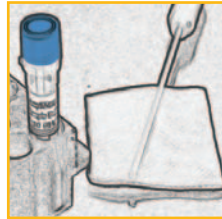


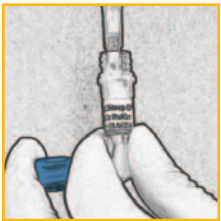
BD GeneOhm™ Cdiff

Test Procedure



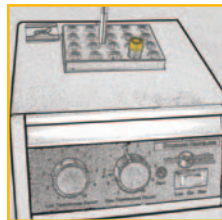
1 Specimen Preparation

- Place the swab in a sample buffer tube (blue cap)
- Break swab
- Vortex at high speed



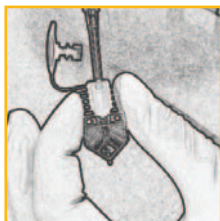
2 Lysis – DNA Extraction

- Add sample buffer from additional sample buffer tube (blue cap) to the lysis tube (yellow cap)
- Transfer cell suspension (blue cap) to the lysis tube (yellow cap)
- Vortex, centrifuge briefly, then heat to inactivate potential inhibitors
- Place lysis tube on a cooling block



A

B



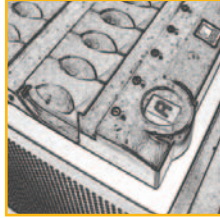
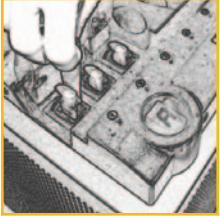
C

3 Reconstitution of Molecular Reagents

- Reconstitute 1 master mix (white label) for up to 6 specimens and 2 controls
 - Add diluent to lyophilized master mix (A) and transfer master mix to the reservoir of each reaction tube (C)
 - Transfer lysate solution (B) to the specimen reaction tube (C)
 - Add control DNA to positive control tube
 - Add sample buffer (blue cap) to negative control tube
 - Centrifuge all tubes briefly
 - Place tubes on specially adapted cooling block until ready to load

BD GeneOhm™ Cdiff

Test Procedure



4 Real-Time PCR Analysis

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

Assay Protocol Time < 2 Hours

Definitive Test Results

- No interpretation required
- Internal control monitors inhibition

Site ID	Sample ID	Assay Result	IC Result	Warning/Error Code	Sample Type	Notes	Cdiff Result
A1	P1	Positive	NA		SPEC		NA
A2	P2	Positive	NA		SPEC		NA
A3	P3	Positive	NA		SPEC		NA
A4	P4	Positive	NA		SPEC		NA
A5	P5	Positive	NA		SPEC		NA
A6	N1	Negative	PASS		SPEC		NA
A7	N2	Negative	PASS		SPEC		NA
A8	N3	Negative	PASS		SPEC		NA
A9	N4	Negative	PASS		SPEC		NA
A10	N5	Negative	PASS		SPEC		NA
A11	S1	Positive	NA		SPEC		NA
A12	S2	Negative	PASS		SPEC		NA
A13	S3	Negative	PASS		SPEC		NA
A14	S4	Positive	NA		SPEC		NA
A15	Pos Cntrl 1	Valid	NA		PC 1		Valid
A16	Neg Cntrl 1	Valid	PASS		NC 1		Valid



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

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