ImmunoStrip® Validation Report

On-site Plant Pathogen Testing

Bean yellow mosaic virus (BYMV)

ISK/STX 91000

ImmunoStrip®

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Test Characteristics

Test Name	Bean yellow mosaic virus
Catalog Number	91000
Acronym	BYMV
Genus	Potyvirus
Capture Antibody	Polyclonal (Rabbit)
Detection Antibody	Polyclonal (Rabbit)
Format	Lateral Flow Device
Diluents	SEB1
Sample Dilution	1:20

Summary

The Bean yellow mosaic virus (BYMV) ImmunoStrip is used to detect the presence of BYMV in ornamental and vegetable crops. BYMV is a member of the Potyvirus genus known for their non-enveloped, flexuous, filamentous virus particles. ImmunoStrips are the perfect screening tool for use in the field, greenhouse, and the lab.

Diagnostic Sensitivity

True Positives	88
Correct Diagnoses	88
Percent	100%

Analytical Sensitivity

Limit of Detection: 1:5,000 dilution of infected tissue (pathogen titer unknown)

Analytical Specificity

Inclusivity:

Isolates and Geographic Regions Detected:

BYMV-M11	BYMV PV-0287 (Denmark)
BYMV PV-0469 (Germany)	BYMV PV-0470 (Turkey)
BYMV PV-0717 (Germany)	BYMV PV-1213 (Germany)
BYMV-92-1 (Japan)	BYMV-GDD
BYMV-IbG	

Exclusivity:

Cross-reacts With:

None Known	

Does Not Cross-react With:

Alfalfa mosaic virus (AMV)	Bean common mosaic necrosis virus (BCMNV)
Bean common mosaic virus (BCMV)	Beet mosaic virus (BtMV)
Canna yellow streak virus (CaYSV)	Clover yellow vein virus (ClYVV)
Comovirus siliquae (Bean Pod Mottle Virus) (BPMV)	Comovirus vignae (Cowpea mosaic virus) (CPMV)
Fabavirus alphaviciae (Broad bean wilt virus 1) (BBWV-1)	Fabavirus betaviciae (Broad bean wilt virus 2) (BBWV-2)
Lettuce mosaic virus (LMV)	Nepovirus lycopersici (Tomato ringspot virus) (ToRSV)
Nepovirus nicotianae (Tobacco ringspot virus) (TRSV)	Pea seed-borne mosaic virus (PSbMV)

Does Not Cross-react With:

Peanut mottle virus (PeMoV)	Pepper mottle virus (PepMoV)
Pepper yellow mosaic virus (PepYMV)	Plum pox virus (PPV)
Potato virus A (PVA)	Potato virus Y (PVY)
Southern Bean Mosaic Virus (SBMV)	Soybean mosaic virus (SMV)
Tobacco etch virus (TEV)	Tobacco mosaic virus (TMV)
Tomato brown rugose fruit virus (ToBRFV)	Tomato mosaic virus (ToMV)
Turnip mosaic virus (TuMV)	Zucchini yellow mosaic virus (ZYMV)

Diagnostic Specificity

True Negatives 186
Correct Diagnoses 186
Percent 100%

Selectivity:

No Matrix Effect Observed With:			
Alfalfa leaves	Alfalfa petioles	Alfalfa stems	Bean leaves
Bean petioles	Bean stems	Calla Lily leaves	Calla Lily petioles
Canna leaves	Canna petioles	Canna stems	Cannabis (Hemp) leaves
Chickpea leaves	Chickpea petioles	Chickpea stems	Clover leaves
Clover petioles	Clover stems	Cowpea leaves	Cowpea petioles
Cowpea stems	Faba bean leaves	Faba bean petioles	Faba bean stems
Gladiolus leaves	Lisianthus leaves	Pea leaves	Pea petioles
Pea stems	Peanut leaves	Peanut petioles	Peanut stems
Soybean leaves	Soybean petioles	Soybean stems	Turnip leaves
Turnip petioles	Turnip stems	Vetch leaves	Vetch petioles
Vetch stems			

Matrix Effect Observed With:			
Alfalfa seeds	Bean seeds	Clover seeds	Faba Bean seeds
Soybean seeds			

Repeatability

Number of Samples 265
Replicates per Sample 2 - 22
Total Replicates 941
Replicates in Agreement 940
Percent Agreement 99.9%

Reproducibility

Number of Samples 47
Replicates per Sample 3
Number of Operators 3
Total Replicates 423
Replicates in Agreement 419
Percent Agreement 99.1%

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.