

tanja.dreo@nib.si

Flexible scope experience at NIB in Slovenia



**SLOVENSKA
AKREDITACIJA**



LP-028

akreditacijska listina accreditation certificate

NACIONALNI INŠTITUT ZA BIOLOGIJO

Večna pot 111, 1000 Ljubljana

Organizacija je akreditirana pri Slovenski akreditaciji (SA) kot preskuševalni laboratorij. S to akreditacijsko listino se priznava izpolnjevanje zahtev standarda

SIST EN ISO/IEC 17025:2005

za dejavnosti, ki so opisane v prilogi te listine. Akreditacijska listina se uporablja le v povezavi s to prilogo.

Datum podelitve akreditacije: 22. avgust 2003

Akreditacija je voljavna do preklica. Veljavnost akreditacije je mogoče preveriti na spletni strani SA, www.slo-akreditacija.si, in v katalogu akreditiranih organov na sedežu SA.

Slovenska akreditacija je podpisnica sporazumov o medsebojnem priznavanju akreditacij na področju preskušanja pri Evropskem združenju za akreditacijo (EA) in pri Mednarodnem združenju za akreditacijo laboratorijev (ILAC).

The above organization has been accredited by Slovenian Accreditation (SA) as a testing laboratory. This Accreditation Certificate is to certify compliance with the requirements of the SIST EN ISO/IEC 17025:2005 for the activities as described in the Annex hereto. The Accreditation Certificate shall only be used in conjunction with this Annex.

Grant of accreditation: 22 August 2003

This accreditation shall remain in force until withdrawn. Validity of accreditation may be verified on the SA website, www.slo-akreditacija.si, and in the Catalogue of accredited bodies at the SA head office.

Slovenian Accreditation (SA) is a signatory of the Multilateral Agreements of the European Co-operation for Accreditation (EA) and International Laboratory Accreditation Co-operation (ILAC) for testing.

- testing laboratory
- fixed scope since 2003 (GMO)
- flexible scope since 2012 (GMO & ,plant health')



annexes

Scope of accreditation

Testing fields:

- biology, biochemistry (GMO detection)
- **microbiology (molecular methods)**

Test items:

- **foodstuffs**
- **agricultural products**
- **biological samples**

Tip obsega: fleksibilni (možnost uvajanja manjših sprememb metode ali dodatnih vrst preskušancev ali dodatnih parametrov)
 / *Type of scope: flexible (possibility of implementing minor modifications of the method or introducing additional types of test items or additional parameters)**

Mesto izvajanja: v laboratoriju / *Site: in the laboratory/*

Področja preskušanja glede na vrsto preskušanja: mikrobiologija (molekularne metode) / *Testing fields with reference to the type of test: microbiology (molecular methods)*

Področja preskušanja glede na vrsto preskušanca: živila; kmetijski proizvodi; biološki vzorci / *Testing fields with reference to the type of test item: foodstuffs; agricultural products; biological samples*

Št No	Oznaka standarda ali nestandardne preskusne metode <i>Reference to standard or non-standard testing method</i>	Naslov standarda ali nestandardne preskusne metode in morebitne navezave na druge standarde ali metode <i>Title of standard or non-standard testing method and eventual relations to other standards or methods</i>	Območje preskušanja, Negotovost rezultata preskušanja (kjer je to pomembno) <i>Range of testing, Uncertainty of the result of testing (where relevant)</i>	Materiali; proizvodi <i>Materials; products</i>
2.	02D-Pos48 interna metoda <i>in-house method</i>	PCR v realnem času za določanje mikroorganizmov - povzročiteljev bolezni rastlin / <i>Real time PCR for testing of microorganisms – plant pathogens</i> Kvalitativna metoda na osnovi nukleinske kisline v povezavi z internimi postopki / <i>Qualitative nucleic acid based methods in connection with internal procedures:</i> 02D-Pos06 - Ekstrakcija DNA za analizo fitoplazem / <i>DNA extraction for phytoplasma analysis</i>		živila, kmetijski pridelki in biološki vzorci (razen semen) <i>foodstuffs, agricultural produce and biological samples (except seeds)</i>

