



The ISTA Accreditation Programme for laboratories testing for specified traits in seed

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Elements of accreditation

- **Accreditation Standard/ISTA Rules**
 - **Scope of accreditation**
- 1. Participation in proficiency testing**
 - 2. Performance data evaluation**
 - 3. On-site assessment**



Accreditation Standard/ ISTA Rules

- **General requirements for the operation of a quality management system to demonstrate technical competence**
- **Principles for testing for the presence of specified traits (Chapter 8)**



Scope of accreditation

Must be defined in sufficient detail

Example:

Species	Testing principle	Trait	Detection/ Quantification	Reference
<i>Zea mays</i>	PCR	35S Promoter	Detection	SOPXY-01
	Rt-PCR	Bt 176	Quantification	SOPXY-02
	ELISA	Cry3Bb	Detection	SOPXY-03
...



Proficiency Test Participation

- Two test rounds per year
- Participation is mandatory
- Rating is given
- Satisfactory performance is required



Performance Data Evaluation (PDE) - detection

- Performance data for each method/species/trait combination that is part of the scope of accreditation
- At least one set of data per species and methodology according the PDE protocol
- A grade is given to evaluate performance
- The material used must be seeds



Performance Data Evaluation (PDE) - detection

10 samples of 400 seeds each containing 3 seeds with the specified trait (spiking level 0.75%)

Sample	1	2	3	4	5	6	7	8	9	10
Result	P	P	P	P	P	P	P	P	P	P

10 samples of 400 seeds each containing 2 seeds with the specified trait (spiking level 0.5%)

Sample	1	2	3	4	5	6	7	8	9	10
Result	P	P	P	P	P	P	P	P	P	P

10 samples of 400 seeds each containing NO seeds with the specified trait

Sample	1	2	3	4	5	6	7	8	9	10
Result	A	A	A	A	A	A	A	A	A	A



Performance Data Evaluation (PDE) - detection

Grade 1: all 30 samples correctly identified

Grade 2: 1 or 2 samples wrongly identified

Grade 3: more than 2 samples wrongly identified



Performance Data Evaluation (PDE) - quantification

28 samples of 2000 seeds with 7 different spiking levels

3 levels given (level in # of seeds)

0.1% (2 seeds spiked)

0.5% (10 seeds spiked)

1.0% (20 seeds spiked)

4 blind levels (to be determined by the applicant) between

0.1 - 0.5%

0.5 - 1.0%

1.0 - 2.0%

2.0 - 3.0%



Performance Data Evaluation (PDE) - quantification

Accuracy is...

... a way to measure the closeness of agreement between a test result and the true value

Based on the difference between the test result and the true value, three grades are given:

Grade 1: 28 samples with accuracy within -0.25 and +0.5

Grade 2: no samples have an accuracy smaller than -0.5 or greater than +1

Grade 3: some samples have an accuracy smaller than -0.5 or greater than 1



Performance Data Evaluation (PDE) - quantification

Accuracy evaluation

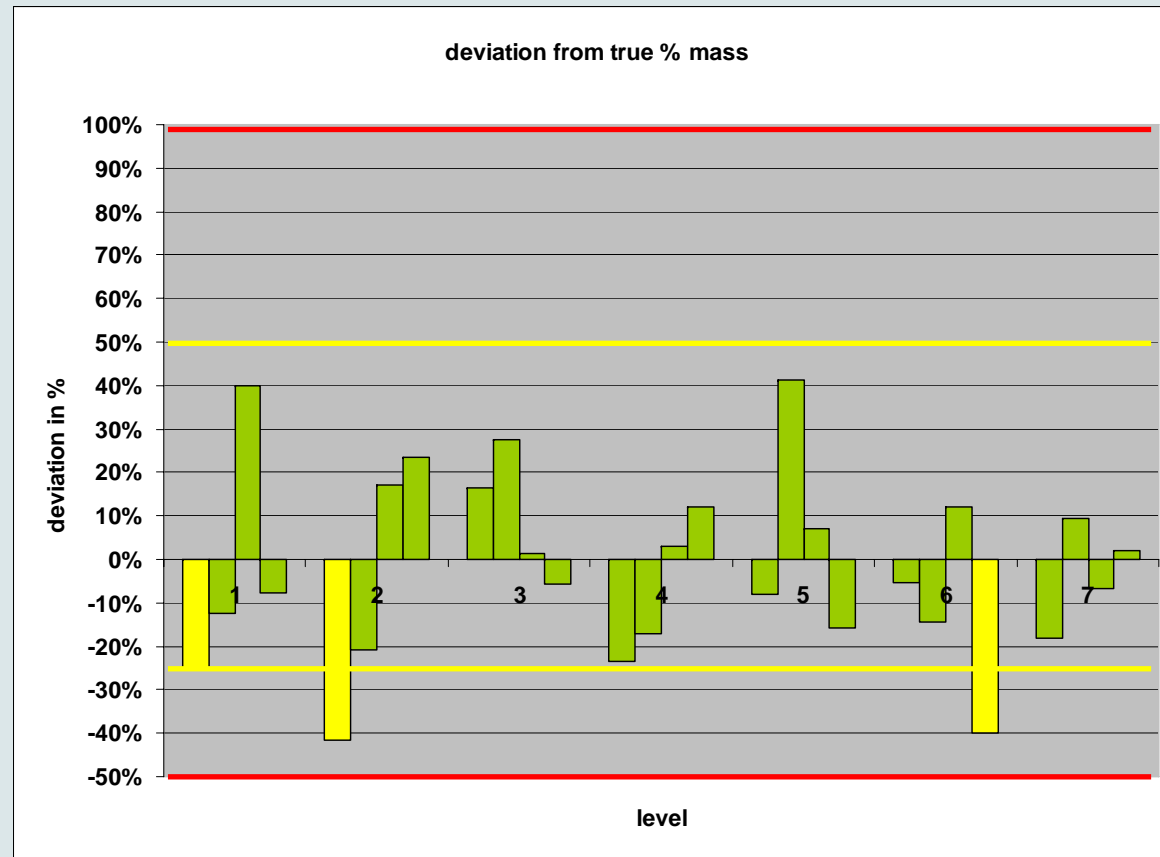
Spiking level	1	2	3	4	5	6	7
Test result							
sample 1	0.07	0.23	0.62	0.61	0.99	1.48	2.18
sample 2	0.09	0.28	0.64	0.65	1.4	1.32	2.79
sample 3	0.13	0.47	0.52	0.81	1.03	1.65	2.55
Sample4	0.09	0.51	0.45	0.95	0.81	0.89	2.49

