



Test Characteristics

Test Name	Fusarium oxysporum f. sp. cubense Tropical Race 4	Test Label	FAM-labeled target probe
Catalog Number	48300	Internal Control	ROX-labeled control probe (exogenous)
Acronym	Foc TR4	Format	XRT
Genus	Fusarium	Diluents	AMP1/PD1
		Sample Dilution	1:10

Summary

AmplifyRP XRT for Foc TR4 is a rapid DNA amplification and detection platform designed for testing banana root, rhizome, stem, pseudostem, and leaf for *Fusarium oxysporum* f. sp. *cubense* Tropical Race 4 (*Fusarium odoratissimum*), the causal agent of Panama Disease. This kit includes lyophilized reaction pellets containing the necessary reagents to amplify Foc TR4 DNA and an exogenous DNA control at a single operating temperature (42 °C).

Diagnostic Sensitivity

True Positives	48
Correct Diagnoses	48
Percent	100%

Analytical Sensitivity

Limit of Detection: Approximately 1 pg/μL of total genomic DNA

Analytical Specificity

Inclusivity:

Isolates and Geographic Regions Detected:

Foc TR4 NRRL 36114 (Indonesia)	Foc TR4 NRLL 54006 (MN, USA)
Foc TR4 VCG 01213/16	

Exclusivity:

Cross-reacts With:

None Known	
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Does Not Cross-react With:

<i>Alternaria alternata</i> ¹	<i>Botryosphaeria dothoidea</i> ¹
<i>Cladosporium musae</i> ¹	<i>Colletotrichum gloeosporioides</i>
<i>Colletotrichum musae</i> ¹	<i>Fusarium moniliforme</i>
<i>Fusarium oxysporum</i> f. sp. <i>cubense</i> R1	<i>Fusarium oxysporum</i> f. sp. <i>cubense</i> R2
<i>Fusarium oxysporum</i> f. sp. <i>cubense</i> R3	<i>Fusarium oxysporum</i> f. sp. <i>cubense</i> STR4
<i>Fusarium pallidoroseum</i>	<i>Fusarium solani</i>
<i>Fusarium subglutinans</i>	<i>Mychosphaerella fijienses</i> ¹
<i>Mycorrhizae</i> spp. ¹	<i>Phytophthora citrophthora</i>
<i>Phytophthora cryptogea</i>	<i>Phytophthora heveae</i>
<i>Phytophthora kernoviae</i>	<i>Phytophthora palmivora</i>

Does Not Cross-react With:

Phytophthora ramorum	Pythium aphanidermatum
Pythium irregulare	Pythium ultimum
Ralstonia spp. ¹	Rhizoctonia solani
Xanthmonas spp. ¹	
¹ Predicted non-detection by <i>in silico</i> analysis only.	

Diagnostic Specificity

True Negatives 21
 Correct Diagnoses 21
 Percent 100%

Selectivity:

No Matrix Effect Observed With:			
Banana leaves	Banana pseudostems	Banana rhizomes	Banana roots
Banana stems			

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 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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