ImmunoStrip® Validation Report

On-site Plant Pathogen Testing

Potyvirus group (Poty)

ISK/STX 27200

ImmunoStrip®

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Test Characteristics

Test Name	Potyvirus group
Catalog Number	27200
Acronym	Poty
Genus	Potyvirus
Capture Antibody	Monoclonal (Mouse)
Detection Antibody	Monoclonal (Mouse)
Format	Lateral Flow Device
Diluents	SEB1
Sample Dilution	1:20

Summary

Agdia's Poty ImmunoStrip can quickly identify more than 20 members of the Potyvirus genus and can be used to test more than 70 different crops. The test can be used in the field or in the lab and requires no experience to perform. Results are available in as little as 5 minutes with a maximum run time of 30 minutes.

Diagnostic Sensitivity

True Positives	127
Correct Diagnoses	125
Percent[1]	98.4%

[1]Diagnostic sensitivity calculation based only on species detected in the Inclusivity chart below. Species not detected are not included in the calculation.

Analytical Sensitivity

Limit of Detection (PVY):	1:500 dilution of infected tissue (pathogen titer unknown)
Limit of Detection (TEV):	1:2,500 dilution of infected tissue (pathogen titer unknown)
Limit of Detection (ZYMV):	1:500 dilution of infected tissue (pathogen titer unknown)

Analytical Specificity

Inclusivity:

Species Detected[1]**:**

Alstroemeria mosaic virus (AlMV)	Bean common mosaic virus (BCMV)
Bean yellow mosaic virus (BYMV)	Kalanchoe mosaic virus (KMV)
Leek yellow stripe virus (LYSV)	Lettuce mosaic virus (LMV)
Maize dwarf mosaic virus (MDMV)	Moroccan watermelon mosaic virus (MWMV)
Onion yellow dwarf virus (OYDV)	Papaya ringspot virus (PRSV)
Pea seed borne-mosaic virus (PSbMV)	Peanut mottle virus (PeMoV)
Pepper mottle virus (PepMoV)	Potato virus V (PVV)
Potato virus Y (PVY)	Soybean mosaic virus (SMV)
Sugarcane mosaic virus (SCMV)	Sweet potato feathery mottle virus (SPFMV)
Tobacco etch virus (TEV)	Tobacco vein mottling virus (TVMV)
Tomato necrotic stunt virus (TNSV)	Turnip mosaic virus (TuMV)
Watermelon mosaic virus (WMV)	Zucchini yellow mosaic virus (ZYMV)

[1]The list above represents Potyviruses that have been shown to be detected by the Potyvirus group ImmunoStrip test and does not represent all viruses that may be detected. If you have confirmed detection of a Potyvirus not on this list, please contact us. We would like to work with you to further validate the Potyvirus group ImmunoStrip detection capabilities.

Species Not Detected:

Banana bract mosaic virus (BBrMV)	Bean common mosaic necrosis virus (BCMNV)
Beet mosaic virus (BtMV)	Clover yellow vein virus (ClYVV)
Dasheen mosaic virus (DsMV)	Johnsongrass mosaic virus (JGMV)
Plum pox virus (PPV)	Potato virus A (PVA)
Ranunculus mild mosaic virus (RanMMV)	Shallot yellow stripe virus (SYSV)
Sweet potato virus G (SPVG)	

Exclusivity:

Cross-reacts With:

None Known	

Does Not Cross-react With:

Alfalfa mosaic virus (AMV)	Chrysanthemum virus B (CVB)
Cucumber mosaic virus (CMV)	Odontoglossum ringspot virus (ORSV)
Tobacco mosaic virus (TMV)	Tobacco ringspot virus (TRSV)
Tomato mosaic virus (ToMV)	Tomato ringspot virus (ToRSV)
Tomato spotted wilt virus (TSWV)	Wheat spindle streak mosaic virus (WSSMV)
Wheat streak mosaic virus (WSMV)	

Diagnostic Specificity

True Negatives 203
Correct Diagnoses 203
Percent 100%

Selectivity:

No Matrix Effect Observed With:			
Alfalfa leaves	Angelonia leaves	Apricot leaves	Aster leaves
Bacopa leaves	Banana leaves	Barley leaves	Bean leaves
Beet leaves	Begonia leaves	Broccoli leaves	Cabbage leaves
Calla lily leaves	Cannabis (Hemp) leaves	Cantaloupe leaves	Carnation leaves
Catharanthus leaves	Celery leaves	Chrysanthemum leaves	Clover leaves
Coleus leaves	Corn leaves	Cowpea leaves	Crassula leaves
Cucumber leaves	Cucurbit leaves	Dahlia leaves	Dianthus leaves
Echinacea leaves	Eggplant leaves	Endive leaves	Fava bean leaves
Geranium leaves	Grape leaves	Helleborus leaves	Hibiscus leaves
Hydrangea leaves	Hypoestes leaves	Impatiens leaves	Lantana leaves
Lavender leaves	Lettuce leaves	Lysimachia leaves	Marigold leaves
Melon leaves	Onion leaves	Orchid leaves	Osteospermum leaves
Pachysandra leaves	Pea leaves	Peach leaves	Peanut leaves
Pepper leaves	Petunia leaves	Phlox leaves	Plum leaves
Portulaca leaves	Potato leaves	Rice leaves	Rosemary leaves
Rubus leaves	Salvia leaves	Sedum leaves	Snapdragon leaves
Soybean leaves	Spearmint leaves	Spinach leaves	Squash leaves
Statice leaves	Sugarcane leaves	Sunflower leaves	Sweet potato leaves
Thyme leaves	Tobacco leaves	Tomato leaves	Tulip leaves

No Matrix Effect Observed With:			
Turnip leaves	Verbena leaves	Vinca leaves	Watercress leaves
Watermelon leaves	Wheat leaves	Zinnia leaves	

Repeatability

Number of Samples	330
Replicates per Sample	2 - 8
Average Percent Agreement Between Replicates	99.3%

Reproducibility

Number of Samples	23
Replicates per Sample	3
Number of Operators	6
Average Percent Agreement Between Replicates Between Operators	98.3%

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.