Deviation from true values in % of true value

<i>deviations</i>	-0.25	-0.42	0.16	-0.24	-0.08	-0.05	-0.18
"-0.25 to 0.5"	-0.13	-0.21	0.28	-0.17	0.41	-0.14	0.10
"-0.5 to 1"	0.40	0.17	0.01	0.03	0.07	0.12	-0.07
"<-0.5 >1"	-0.08	0.24	-0.06	0.12	-0.16	-0.40	0.02



Performance Data Evaluation (PDE) - quantification



⇒ **Grade 2 for accuracy!**



Performance Data Evaluation (PDE) - quantification

Repeatability is...

... *a measure of dispersion of test results under repeatable conditions*

Based on the square-root of the average of the variances of the four samples per level the following grades are given:

Grade 1: Repeatability std-dev in % is below 20%

Grade 2: Repeatability std-dev in % is below 30%

Grade 3: Repeatability std-dev in % is greater than 30%



Performance Data Evaluation (PDE) - quantification

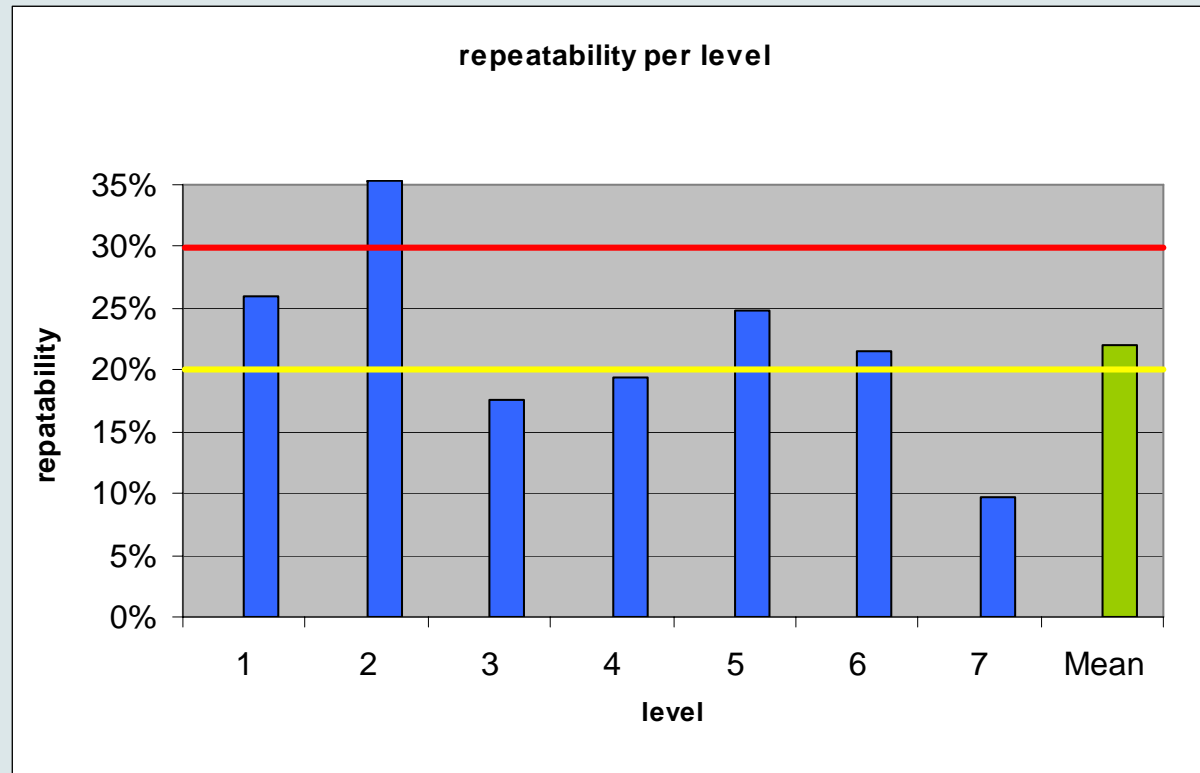
Evaluation of the repeatability

Spiking level	1	2	3	4	5	6	7	
Mean of the four samples	0.10	0.39	0.51	0.80	1.00	1.51	2.59	
Variance of the four samples	0.00	0.02	0.01	0.02	0.06	0.11	0.06	
Repeatability [%]	0.26	0.35	0.18	0.19	0.25	0.22	0.10	22.05



Performance Data Evaluation (PDE) - quantification

Evaluation of the repeatability



⇒ **Grade 2 for repeatability!**



Performance Data Evaluation (PDE) - quantification

Grades

Grade 1: No problem is detected from the experiment

Grade 2: Improvement is possible

Grade 3: There is a serious problem



On-site assessment

- **Verification of implementation aspects of performance approved methods**
- **Assessment of technical and system aspects according to the requirements of the Accreditation Standard**



Related documents

- **Acc-D-04-Accreditation under the PBA**
- **Acc-D-05-Performance Data Evaluation_1**
- **Acc-D-05-Performance Data Evaluation_2**



Information on the ISTA website



ISTA Online

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Accreditation of Laboratories for the Testing of Specified Traits

Relevant Accreditation Documents for the Accreditation of laboratories for the testing of specified traits under a performance based approach

