



International Seed Testing Association

What are the principles and conditions for Laboratory accreditation under the performance based approach

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Outline

Performance approved methods

Accreditation Standard/ISTA Rules:

Proficiency test participation

Performance data

On-site assessment



Performance approved methods

A method that is used in the laboratory after being accepted and implemented on the basis of its proven performance.



Performance approved methods

Limited to test methods for the object of testing for the presence of specified traits.



Proficiency test participation

Laboratories seeking accreditation for performance approved methods and accredited laboratories must participate in the corresponding ISTA Proficiency Test rounds.



Proficiency test participation

Before the audit process is initiated, satisfactory PT rating in at least one round must be available.



Proficiency test participation

Satisfactory proficiency test ratings:

A or B ;

C ratings are considered satisfactory when appropriate corrective action has been initiated.



Performance data

Performance data for each method*species*trait combination must be presented in order to demonstrate that it is competently handled by the laboratory.



Scope of accreditation

Testing principle	Attribute/target	Primer	Qual./quant specificity	Species	LOD/quant. range [%]
PCR	35S Promotor	35S-1/35S-2	qual. screening	<i>Glycine max</i>	0.03
Real-time PCR	35S Promotor	35S-F/35S-R	quant. screening	<i>Glycine max</i>	0.1 - 3.0



Performance data

Performance data provide evidence that minimum requirements in terms of repeatability and accuracy are met.



Performance data

Performance data refer to the laboratory and how it applies a specific method for a defined purpose – not to a general method validation



On-site assessment

During the on-site visit implementation aspects of performance approved methods are assessed.



On-site assessment

Is the documented protocol consistent with routine work?

Is the equipment management adequate?

Are staff qualification and training appropriate?

Is testing according to PBA imbedded in a suitable overall quality management system?



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Thank you for your attention!