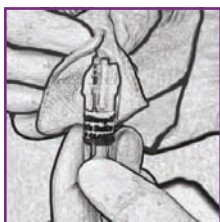


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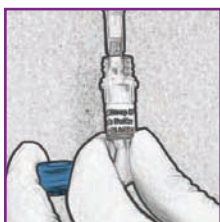
Test Procedure



A



B



C



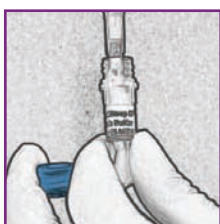
D

1 Specimen Preparation

- Place swab in sample buffer tube (blue cap)
- Break swab
- Vortex at high speed
- Transfer cell suspension from sample buffer (blue cap) to lysis tube (split septum) (C to D)



POS Control Preparation

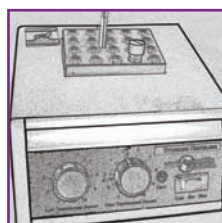
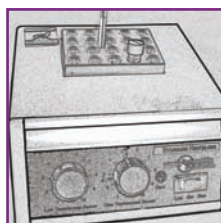


NEG Control Preparation



2 Prepare Processing Controls

- Reconstitute POS control DNA, vortex briefly, and add to lysis tube (split septum)
- Add NEG control (sample buffer) to lysis tube (split septum)

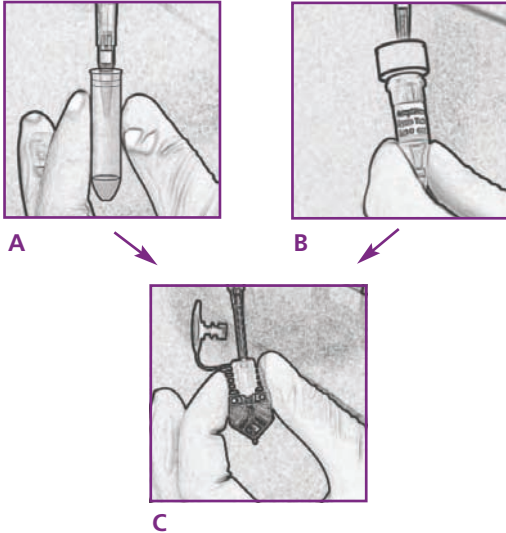


3 Lysis – DNA Extraction

- Heat lysis tubes at 37°C for 20 minutes
- Transfer tubes to a second heating block and heat at 99°C for 5 minutes
- Place tubes on a cooling block

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Test Procedure

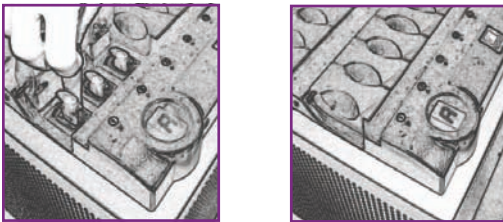


4 Preparation of Molecular Reagents

- Add diluent to lyophilized Master Mix, vortex briefly, and transfer to each reaction tube (C)

Note: 1 reconstituted Master Mix is sufficient for up to 8 reactions.

- Transfer sample lysate (B) and control lysates to corresponding reaction tubes (C)
- Centrifuge all tubes briefly and place on cooling block until ready to load



5 Real-Time PCR Analysis

- Insert each reaction tube into the instrument
- Start run and obtain results in approximately 1 hour

Full Process Run Time < 2 hours

Definitive Test Results

- No interpretation required
- Internal control monitors inhibition

Assay Performance

- Sensitivity: 92.0%
- Specificity: 94.6%
- Negative Predictive Value: 98.5%

User Logs Setup Tools Help							
Results Table							
Site ID	Sample ID	Assay Result	IC Result	Warning/Error Code	Sample Type	Notes	FAM Result
A1	98670	POS	NA		SPEC		NA
A2	23444	NEG	PASS		SPEC		NA
A3	57945	NEG	PASS		SPEC		NA
A4	82455	NEG	PASS		SPEC		NA
A5	19244	NEG	PASS		SPEC		NA
A6	20295	NEG	PASS		SPEC		NA
A7	54630	POS	NA		SPEC		NA
A8	67832	POS	NA		SPEC		NA
A9	90231	NEG	PASS		SPEC		NA
A10	76940	NEG	PASS		SPEC		NA
A11	23008	NEG	PASS		SPEC		NA
A12	45671	NEG	PASS		SPEC		NA
A13	87399	NEG	PASS		SPEC		NA
A14	Pos Cntrl1	Valid	NA		PC 1		Valid
A15	Neg Cntrl1	Valid	PASS		NC 1		Valid



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Not for Lab Use • See package insert for test protocol.

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