



**AmplifyRP® XRT for *Cmn***  
**Validation Report**  
**Clavibacter michiganensis subsp. nebraskensis**  
**Product No. XCS 70100**



## Test Characteristics

<b>Test Name</b>	Clavibacter michiganensis subsp. nebraskensis	<b>Test Label</b>	FAM-labeled target probe
<b>Catalog Number</b>	70100	<b>Internal Control</b>	Exogenous
<b>Acronym</b>	Cmn	<b>Format</b>	XRT
<b>Genus</b>	Clavibacter	<b>Diluents</b>	AMP1/PD1
<b>Binomial Name</b>	Clavibacter michiganensis subsp. nebraskensis	<b>Sample Dilution</b>	1:15 (leaf) / 1:1 (culture) / 1mL:1 seed (seed)

## Summary

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

## Diagnostic Sensitivity

<b>True Positives</b>	89
<b>Correct Diagnoses</b>	88
<b>Percent</b>	98.9%

## Analytical Sensitivity

**Limit of Detection:** Approximately 500 CFU/mL or 300 copies/μL

## Analytical Specificity

### Inclusivity:

#### Isolates and Geographic Regions Detected:

Cmn-004D (NE, USA)	Cmn-010B (NE, USA)
Cmn-072A (IA, USA)	Cmn-098A (IA, USA)
Cmn-161CA (NE, USA)	Cmn-167A (IA, USA)
Cmn-194C (NE, USA)	Cmn-195B (IA, USA)
Cmn-20037 (NE, USA)	Cmn-225A (NE, USA)
Cmn-225C (NE, USA)	Cmn-228C (CO, USA)
Cmn-273B (IN, USA)	Cmn-312A (SD, USA)
Cmn-371C (IA, USA)	Cmn-374C (SD, USA)
Cmn-376B (NE, USA)	Cmn-419B (NE, USA)
Cmn-438B (IA, USA)	Cmn-447B (IN, USA)
Cmn-485NDB (MN, USA)	Cmn-504NDA (ND, USA)
Cmn-521CA (MN, USA)	Cmn-CN9-1
Cmn-DP104	Cmn-DP114A (TX, USA)
Cmn-DP115A	Cmn-DP117A
Cmn-DP121A	Cmn-DP122A (NE, USA)
Cmn-DP137 (TX, USA)	Cmn-DP139B (TX, USA)
Cmn-DSM-20401	Cmn-NCPPB 2579 (NE, USA)

#### Isolates and Geographic Regions Not Detected:

Cmn-A6096 (NE, USA)	
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**Exclusivity:****Cross-reacts With:**

Virus Name	Species Name
None Known	

**Does Not Cross-react With:**

Virus Name	Species Name
Barley stripe mosaic virus (BSMV)	Hordeivirus hordei
Barley yellow dwarf virus (BYDV-SGV)	Luteovirus sgvhordei
Barley yellow dwarf virus MAV (BYDV-MAV)	Luteovirus mavhordei
Barley yellow dwarf virus PAV (BYDV-PAV)	Luteovirus pavhordei
Brome mosaic virus (BMV)	Bromovirus BMV
Cereal yellow dwarf virus (CYDV-RPV)	Polerovirus CYDVRPV
Corn stunt Spiroplasma (Css)	Spiroplasma kunkelii
Cucumber mosaic virus (CMV)	Cucumovirus CMV
High plains wheat mosaic virus (HPWMoV)	Emaravirus tritici
Johnsongrass mosaic virus (JGMV)	Potyvirus halapensis
Maize chlorotic mottle virus (MCMV)	Machlomovirus zeae
Maize dwarf mosaic virus (MDMV)	Potyvirus zeae
Maize streak virus (MSV)	Mastrevirus storeyi
Maize stripe virus (MSpV)	Tenuivirus zeae
Maize white line mosaic virus (MWLMV)	Aureusvirus zeae
Maize yellow dwarf virus RMV (MYDV-RMV)	Polerovirus MYDVRMV
N/A	Clavibacter michiganensis subsp. michiganensis (Cmm)
N/A	Acidovorax avenae
N/A	Acidovorax citrulli (Aac)
N/A	Clavibacter michiganensis subsp. insidiosus (Cmi)
N/A	Clavibacter michiganensis subsp. sepedonicus (Cms)
N/A	Clavibacter michiganensis subsp. tessellarius (Cmt)
N/A	Dickeya zeae
N/A	Fusarium graminearum
N/A	Fusarium verticilloides
N/A	Ochrabactrum sp.
N/A	Pantoea stewartii (Pstew)
N/A	Xanthomonas campestris
N/A	Xanthomonas vasicola pv. vasculorum (Xvv)
Soil-borne wheat mosaic virus (SBWMV)	Furovirus tritici
Sugarcane mosaic virus (SCMV)	Potyvirus sacchari
Tobacco ringspot virus (TRSV)	Nepovirus nicotianae
Tobacco streak virus (TSV)	Ilarvirus TSV
Wheat spindle streak mosaic virus (WSSMV)	Bymovirus tritici
Wheat streak mosaic virus (WSMV)	Tritimovirus tritici

## Diagnostic Specificity

True Negatives 105  
Correct Diagnoses 105  
Percent 100%

### Selectivity:

No Matrix Effect Observed With:			
Corn leaves	Corn seeds	Corn 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			

## 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>2</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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