MTD Amplification Controls

For Export Use Only

(bioMérieux ref. 39223/Hologic Cat. No. 301043F)

INTENDED USE

The reagents in the Hologic MTD Amplification Controls may be used as additional controls with the Amplified Mycobacterium Tuberculosis Direct (MTD) Test.

REAGENTS AND MATERIALS PROVIDED

Note: *For information on any hazard and precautionary statements that may be associated with reagents, refer to the Safety Data Sheet Library at www.hologic.com/sds.*

MTD Amplification Negative Control (NC) 2 x 1 mL
Buffered solution.

MTD Amplification Positive Control (PC) 2 x 1 mL
Non-infectious nucleic acid in buffered solution.

WARNINGS AND PRECAUTIONS

A. For in vitro Diagnostic Use.

B. MTD Amplification Controls may be used in conjunction with the Amplified Mycobacterium Tuberculosis Direct (MTD) Test.

C. MTD Amplification Controls do not monitor the sonication (lysis) step of the assay.

D. The Test Procedure of the MTD package insert requires cell controls to monitor both lysis and amplification.

STORAGE AND HANDLING REQUIREMENTS

The reagents contained in the MTD Amplification Controls are to be stored at 2°C to 8°C and are stable until the date indicated on the containers.

PROCEDURE

Refer to the Amplified Mycobacterium Tuberculosis Direct (MTD) Test package insert for the Amplification section of the TEST PROCEDURE.

1. Add 25 µL Mycobacterium Amplification Negative Control or Mycobacterium Tuberculosis Amplification Positive Control to the bottom of an amplification tube containing 50 µL reconstituted Mycobacterium Tuberculosis Amplification Reagent and 200 µL Oil Reagent.
2. Continue with the assay at the Amplification Section, Step 4, of the Amplified Mycobacterium Tuberculosis Direct (MTD) Test package insert.

EXPECTED RESULTS

	RLU
Amplification Negative Control	< 20,000
Amplification Positive Control	≥ 500,000



Hologic, Inc.
10210 Genetic Center Drive
San Diego, CA 92121 USA

Customer Support: +1 844 Hologic (+1 844 465 6442)
customersupport@hologic.com

Technical Support: +1 888 484 4747
molecularsupport@hologic.com

For more contact information visit www.hologic.com.

Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

AW-12602-001 Rev. 002 (EN)

2017-05