



### Test Characteristics

<b>Test Name</b>	Clavibacter michiganensis subsp. michiganensis	<b>Test Label</b>	FAM-labeled target probe
<b>Catalog Number</b>	44001	<b>Internal Control</b>	N/A
<b>Acronym</b>	Cmm	<b>Format</b>	XRT
<b>Genus</b>	Clavibacter	<b>Diluents</b>	AMP1/PD1
		<b>Sample Dilution</b>	1:10

### Summary

AmplifyRP XRT for Cmm is a rapid DNA amplification and detection platform designed for testing tomato crops for *Clavibacter michiganensis* subsp. *michiganensis*. This kit includes lyophilized reaction pellets containing the necessary reagents to amplify Cmm DNA at a single operating temperature (39 °C).

### Diagnostic Sensitivity

<b>True Positives</b>	141
<b>Correct Diagnoses</b>	141
<b>Percent</b>	100%

### Analytical Sensitivity

**Limit of Detection:** The assay has a 100% detection rate at 200 fg/μL with DNA fragment. (n=2)

### Analytical Specificity

#### Inclusivity:

#### Isolates and Geographic Regions Detected:

Cmm-K0073 (ID, USA)	Cmm-K0074 (China)
Cmm-K0075 (Morocco)	Cmm-K0083 (HI, USA)
Cmm-K0093 (South Africa)	Cmm-K0094 (China)
Cmm-K0385 (HI, USA)	Cmm-K0386 (CA, USA)
Cmm-K0387 (OH, USA)	Cmm-K0388 (OH, USA)
Cmm-K0389 (OH, USA)	Cmm-K0390 (OH, USA)
Cmm-K0392 (OH, USA)	Cmm-K0393 (CA, USA)
Cmm-K0394 (CA, USA)	Cmm-K0399 (NC, USA)
Cmm-K0400 (NC, USA)	Cmm-K0402 (NC, USA)
Cmm-K0404 (IA, USA)	Cmm-K0406 (OH, USA)
Cmm-K0407 (OH, USA)	Cmm-K0410 (OH, USA)
Cmm-K0432 (OH, USA)	Cmm-K0437 (OH, USA)
Cmm-K0439 (IA, USA)	Cmm-K0440 (IA, USA)
Cmm-K0462 (WA, USA)	Cmm-K0463 (WA, USA)
Cmm-K0465 (Portugal)	Cmm-K0467 (United Kingdom)
Cmm-K0470 (Italy)	Cmm-K0471 (Hungary)
Cmm-K0473 (Chile)	Cmm-K0476 (Chile)
Cmm-K0477 (Chile)	Cmm-K0478 (Chile)
Cmm-A4775	

**Exclusivity:****Cross-reacts With:**

None Known	
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**Does Not Cross-react With:**

Clavibacter michiganensis subsp. insidiosus (Cmi)	Clavibacter michiganensis subsp. nebraskensis (Cmn)
Clavibacter michiganensis subsp. sepedonicus (Cms)	Clavibacter michiganensis subsp. tessellaris (Cmt)
Fusarium oxysporum f. sp. lycopersici (FOL)	Fusarium oxysporum f. sp. radices-lycopersici (FORL)
Microbacterium oleivorans strain CU31	Microbacterium paraoxydans
Microbacterium sp. 3498BRRJ	Ochrobactrum lupine
Ochrobactrum sp. N11	Ochrobactrum sp. R-26465
Pectobacterium carotovorum subsp. carotovorum	Pseudomonas syringae pv. syringae (Pss)
Verticillium dahliae/albo-atrum	Xanthomonas axonopodis
Xanthomonas campestris pv. vesicatoria (Xcv)	Xanthomonas euvesicatoria
Xanthomonas gardneri	Xanthomonas perforans
Xanthomonas vesicatoria	

**Diagnostic Specificity**

True Negatives 56  
 Correct Diagnoses 56  
 Percent 100%

**Selectivity:**

<b>No Matrix Effect Observed With:</b>			
Tomato fruit	Tomato leaves	Tomato peduncles	Tomato petioles
Tomato roots	Tomato seeds	Tomato stems	

**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
Positive Sample (Low)	Pass	Monitoring
Negative Sample	Pass	Monitoring
Negative Sample	Pass	Monitoring

## Glossary

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<b>Diagnostic sensitivity<sup>1</sup>:</b>	The percentage of positive samples correctly identified in an experiment with known positive controls.
<b>Diagnostic specificity<sup>1</sup>:</b>	The percentage of negative samples correctly identified in an experiment with known negative controls.
<b>Analytical sensitivity<sup>3</sup>:</b>	The smallest amount of target that can be detected reliably (this is sometimes referred to as the 'limit of detection')
<b>Analytical specificity<sup>3</sup>:</b>	(comprises inclusivity and exclusivity)
<b>Inclusivity<sup>3</sup>:</b>	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.
<b>Exclusivity<sup>3</sup>:</b>	The performance of a test with a range of non-targets (e.g. cross-reaction with closely related organisms, contaminants)
<b>Selectivity<sup>2</sup>:</b>	The level of effect that matrices and relevant plant parts have on the performance of the assay.
<b>Repeatability<sup>2</sup>:</b>	The agreement between test replicates of the same sample tested by the same operator.
<b>Reproducibility<sup>3</sup>:</b>	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)
<b>Robustness<sup>1,3</sup>:</b>	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.
<b>Stability<sup>1</sup>:</b>	The performance of test reagents or controls over time.

### References:

<sup>1</sup>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*.

<sup>2</sup>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*.

<sup>3</sup>EPPO (2018) PM 7/76 (5) Use of EPPO Diagnostic Standards, EPPO Bulletin 48, 373– 377.

### Questions or Technical Support:

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AmplifyRP Test Kits employ recombinase polymerase amplification (RPA) technology, developed by TwistDx Limited, U.K. Use of the RPA process and probe technologies are protected by US patents 7,270,981 B2, 7,399,590 B2, 7,435,561 B2, 7,485,428 B2 and foreign equivalents in addition to pending patents.

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