



AmplifyRP® XRT+ for Cms
Validation Report
Clavibacter michiganensis subsp. *sepedonicus*
 Product No. XCS 70002



Test Characteristics

| | | | |
|-----------------------|--|-------------------------|--------------------------|
| Test Name | Clavibacter michiganensis subsp. sepedonicus | Test Label | FAM-labeled target probe |
| Catalog Number | 70002 | Internal Control | N/A |
| Acronym | Cms | Format | XRT+ |
| Genus | Clavibacter | Diluents | AMP1/PD1 |
| | | Sample Dilution | 1:1 (tuber soaks) |

Summary

AmplifyRP XRT+ for Cms is a rapid DNA amplification and detection platform designed for end-point or real-time detection of *Clavibacter michiganensis* subsp. *sepedonicus* in potato tubers and bacterial culture. This kit includes lyophilized reaction pellets containing the necessary reagents to amplify Cms DNA a single operating temperature (39 °C).

Diagnostic Sensitivity

| | |
|--------------------------|-------|
| True Positives | 91 |
| Correct Diagnoses | 89 |
| Percent | 97.8% |

Analytical Sensitivity

| | |
|----------------------------|--|
| Limit of Detection: | Approximately 1 copy/μL of plasmid DNA fragments |
| Limit of Detection: | Approximately 20 fg/μL of genomic DNA fragments |

Analytical Specificity

Inclusivity:

Isolates and Geographic Regions Detected:

| | |
|---------------------------------------|-------------------------------------|
| Cms-AS-1 (MN, USA) | Cms-BCP45 |
| Cms-BCP45 (Rif ^R mutation) | Cms-CIC4 |
| Cms-CIC77 | Cms-CIC8 |
| Cms-CS R8 | Cms-CS101 (Canada) (ATCC® 33113™) |
| Cms-Cs2 | Cms-Cs2 (Rif ^R mutation) |
| Cms-Cs3 (Canada) | Cms-Cs3 (Rif ^R mutation) |
| Cms-Cs3-1 | Cms-Cs3-2 |
| Cms-Cs3M | Cms-Cs3NM (avirulent) |
| Cms-Cs3NM (virulent) | Cms-Cs3RC |
| Cms-Cs4 | Cms-Cs5 (NY, USA) (ATCC® 9850™) |
| Cms-Cs7 | Cms-Cs7 (Rif ^R mutation) |
| Cms-Cs9 | Cms-CsR8 |
| Cms-P45 (lacks pCS1) | Cms-R5 |

Exclusivity:

Cross-reacts With:

| | |
|------------|--|
| None Known | |
|------------|--|

Does Not Cross-react With:

| | |
|---|--|
| Clavibacter michiganensis subsp. insidiosus (Cmi) | Clavibacter michiganensis subsp. michiganensis (Cmm) |
|---|--|

Does Not Cross-react With:

| | |
|---|---|
| Clavibacter michiganensis subsp. nebraskensis (Cmn) | Clavibacter michiganensis subsp. tessellarius (Cmt) |
| Curtobacterium flaccumfaciens pv. batae | Curtobacterium flaccumfaciens pv. flaccumfaciens |
| Curtobacterium flaccumfaciens pv. oortii | Curtobacterium flaccumfaciens pv. poinsettiae |
| Dickeya chrysanthemi | Dickeya dianthicola |
| Dickeya zeae | Pectobacterium carotovorum |
| Pectobacterium carotovorum subsp. atrocepticum | Pectobacterium carotovorum subsp. carotovorum |
| Pectobacterium wasabiae | |

Diagnostic Specificity

True Negatives 49
Correct Diagnoses 49
Percent 100%

Selectivity:

| | | | |
|---------------------------------|---------------|--------------|---------------|
| No Matrix Effect Observed With: | | | |
| Bacterial cultures | Potato leaves | Potato stems | Potato tubers |

Repeatability

Number of Samples 35
Replicates per Sample 2
Average Percent Agreement 100%
Between Replicates

Glossary

| | |
|--|--|
| Diagnostic sensitivity¹: | The percentage of positive samples correctly identified in an experiment with known positive controls. |
| Diagnostic specificity¹: | The percentage of negative samples correctly identified in an experiment with known negative controls. |
| Analytical sensitivity²: | The smallest amount of target that can be detected reliably (this is sometimes referred to as the 'limit of detection') |
| Analytical specificity²: | (comprises inclusivity and exclusivity) |
| Inclusivity³: | 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. |
| Exclusivity³: | The performance of a test with a range of non-targets (e.g. cross-reaction with closely related organisms, contaminants) |
| Selectivity²: | The level of effect that matrices and relevant plant parts have on the performance of the assay. |
| Repeatability²: | The agreement between test replicates of the same sample tested by the same operator. |
| Reproducibility³: | 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. |
| Stability¹: | The performance of test reagents or controls over time. |

References:

¹Groth-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*.

²Eads, 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*.

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

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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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