STD Proficiency Panel

For *In Vitro* Diagnostic Use

INTENDED USE

The reagents in the Hologic® STD Proficiency Panel are used according to the instructions in the package insert for the Aptima® Combo 2 Assay. These reagents are to be used as a training aid and to demonstrate the precision of the operator in performing the Aptima Combo 2 Assay.

Although these panel members DO NOT HAVE ASSIGNED VALUES, each panel member is designed to reproducibly yield a specific result (positive or negative) when tested in the Aptima Combo 2 Assay.

REAGENTS AND MATERIALS PROVIDED

Catalog No. 2325:

#1	Non-infectious *N. gonorrhoeae* nucleic acid in a buffered solution	1 x 4 mL
#2	Non-infectious *N. gonorrhoeae* and *C. trachomatis* nucleic acid in a buffered solution	1 x 4 mL
#3	Non-infectious *C. trachomatis* nucleic acid in buffered solution	1 x 4 mL

WARNINGS AND PRECAUTIONS

For use in proficiency testing. These reagents are to be used as a training aid and to demonstrate the precision of the operator in performing the Aptima Combo 2 assay.

STORAGE AND HANDLING REQUIREMENTS

The reagents contained in the STD Proficiency Panel are to be stored at 2° to 25°C and are stable until the date indicated on the containers.

PROCEDURE

1. Label tubes for each proficiency panel to be tested.
2. Remove cap, Pipette 25 µL of each proficiency panel member into three separate Aptima Combo 2 Endocervical and Male Urethral Swab Specimen Collection Kit Transport Tubes, replace cap, and mix well.
3. Assay 400 µL from each collection kit tube according to the assay procedure outlined in the Aptima Combo 2 package insert.

ASSAY EXPECTED RESULTS

STD Proficiency Panel	Aptima Combo 2 Result for *C. trachomatis*	Aptima Combo 2 Result for *N. gonorrhoeae*
#1	Negative	Positive
#2	Positive	Positive
#3	Positive	Negative

Should results fall outside these expected results, please contact Hologic Technical Support for assistance.

IVD

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