*Laboratorij lahko po potrebi uvede manjše spremembe metode ali dodatne vrste preskušancev znotraj skupin navedenih v zadnjem stolpcu tabele, ali dodatne parametre v okviru namembnosti metode. Podatke o trenutnem stanju obsega vzdržuje laboratorij. / *Laboratory can implement minor modifications of the method or introduce additional types of test items from a group defined in the last column of the table or introduce additional parameters within limits of the purpose of the method as necessary. Details on the actual extent of the scope are maintained by the laboratory.*

List of accredited methods precisely defines methods listed in Annex to the accreditation certificate no. LP-028, and used by the Department of biotechnology and systems biology for detection of microorganisms - plant pathogens.

Reference to standard or non-standard testing method	Title of standard or non-standard testing method and eventual relations to other standards or methods	Range of testing	Materials; products	Internal procedure code	Issue	Title of procedure for detection of genetic elements	Method accredited from
02D-Pos48 (issue 06) in-house method	<p>Real time PCR for testing of microorganisms - plant pathogens</p> <p>Qualitative nucleic acid based methods in connection with internal procedures:</p> <p>02D-Pos06 (issue 08) – DNA extraction for phytoplasma analysis</p>	<p><i>Stolbur group, 16SrXII, Stol11 genomic fragment (including BN and MR phytoplasma: 'Ca. P. solani')- qualitative</i></p> <p><i>Elm yellows group. 16SrV, FD9 genomic fragment (including FD phytoplasma) - qualitative</i></p> <p>AP phytoplasma ('apple proliferation, <i>Ca. P. mali</i>', IGS region)</p> <p>PD phytoplasma (pear decline, '<i>Ca. P. pyri</i>', IGS region)</p> <p>ESFY phytoplasma (European stone fruit yellows, '<i>Ca. P. prunorum</i>', IGS region)</p>	plants and insects	02D-Pos43	08	Detection of phytoplasmas with real-time PCR	<p>11-10-2012 FD and BN phytoplasma</p> <p>03-07-2014 AP PD and ESFY phytoplasma</p> <p>07-07-2015 Maize redness phytoplasma</p>

- to be added: more detailed definition of matrices
- can extend range of testing, materials tested
- even before an external audit results can be reported as ,accredited'
- validation

Dealing with validation

- internal procedures for **planning** of validation, **validation** and **reporting**
 - in-line with EPPO recommendations
 - implementation of a validated method
 - critical points analysis
- in-house developed methods
 - comparison with current methods
 - analysis of samples
 - **spiked positive controls** →
- **not modular**
 - validation of [DNA extraction + qPCR]
 - GMO: DNA extraction = good → any qPCR



Implementing quality assurance

- different approaches: GMO/phytoplasma/bacteriology
 - use of internal amplification controls (mostly yes)
 - positive isolation controls (used in bacteriology)
 - **decisions based on analysis of critical points and generated data**
 - **useful VS necessary**
- internal procedure: **managing rarely used methods**
 - less than once per year
 - precautionary measures
 - literature review
 - read the relevant documents
 - check chemicals and reagents
 - check instruments
 - use positive and negative controls

Demonstrating expertise

- performance
 - testing
 - on-time analysis
 - positive findings / interceptions / detection of outbreaks
 - blind samples
 - results of controls
 - proficiency tests
- validation data
- international collaboration
- peer-reviewed publications

Conclusions

- broad **flexible scope based on a methodology** (real-time PCR) and a range of **matrices**
- answering **,is this present?‘**
- additions supported by additional validation data
- on-going discussions about **,the Scope‘**
 - should testing of everything within the scope be possible without additional validation data?
- **not fully exploited yet**
 - e.g. reproducibility and repeatability so far determined for all accredited qPCRs