



AmplifyRP® XRT for PVY

Validation Report

Potato virus Y

Product No. XCS 20001



Test Characteristics

Test Name	Potato virus Y	Test Label	FAM-labeled target probe
Catalog Number	20001	Internal Control	Endogenous
Acronym	PVY	Format	XRT
Genus	Potyvirus	Diluents	GEB/PD1
Binomial Name	Potyvirus yituberosi	Sample Dilution	1:20

Summary

AmplifyRP XRT for PVY is a rapid RNA amplification and detection platform designed for testing potatoes and ornamentals for Potato virus Y. This kit includes lyophilized reaction pellets containing the necessary reagents to amplify PVY RNA and an endogenous RNA control at a single operating temperature (42 °C).

Diagnostic Sensitivity

True Positives	50
Correct Diagnoses	48
Percent	96.0%

Analytical Sensitivity

Analytical Sensitivity: Approximately 10 fg/μL of RNA transcripts

Analytical Specificity

Inclusivity:

Isolates and Geographic Regions Detected:

PVY ^C	PVY ^N
PVY ^{N:O}	PVY ^{NaN}
PVY ^{NN}	PVY ^{NTN}
PVY ^{N-Wi}	PVY ^O
PVY ^{O+C}	PVY ^{O5}
PVY ^C -E48 (Iran) ¹	PVY ^C -PRI-509 (Netherlands) ¹
PVY-LYE84.2 (Spain) ¹	PVY ^{N:O} -A95 (USA) ¹
PVY ^{N:O} -Alt ¹	PVY ^{N:O} -LW (Poland) ¹
PVY ^N -605 ¹	PVY ^{NaN} -Nicola (Germany) ¹
PVY ^{NaN} -RRA-1 ¹	PVY ^{NaN} -Tu 660 ¹
PVY ^{NE11} -ID20 (USA) ¹	PVY ^{NE11} -NE11 ¹
PVY ^N -Mont ¹	PVY ^{NTN} -156 (Germany) ¹
PVY ^{NTN} -HR1 (USA) ¹	PVY ^{NTN} -PB312 (USA) ¹
PVY ^{N-Wi} -LR (USA) ¹	PVY ^{N-Wi} -N1 (USA) ¹
PVY ^{N-Wi} -PN10A ¹	PVY ^{O5} -ID269 (USA) ¹
PVY ^{O5} -ID968 (USA) ¹	PVY ^{O5} -ME56 (USA) ¹
PVY ^O -ME173 (USA) ¹	PVY ^O -Oz (USA) ¹
PVY ^O -SCRI-O (UK) ¹	PVY-SON41 (France) ¹
¹ Predicted detection by <i>in silico</i> analysis only	

Exclusivity:**Cross-reacts With:**

Virus Name	Species Name
None Known	

Does Not Cross-react With:

Virus Name	Species Name
Alfalfa mosaic virus (AMV)	Alfavirus AMV
Alstroemeria mosaic virus (AIMV)	Potyvirus alstroemeriae
Andean potato mottle virus (APMoV)	Comovirus andesense
Bean common mosaic virus (BCMV)	Potyvirus phaseovulgaris
Bean yellow mosaic virus (BYMV)	Potyvirus phaseoliteum
Beet mosaic virus (BtMV)	Potyvirus betaceum
Bidens mosaic virus (BiMV) ¹	Potyvirus bidensia
Clover yellow vein virus (CIYVV)	Potyvirus trifolii
Dasheen mosaic virus (DsMV)	Potyvirus dasheenii
Johnsongrass mosaic virus (JGMV)	Potyvirus halapensis
Leek yellow stripe virus (LYSV)	Potyvirus ampeloprasi
Maize dwarf mosaic virus (MDMV)	Potyvirus zeae
Papaya ringspot virus (PRSV)	Potyvirus papayanuli
Pea seed-borne mosaic virus (PSbMV)	Potyvirus pisumsemenportati
Pepper mottle virus (PepMoV)	Potyvirus capsimaculæ
Pepper severe mosaic virus (PepSMV) ¹	Potyvirus capsiseverum
Plum pox virus (PPV)	Potyvirus plumipoxi
Potato aucuba mosaic virus (PAMV)	Potexvirus marmoratae
Potato latent virus (PotLV)	Carlavirus latensolani
Potato leafroll virus (PLRV)	Potexvirus PLRV
Potato mop-top virus (PMTV)	Potexvirus solani
Potato virus A (PVA)	Potyvirus atuberosi
Potato virus M (PVM)	Carlavirus misolani
Potato virus S (PVS)	Carlavirus sigmasolani
Potato virus T (PVT)	Tepovirus tafaolani
Potato virus V (PVV)	Potyvirus vetuberosi
Potato virus X (PVX)	Potexvirus ecspotati
Potato yellow dwarf virus (PYDV)	Alphanucleorhabdovirus tuberosum
Soybean mosaic virus (SMV)	Potyvirus glycitesellati
Sugarcane mosaic virus (SCMV)	Potyvirus sacchari
Sunflower ring blotch virus (SuRBV) ¹	Potyvirus heliannulabii
Sweet potato feathery mottle virus (SPFMV)	Potyvirus batataplumei
Sweet potato virus G (SPVG)	Potyvirus gebatatae
Tobacco etch virus (TEV)	Potyvirus nicotianainsculpentis
Tobacco rattle virus (TRV)	Tobravirus tabaci
Tobacco vein mottling virus (TVMV)	Potyvirus nicotianavenamaculæ
Tomato spotted wilt virus (TSWV)	Orthotospovirus tomatomaculæ
Turnip mosaic virus (TuMV)	Potyvirus rapae

¹Predicted non-detection by *in silico* analysis only

Diagnostic Specificity

True Negatives 38
Correct Diagnoses 38
Percent 100%

Selectivity:

No Matrix Effect Observed With:			
Potato leaves	Potato sprouts	Potato tubers	
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 80
Replicates per Sample 2 - 3
Total Replicates 165
Replicates in Agreement 163
Percent Agreement 98.8%

Reproducibility

Number of Samples 18
Replicates per Sample 2
Number of Operators 3
Total Replicates 108
Replicates in Agreement 94
Percent Agreement 87.0%

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 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 sensitivity³:	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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