AmplifyRP® XRT for *Dickeya* spp.
Validation Report
Dickeya spp.
Product No. XCS 55500

Test Characteristics

Test Name	Dickeya spp.	**Test Label**	FAM-labeled target probe
Catalog Number	55500	**Internal Control**	N/A
Acronym	Dickeya spp.	**Format**	XRT
Genus	Dickeya	**Diluents**	AMP1/PD1
		Sample Dilution	1:20 (Plant tissue) / 1:1 (tuber soaks and cultures)

Summary

AmplifyRP XRT for Dickeya is a rapid DNA amplification and detection platform designed for testing potato tubers, stem, and bacterial culture for Dickeya spp. This kit includes lyophilized reaction pellets containing the necessary reagents to amplify Dickeya DNA at a single operating temperature (39 °C).

Diagnostic Sensitivity

True Positives	211
Correct Diagnoses	206
Percent	97.6%

Analytical Sensitivity

Analytical Sensitivity:	The assay is 90.0% sensitive between 20 fg/µL and 10 fg/µL. (n=6)
Limit of Detection:	The assay has a 100% detection rate at 20 fg/µL with DNA. (n=1)
	The assay has a 80.0% detection rate at 10 fg/µL with DNA. (n=5)

Analytical Specificity

Inclusivity:

Species Detected:

Dickeya chrysanthemi	Dickeya dadantii
Dickeya dianthicola	Dickeya diffenbachiae
Dickeya fangzhongdai	Dickeya oryzae
Dickeya solani	Dickeya zeae

Exclusivity:

Cross-reacts With:

None Known	

Does Not Cross-react With:

Candidatus Liberibacter solanacearum (Las)	Clavibacter michiganensis subsp. sepidonicus (Cms)
Fusarium oxysporum f.sp. vasinfectum, Race 4	Fusarium oxysporum f.sp. vasinfectum, Race 8
Pectobacterium atrocepticum	Pectobacterium betavasculorum
Pectobacterium carotovora subsp. brasiliensis	Pectobacterium carotovora subsp. carotovorum
Pectobacterium wasabiae	Phytophthora cryptogea
Phytophthora drechsleri	Phytophthora erythroseptica
Phytophthora infestans	Phytophthora irregularis
Phytophthora megasperma	Pseudomonas fluoresens
Ralstonia solanacearum (Rs)	

Diagnostic Specificity

True Negatives	82
Correct Diagnoses	82
Percent	100%

Selectivity:

No Matrix Effect Observed With:			
Bacteria cultures	Corn leaves	Potato stems	Potato tubers

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

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.

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