ImmunoStrip® Validation Report

On-site Trait Diagnostics Testing
Bt-Cry1Da
STX 12000

ImmunoStrip®

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Test Characteristics

Test Name	Bt-Cry1Da	**Format**	Lateral Flow Device
Catalog Number	12000	**Diluents**	Tap Water (seed) / SEB4 (leaf)
Acronym	Bt-Cry1Da	**Sample Dilution**	1:20 (leaf), 1:3 (composite seed), 1:1 (single seed)
Capture Antibody	Monoclonal (Mouse)		
Detection Antibody	Monoclonal (Mouse)		

Summary

This ImmunoStrip® test is intended for seed and leaf quality purposes to determine the presence or absence of Bt-Cry1Da in transgenic corn grain, leaf, and single seed.

Diagnostic Sensitivity and Specificity

True Positives	1440	**True Negatives**	1440	**Total Samples**	2880
Correct Diagnoses	1439	**Correct Diagnoses**	1433	**Correct Diagnoses**	2872
Percent	99.9%	**Percent**	99.5%	**Number of Operators**	9
				Number of Production Lots	3
				Percent	99.7%

Selectivity:

No Matrix Effect Observed With:			
Corn leaves	Corn single seeds	Corn composite seed	

Analytical Specificity

Inclusivity:

Protein Detected:

Bt-Cry1Da	

Exclusivity:

Cross-reacts With:

None Known	

Does Not Cross-react With:

AAD-1	Bt-Cry1A.105
Bt-Cry1Ab	Bt-Cry1F
Bt-Cry2A	Bt-Cry34Ab1
Bt-Cry3Bb1	CP4 EPSPS
CspB	eCry3.1Ab
mBt-Cry3A	mEPSPS (GA21)
PAT/bar	PAT/pat
Vip3A	

Robustness

Planned deviation analysis:
No deviations from the user guide protocol were validated.

Stability:

	1-year stability (accelerated)	Real-time Stability Verification
Positive Sample (High)	Pass	Monitoring
Positive Sample (High)	Pass	Monitoring
Positive Sample (Low)	Pass	Monitoring
Positive Sample (Low)	Pass	Monitoring
Positive Sample (Low)	Pass	Monitoring
Negative Sample	Pass	Monitoring
Negative Sample	Pass	Monitoring
Negative Sample	Pass	Monitoring

Glossary

Diagnostic sensitivity[1]: The percentage of positive samples correctly identified in an experiment with known positive controls.

Diagnostic specificity[1]: The percentage of negative samples correctly identified in an experiment with known negative controls.

Analytical sensitivity[3]: The smallest amount of target that can be detected reliably (this is sometimes referred to as the 'limit of detection')

Analytical specificity[3]: (comprises inclusivity and exclusivity)

Inclusivity[3]: The performance of a test with a range of target isolates covering genetic diversity, different geographical origin and/or hosts associated with the target organism.

Exclusivity[3]: The performance of a test with a range of non-targets (e.g. cross-reaction with closely related organisms, contaminants)

Selectivity[2]: The level of effect that matrices and relevant plant parts have on the performance of the assay.

Repeatability[2]: The agreement between test replicates of the same sample tested by the same operator.

Reproducibility[3]: The ability of a test to provide consistent results when applied to aliquots of the same sample tested under different conditions (e.g. time, users, equipment, location)

Robustness[1,3]: The extent to which varying test conditions (e.g. temperature, volume, change of buffers) affect the established test performance values. May also be referred to as planned deviation analysis.

Stability[1]: The performance of test reagents or controls over time.

References:
[1]Groth-Helms, D., Rivera, Y., Martin, F. N., Arif, M., Sharma, P., Castlebury, L. A. (in press). Terminology and Guidelines for Diagnostic Assay Development and Validation: Best Practices for Molecular Tests. PhytoFrontiers.
[2]Eads, A., Groth-Helms, D., Davenport, B., Cha, X., Li, R., Walsh, C., Schuetz, K., (in press). The Commercial Validation of Three Tomato Brown Rugose Fruit Virus Assays. PhytoFrontiers.
[3]EPPO (2018) PM 7/76 (5) Use of EPPO Diagnostic Standards, EPPO Bulletin 48, 373– 377.