ImmunoStrip® Validation Report

On-site Plant Pathogen Testing

Pseudomonas spp.

ISK/STX 82200

ImmunoStrip®

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Test Characteristics

Test Name	Pseudomonas spp.	**Capture Antibody**	Polyclonal (Rabbit)
Catalog Number	82200	**Detection Antibody**	Polyclonal (Rabbit)
Acronym	Pseudomonas spp.	**Format**	Lateral Flow Device
Genus	Pseudomonas	**Diluents**	BEB1
		Sample Dilution	1:20

Summary

The Pseudomonas spp. ImmunoStrip is used to detect the presence of Pseudomonas species in fruit, ornamental, and vegetable crops. ImmunoStrips® are the perfect screening tool for use in the field, greenhouse, and the lab.

Diagnostic Sensitivity

True Positives	148
Correct Diagnoses	137
Percent	92.6%

Analytical Sensitivity: Varies depending on which species is present in the sample. Below are several examples of analytical sensitivity tested during product validation.

P. syringae pv. syringae	**Analytical Sensitivity:**	The assay is 87.5% sensitive between 10^4 CFU and 10^3 CFU. (n=16)
	Limit of Detection:	The assay has a 100% detection rate at 10^4 CFU with bacterial culture. (n=8)
		The assay has a 75% detection rate at 10^3 CFU with bacterial culture. (n=8)
P. syringae pv. pisi	**Analytical Sensitivity:**	The assay is 66.7% sensitive between 10^6 CFU and 10^5 CFU. (n=12)
	Limit of Detection:	The assay has a 100% detection rate at 10^6 CFU with bacterial culture. (n=6)
		The assay has a 33.3% detection rate at 10^5 CFU with bacterial culture. (n=6)
P. syringae pv. tomato	**Analytical Sensitivity:**	The assay is 87.5% sensitive between 10^6 CFU and 10^5 CFU. (n=12)
	Limit of Detection:	The assay has a 100% detection rate at 10^6 CFU with bacterial culture. (n=4)
		The assay has a 75% detection rate at 10^5 CFU with bacterial culture. (n=8)
P. capsici	**Analytical Sensitivity:**	The assay is 62.5% sensitive between 10^6 CFU and 10^5 CFU. (n=12)
	Limit of Detection:	The assay has a 100% detection rate at 10^6 CFU with bacterial culture. (n=4)
		The assay has a 25% detection rate at 10^5 CFU with bacterial culture. (n=8)

Analytical Specificity

Inclusivity:

Species Detected:

Pseudomonas aeruginosa	Pseudomonas amygdali pv. lachrymans
Pseudomonas amygdali pv. morsprunorum	Pseudomonas cannabina
Pseudomonas cannabina pv. alisalensis	Pseudomonas capsici

Species Detected:

Pseudomonas cichorii	Pseudomonas corrugata
Pseudomonas fluorescens	Pseudomonas lini
Pseudomonas savastanoi pv. glycinea	Pseudomonas savastanoi pv. phaseolicola
Pseudomonas syringae pv. aceris	Pseudomonas syringae pv. aptata
Pseudomonas syringae pv. atrofaciens	Pseudomonas syringae pv. japonica
Pseudomonas syringae pv. pisi	Pseudomonas syringae pv. syringae
Pseudomonas syringae pv. tomato	Pseudomonas tremae
Pseudomonas viridiflava	

Species Not Detected:

Pseudomonas chlororaphis	Pseudomonas coronafaciens

Exclusivity:

Cross-reacts With:

Ectopseudomonas mendocina	Stutzerimonas stutzeri
Xanthomonas campestris pv. incanae	Xanthomonas hortorum pv. vitians

Does Not Cross-react With:

Agrobacterium tumefaciens	Burkholderia glumae
Clavibacter michiganensis subsp. michiganensis	Dickeya chrysanthemi
Metapseudomonas resinovorans	Pectobacterium carotovorum
Ralstonia solanacearum	Xanthomonas axonopodis pv. poinsettiicola
Xanthomonas campestris pv. armoraciae	Xanthomonas campestris pv. raphani
Xanthomonas campestris pv. zinniae	Xanthomonas euvesicatoria pv. allii
Xanthomonas hortorum pv. carotae	Xanthomonas hortorum pv. pelargonii
Xanthomonas phaseoli pv. phaseoli	Xanthomonas translucens pv. translucens

Diagnostic Specificity

True Negatives 184
Correct Diagnoses 183
Percent 99.5%

Selectivity:

No Matrix Effect Observed With:			
Barley leaves	Barley stems	Bean leaves	Bean midribs
Bean petioles	Bean stems	Beet leaves	Beet roots
Beet stems	Beet stems	Broccoli leaves	Broccoli roots
Brussels sprouts leaves	Brussels sprouts roots	Brussels sprouts stems	Cabbage leaves
Cannabis leaves	Cannabis stems	Celery leaves	Celery roots
Celery stems	Chrysanthemum leaves	Chrysanthemum roots	Chrysanthemum stems
Citrus leaves	Citrus leaves	Citrus stems	Cucumber leaves
Cucumber stems	Geranium leaves	Geranium roots	Geranium stems
Hosta leaves	Hosta stems	Impatiens leaves	Impatiens roots
Impatiens stems	Kale leaves	Kale stems	Kiwi leaves
Kiwi stems	Lettuce leaves	Lettuce stems	Melon leaves
Melon roots	Melon stems	Oats leaves	Oats stems

Pea leaves	Pea stems	Pepper leaves	Pepper midribs
Pepper petioles	Pepper stems	Prunus leaves	Rye leaves
Rye stems	Soybean leaves	Soybean stems	Squash leaves
Squash roots	Squash stems	Sunflower leaves	Sunflower midribs
Sunflower petioles	Sunflower stems	Tomato leaves	Tomato roots
Tomato stems	Turnip leaves	Turnip stems	Vetch leaves
Wheat leaves	Wheat roots	Wheat stems	
The hosts on the above list have been chosen to represent those which historically cause a range of matrix effects, in addition to those expected to be screened for this pathogen. Not all plant species susceptible to this pathogen have been screened, but may still be used with this assay unless otherwise noted below. As with all diagnostic tools, Agdia recommends confirming all results with a secondary detection method before making any economic decisions (ex: discarding plants due to positive test results, etc.).			

Matrix Effect Observed With:			
Barley roots	Bean roots	Cabbage roots	Cannabis roots
Cucumber roots	Kale roots	Kiwi roots	Lettuce roots
Oats roots	Pea roots	Pepper roots	Rye roots
Sunflower roots			

Repeatability

Number of Samples	332
Replicates per Sample	2 - 12
Total Replicates	778
Replicates in Agreement	754
Percent Agreement	96.9%

Reproducibility

Number of Samples	44
Replicates per Sample	3
Number of Operators	3
Total Replicates	396
Replicates in Agreement	387
Percent Agreement	97.7%

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.