



AmplifyRP® XRT for BBTV
Validation Report
Banana bunchy top virus
Product No. XCS 24700



Test Characteristics

Test Name	Banana bunchy top virus	Test Label	FAM-labeled target probe
Catalog Number	24700	Internal Control	N/A
Acronym	BBTV	Format	XRT
Genus	Babuvirus	Diluents	AMP1/PD1
Binomial Name	Babuvirus musae	Sample Dilution	1:10

Summary

AmplifyRP XRT for BBTV is a rapid DNA amplification and detection platform designed for field-based or laboratory testing of bananas for Banana bunchy top virus. This kit includes lyophilized reaction pellets containing the necessary reagents to amplify BBTV DNA at a single operating temperature (39 °C).

Diagnostic Sensitivity

True Positives	31
Correct Diagnoses	31
Percent	100%

Analytical Sensitivity

Limit of Detection: Approximately 30 ag DNA fragment/μL; 10 copies/μL

Analytical Specificity

Inclusivity:

Isolates and Geographic Regions Detected:

BBTV Burundi isolate	BBTV China isolate
BBTV Congo isolate	BBTV Rwanda isolate

Exclusivity:

Cross-reacts With:

Virus Name	Species Name
None Known	

Does Not Cross-react With:

Virus Name	Species Name
Abaca bunchy top virus (ABTV)	Babuvirus abacae
Banana bract mosaic virus (BBrMV)	Potyvirus musae
Banana streak GF virus (BSGFV)	Badnavirus alphavirgamusae
Banana streak IM virus (BSIMV)	Badnavirus betavirgamusae
Banana streak MY virus (BSMYV)	Badnavirus gammavirgamusae
Banana streak OL virus (BSOLV)	Badnavirus deltavirgamusae
Banana streak UA virus (BSUAV)	Badnavirus epsilonvirgamusae
Banana streak UI virus (BSUIV)	Badnavirus zetavirgamusae
Banana streak UL virus (BSULV)	Badnavirus etavirgamusae
Banana streak UM virus (BSUMV)	Badnavirus thetavirgamusae
Banana streak VN virus (BSVNV)	Badnavirus iotavirgamusae

Does Not Cross-react With:

Virus Name	Species Name
Cardamom bushy dwarf virus (CBDV)	Babuvirus cardamomi
Cucumber mosaic virus (CMV)	Cucumovirus CMV
N/A	Pseudomonas spp.
N/A	Xanthomonas vasicola pv. musacearum (Xvm)

Diagnostic Specificity

True Negatives 10
Correct Diagnoses 10
Percent 100%

Selectivity:

No Matrix Effect Observed With:			
Banana leaves			
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

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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