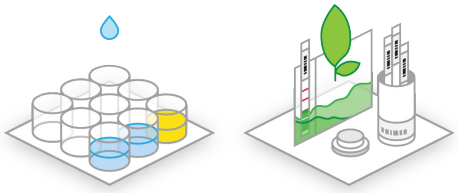
Comparison Report

ELISA vs. ImmunoStrip®

Alfalfa mosaic virus (AMV)

PSA/SRA vs. ISK/STX 87601



Test Characteristics

Test Name	Alfalfa mosaic virus	**Acronym**	AMV
Catalog Number	87601	**Genus**	Alfamovirus

ELISA

Test Characteristics

Capture Antibody	Monoclonal (Mouse)
Detection Antibody	Monoclonal (Mouse)
Format	DAS-ELISA
Diluents	GEB/ECI
Sample Dilution	1:10
Intended Use	High-throughput laboratory assay

Diagnostic Sensitivity and Specificity

Diagnostic Sensitivity	97.8%	**Diagnostic Specificity**	99.8%
True Positives	325	**True Negatives**	498
Correct Diagnoses	318	**Correct Diagnoses**	497

Analytical Sensitivity

83.3% sensitive from 1000 ng/mL to 10 ng/mL. (n=18)	**Analytical Sensitivity**
100% detection rate at 100 ng/mL with purified virus. (n=6)	**Limit of Detection**
50% detection rate at 10 ng/mL with purified virus. (n=6)	

ImmunoStrip

Test Characteristics

Capture Antibody	Monoclonal (Mouse)
Detection Antibody	Monoclonal (Mouse)
Format	Lateral Flow Device
Diluents	SEB1
Sample Dilution	1:20
Intended Use	Low-throughput, field screening tool

Diagnostic Sensitivity and Specificity

Diagnostic Sensitivity	98.7%	**Diagnostic Specificity**	99.7%
True Positives	158	**True Negatives**	334
Correct Diagnoses	156	**Correct Diagnoses**	333

Analytical Sensitivity

Analytical Sensitivity	100% sensitive from 1000 ng/mL to 5 ng/mL. (n=8)
Limit of Detection	100% detection rate at 5 ng/mL with purified virus. (n=2)

Analytical Specificity: Inclusivity

Detected	Isolates and Geographic Regions Detected:	Detected
✓	AMV PV-0779 (Germany)	✓
✓	AMV PV-1282 (Czech Republic)	✓
✓	AMV-425M (ATCC® PV-92™) (WI, USA)	✓
✓	AMV-Aman (Argentina)	✓
✓	AMV-Ars2 (Italy)	✓
✓	AMV-ASdE (Argentina)	✓
✓	AMV-BSdE (Argentina)	✓
✓	AMV-Chiba1 (MAFF# 104001) (Japan)	✓
✓	AMV-Nevq (Argentina)	✓
✓	AMV-P (Kanagawa PP84-1) (MAFF# 104002) (Japan)	✓
✓	AMV-PS (Argentina)	✓
✓	AMV-S40 (ATCC® PV-848™) (Australia)	✓

Analytical Specificity: Exclusivity

Cross-reacts With:	Cross-reacts With:
None Known	None Known

Repeatability and Reproducibility

Repeatability	99.0%	Reproducibility	98.8%	Repeatability	99.9%	Reproducibility	94.2%
Number of Samples	692	Number of Samples	92	Number of Samples	492	Number of Samples	44
Replicates per Sample	3 - 12	Replicates per Sample	3	Replicates per Sample	2 - 8	Replicates per Sample	3
Total Replicates	2322	Number of Operators	2 - 3	Total Replicates	1476	Number of Operators	3
Replicates in Agreement	2298	Total Replicates	738	Replicates in Agreement	1474	Total Replicates	396
		Replicates in Agreement	729			Replicates in Agreement	373

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.

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