AmplifyRP® XRT for GPGV
Validation Report
Grapevine pinot gris virus
Product No. XCS 82600

Test Characteristics

Test Name	Grapevine pinot gris virus	**Test Label**	FAM-labeled target probe
Catalog Number	82600	**Internal Control**	Endogenous
Acronym	GPGV	**Format**	XRT
Genus	Trichovirus	**Diluents**	GEB/PD1
Binomial Name	Trichovirus pinovitis	**Sample Dilution**	1:10

Summary

AmplifyRP XRT for GPGV is a rapid RNA amplification and detection platform designed for testing grapevines for Grapevine pinot gris virus. This kit includes lyophilized reaction pellets containing the necessary reagents to amplify GPGV RNA and an endogenous RNA control at a single operating temperature (42 °C).

Diagnostic Sensitivity

True Positives	62
Correct Diagnoses	62
Percent	100%

Analytical Sensitivity

Analytical Sensitivity:	The assay is 75% sensitive between 50 fg/µL and 100 fg/µL. (n=8)
Limit of Detection:	The assay has a 100% detection rate at 100 fg/µL with RNA transcripts. (n=4)
	The assay has a 50% detection rate at 50 fg/µL with RNA transcripts. (n=4)

Analytical Specificity

Inclusivity:

Isolates and Geographic Regions Detected:

GPGV Canada isolate	GPGV Italy isolate
GPGV USA isolate	

Exclusivity:

Cross-reacts With:

Virus Name	Species Name
None Known	

Does Not Cross-react With:

Virus Name	Species Name
Arabis mosaic virus (ArMV)	Nepovirus arabis
Grapevine berry inner necrosis virus (GINV)	Trichovirus necroacini
Grapevine fanleaf virus (GFLV)	Nepovirus foliumflabelli
Grapevine fleck virus (GFkV)	Maculavirus vitis
Grapevine leafroll-associated virus 1 (GLRaV-1)	Ampelovirus univitis
Grapevine leafroll-associated virus 2 (GLRaV-2)	Closterovirus vitis
Grapevine leafroll-associated virus 3 (GLRaV-3)	Ampelovirus trivitis

Does Not Cross-react With:

Virus Name	Species Name
Grapevine leafroll-associated virus 4 (GLRaV-4)	Ampelovirus tetravitis
Grapevine red blotch virus (GRBV)	Grablovirus vitis
Grapevine rupestris stem pitting-associated virus (GRSPaV)[1]	Foveavirus rupestris
Grapevine rupestris vein feathering virus (GRVFV)[1,2]	N/A
Grapevine virus A (GVA)[1]	Vitivirus alphavitis
Grapevine Virus B (GVB)[1]	Vitivirus betavitis
Grapevine virus D (GVD)[1]	Vitivirus deltavitis
N/A	Xylella fastidiosa (Xf)
N/A	Botrytis cinerea (Bcin)
Tobacco ringspot virus (TRSV)	Nepovirus nicotianae
Tomato black ring virus (TBRV)[50]	Nepovirus nigranuli
Tomato ringspot virus (ToRSV)	Nepovirus lycopersici
[1]Predicted detection by *in silico* analysis only	
[2]Unclassified Marafivirus	

Diagnostic Specificity

True Negatives 15
Correct Diagnoses 15
Percent 100%

Selectivity:

No Matrix Effect Observed With:			
Grape leaves	Grape petioles		
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 30
Replicates per Sample 2
Total Replicates 60
Replicates in Agreement 60
Percent Agreement 100%

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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