, the competitors will prioritise other field of interest, as they have already lost the battle of getting their method given as a reference. Normally, proprietary methods are revised very frequently, a method could very well be revised a couple of times before the Codex standard would be finalised.

.. referring to proprietary methods

Cons

- Preference are given to manufacturers:

If a reference to a proprietary method is included in a Codex standard, the manufacturer of that method gets huge financial advantages, which would not be very well received by the competitors.

.. referring to proprietary methods

Cons

- Pressure (lobbying) on the members of the commodity committees and on CCMAS from test-kits manufacturers in order to get a reference to their product included in a standard.

Any proprietary method in Codex standard?

R5 Mendez method for analysis for Gluten

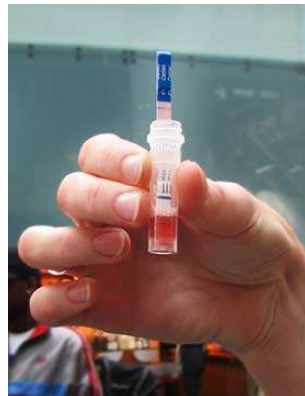
– adopted by Codex in 2008 as type I method

Problems in referring to prop method?

- The R5 antibody is licensed to a few (4) companies, but there are several producers (~10) of test-kits for gluten on market. Many referring to the Codex standard for gluten, claiming satisfactory sensitivity (< 20 ppm and < 100 ppm).
- When the Codex Standard refers to the R5 ELISA Mendez method, which commercial kit is ok to use?
- Is a kit considered to be equivalent to other R5 based ELISAs even though the design of the kit, the quality of reagents and manufacturing standard might differ?

Availability, reliability

- what about qualitative lateral flow based tests – on-site testing for screening – would be cost beneficial





Availability, reliability → criteria for appropriate methods

- Has the method been validated/certified?

Methods validated / reviewed by an independent party (such as by AOAC International, AOAC RI or NordVal) should be preferred, thereafter a method where the sensitivity, precision, and reproducibility of the method should have been demonstrated in a peer-reviewed publication.



Availability, reliability → criteria for appropriate methods

- Is the method sufficiently sensitive?

The limit of detection and the limit of quantification should be below the levels that appear to cause biological responses in most patients with celiac disease.





Availability, reliability → criteria for appropriate methods

- What is the method applicable to? Does the method measure proteins from all relevant foods?
Any limitations e.g. is it available for both raw and baked foods?

The cereal grains associated with celiac disease include wheat, barley, rye, and oats.
Different methods might be needed; each should be validated.



Availability, reliability → criteria for appropriate methods

- What does the method measure?

The storage proteins in cereal grains (generally referred to as gluten) include both prolamin proteins (gliadins) and glutelin proteins (glutenins). What is gluten expressed as in the regulation?





Requirement for methods referred to in Codex

- Collaboratively validated methods (type II and type III)
- Proprietary methods – collaboratively validated and reviewed by an independent party (e.g. SDO)
 - ✓To verify that the method performs according to its claims (like EU regulation for food hygiene in microbiology)



SDO and test-kits?

How has it been dealt within in the Nordic countries

- 1990's Salmonella outbreak in Denmark – need for rapid methods
- Need for methods reviewed by a third party → DanVal
- Discussions raised in NMKL to take over DanVal's activities and including test-kits in the method collection. The NMKL national committees said: NO!
 - lack of transparency in the methods, undisclosed reagents
 - fear of giving preferential treatment to companies
 - lack of resources to validate all kits and for the frequent review





History cont.

- NMKL requested Nordic Council of Ministers to establish a Nordic system for validation of rapid methods
→ NordVal was established 1999.
 - Members of NordVal were appointed by and employees of the national food administrations.
- 2007, NordVal became a committee of NMKL. The secretariat of NordVal is located together with the secretariat of NMKL at National Veterinary Institute in Oslo, Norway
- 2010, NordVal includes chemical test kits.



- 1) NMKL method collection
- 2) NordVal certified methods



SDO's adoption of proprietary methods



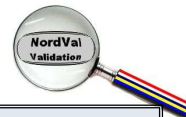
The Scientific Association Dedicated to Analytical Excellence®

- meet the laboratories need for validated proprietary methods
- test-kit manufacturers are obliged to revise the OMA method when their kit has been revised
- AOAC RI performance tested program



Who review proprietary methods

- ✓ AFNOR
- ✓ AOAC RI & AOAC INTERNATIONAL
- ✓ MicroVal
- ✓ NordVal



The persons involved in NordVal shall be independent and cannot have special interest in the production/ distribution of test kits, special reagents or instruments.

NordVal has acceptance criteria.





NordVal / NMKL
c/o National Veterinary Institute
PB 750 Sentrum, N-0106 Oslo, Norway
www.nmkl.org




NordVal Certificate

Issued for:	IQ-Check™ <i>Salmonella</i> II kit
NordVal No:	38
First approval date:	10 October 2009

Certificates includes
Field of application
Principle of the method
Method-performance characteristics
Result and conclusions


reference method was EN
etection of *Salmonella* spp.

the results obtained in
the validations conducted by the exper
Institut Pasteur de Lille and ADRIA
Développement, France, respectively, in acco
16140. NordVal has concluded
that it has been satisfactorily demonstrated that
protocol are fulfilled for all four tested protocols.
document no statistical
difference in the performances between the IQ-Check™ *Salmonella* II kit and the reference
method. Further it was demonstrated that confirmation is not need



Information about certified proprietary methods

- ✓ AFNOR www.afnor-validation.com
- ✓ AOAC RI www.aoac.org
- ✓ MicroVal www.microval.org
- ✓ NordVal www.nmkl.org
click on NordVal
or on the



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General recommendations

- When possible avoid references to methods and in particular proprietary methods, due to:
 - preferential treatment to some manufacturers
 - proprietary methods evolves fast
 - undisclosed reagents
 - new products are soon on the market
 - lobbying

General recommendations

If to be referred to, the methods should be:

- Readily available from several manufacturers
- The kits validated/verified/certified by an independent party to test if the proprietary method perform according to its claims and the specified requirements