During the Ordinary Meeting 2005 in Bangkok, Thailand, the proposed **new version of the ISTA Rules Chapter 8** was adopted by the ISTA voting delegates after an intensive discussion during the Ordinary Meeting. The Ordinary Meeting gave the Executive Committee of the Association the mandate to finalise the relevant accreditation documents in all details and decided that the new version of Chapter 8 will come into force 6 months after the publication of these relevant accreditation documents. After intensive discussions on the level of the Executive Committee, this process could be finalised on July 29, 2005.

Consequently, the new version of Chapter 8 of the ISTA Rules will come into force on February 1, 2006. From that date on it will be possible for laboratories to become ISTA accredited for the testing of seeds with specified traits under the performance based approach.

Relevant accreditation documents:

- [Principles and Conditions for Laboratory Accreditation under the performance based approach](#)
- [Performance data evaluation for the presence of seeds with specified traits in seed lots](#)
- [Performance Data Evaluation for Specified Trait Purity](#)
- [The ISTA Seed Testing Laboratory Accreditation Standard](#)

news

Job opportunities at ISTA Member Laboratories

More info »

ISTA Quality Management Training Course in Bangalore, India

More info »

Seed Science and Technology Print and Online Subscription available for 2008

More info »

SEED TESTING INTERNATIONAL (ISTA News Bulletin) No. 134 October 2007 is



Accredited laboratories

- **Currently eight laboratories are accredited for specified trait testing for the following species/method/trait combinations...**



Scope of accreditation - Detection



Species	Method	Trait
<i>Brassica napus</i>	PCR	GT200/GT73
<i>Glycine max</i>	PCR	RR3
	PCR	GTS 40-3-2
	Lateral flow strip	CP 4
	PCR	35S Promoter
	PCR	NOS Terminator
<i>Zea mays</i>	PCR	T 25
	PCR	NOS Terminator
	PCR	GA 21
	PCR	NK 603
	PCR	CBH 351
	PCR	MON 863
	PCR	35S Promotor
	PCR	MON 810



Scope of Accreditation - Quantification

Species	Method	Trait
<i>Brassica napus</i>	PCR	GT73
<i>Glycine max</i>	PCR	GTS 40-3-2
	PCR	35S Promoter
	PCR	EPSPS
<i>Zea mays</i>	PCR	Bt 11
	PCR	Bt 176/E176
	PCR	35S Promoter
	PCR	GA 21
	PCR	TC1507
	PCR	MON 863
	PCR	MON 810



Feedback

- **Availability of reference material**
- **Cost and labour for performance data evaluation**

