ImmunoStrip® Validation Report

On-site Plant Pathogen Testing

Clavibacter michiganensis subsp. *michiganensis* (Cmm)

ISK/STX 44001

ImmunoStrip®

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Test Characteristics

Test Name	Clavibacter michiganensis subsp. michiganensis	**Capture Antibody**	Monoclonal (Mouse)
Catalog Number	44001	**Detection Antibody**	Monoclonal (Mouse)
Acronym	Cmm	**Format**	Lateral Flow Device
Genus	Clavibacter	**Diluents**	SEB4
		Sample Dilution	1:20

Summary

The Clavibacter michiganensis subsp. michiganensis (Cmm) ImmunoStrip is used to detect the presence of Cmm, the causal agent of bacterial canker, in tomato leaves, petioles, and stems. Cmm is a member of the Clavibacter genus known for their aerobic, non-motile, Gram-positive, non-sporing, curved rod shaped bacteria. ImmunoStrips are the perfect screening tool for use in the field, greenhouse, and the lab.

Diagnostic Sensitivity

True Positives	160
Correct Diagnoses	160
Percent	100%

Analytical Sensitivity

Limit of Detection: $9x10^6$ CFU/mL

Analytical Specificity

Inclusivity:

This assay was designed to detect all strains and isolates of Cmm. One hundred sixty distinct samples of Cmm have been experimentally proven to be detected.

Exclusivity:

Cross-reacts With:

Clavibacter michiganensis subsp. insidiosus (Cmi)	Clavibacter michiganensis subsp. nebraskensis (Cmn)
Clavibacter michiganensis subsp. sepedonicus (Cms)	Exserohilum turcicum
Microbacterium paraoxydans	Ochrobactrum sp.
Septoria lycopersici	Xanthomonas translucens pv. translucens (Xtt)

Does Not Cross-react With:

Acidovorax avenae subsp. citrulli	Burkholderia glumae
Clavibacter michiganensis subsp. tessellarius	Curtobacterium flaccumfaciens subsp. poinsettiae
Dickeya chrysanthemi	Enterobacter agglomerans
Erwinia amylovora	Pectobacterium atrosepticum
Pectobacterium carotovora pv. carotovora	Pseudomonas cannabina pv. cannabina
Pseudomonas fuscovaginae	Pseudomonas savastanoi pv. phaseolicola
Pseudomonas savastanoi pv. glycineae	Pseudomonas syringae pv. tomato
Ralstonia solanacearum	Stenotrophomonas maltophilia
Xanthomonas albilineans	Xanthomonas axonopodis pv. begoniae
Xanthomonas campestris pv. armoraciae	Xanthomonas campestris pv. campestris

Does Not Cross-react With:

Xanthomonas campestris pv. phaseoli	Xanthomonas campestris pv. zinniae
Xanthomonas citri pv. citri	Xanthomonas euvesicatoria
Xanthomonas hortorum pv. pelargonii	Xanthomonas oryzae pv. oryzae
Xanthomonas phaseoli pv. dieffenbachiae	Xanthomonas vesicatoria

Diagnostic Specificity

True Negatives 26
Correct Diagnoses 26
Percent 100%

Selectivity:

No Matrix Effect Observed With:			
Eggplant leaves	Pepper leaves	Potato leaves	Tomato leaves
Tomato petioles	Tomato 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:			
None Known			

Repeatability

Number of Samples 21
Replicates per Sample 3
Average Percent Agreement Between Replicates 100%

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.