



Test Characteristics

| | | | |
|-----------------------|-------------|-------------------------|--------------------------|
| Test Name | StudFinder™ | Test Label | FAM-labeled target probe |
| Catalog Number | 23000 | Internal Control | N/A |
| Acronym | StudFinder | Format | XRT |
| Genus | N/A | Diluents | AMP1/PD2 |
| | | Sample Dilution | 1:5 (disc:drops) |

Summary

StudFinder AmplifyRP XRT is a rapid DNA amplification and detection platform designed for field-based or laboratory testing of *Cannabis* samples for gender determination. This kit includes lyophilized reaction pellets containing the necessary reagents to amplify male *Cannabis* DNA at a single operating temperature (65 °C).

Diagnostic Sensitivity

| | |
|--------------------------|-------|
| True Positives | 75 |
| Correct Diagnoses | 73 |
| Percent | 97.3% |

Analytical Sensitivity

Analytical Sensitivity: The assay is 81.3% sensitive between 1 fg/μL and 500 ag/μL. (n=31)
Limit of Detection: The assay has a 100% detection rate at 1 fg/μL with DNA fragmentation. (n=23)
 The assay has a 62.5% detection rate at 500 ag/μL with DNA fragmentation. (n=8)

Analytical Specificity

Inclusivity:

Genes Detected:

| | |
|------------|--|
| Male MADC2 | |
|------------|--|

Exclusivity:

Cross-reacts With:

| | |
|------------|--|
| None Known | |
|------------|--|

Does Not Cross-react With:

| | |
|--------------|--|
| Female MADC2 | |
|--------------|--|

Diagnostic Specificity

True Negatives 178
Correct Diagnoses 177
Percent 99.4%

Selectivity:

| No Matrix Effect Observed With: | | | |
|---------------------------------|-----------------|-------------------|----------------|
| Cannabis cotyledons | Cannabis leaves | Cannabis petioles | Cannabis roots |
| Cannabis seeds | Cannabis stems | | |

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 253
Replicates per Sample 2 - 3
Total Replicates 554
Replicates in Agreement 546
Percent Agreement 98.6%

Reproducibility

Number of Samples 48
Replicates per Sample 3
Number of Operators 4
Total Replicates 576
Replicates in Agreement 562
Percent Agreement 97.6%

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 specificity³: | (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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