



STD PROFICIENCY PANEL

For In Vitro Diagnostic Use

INTENDED USE

The reagents in the GEN-PROBE® STD PROFICIENCY PANEL are used according to the instructions in the package insert in the GEN-PROBE® PACE® 2 SYSTEM FOR CHLAMYDIA TRACHOMATIS, GEN-PROBE® PACE® 2 SYSTEM FOR NEISSERIA GONORRHOEAE, and 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 GEN-PROBE PACE 2 Tests or 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 GEN-PROBE PACE 2 SYSTEM FOR CHLAMYDIA TRACHOMATIS, GEN-PROBE PACE 2 SYSTEM FOR NEISSERIA GONORRHOEAE, and the APTIMA Combo 2 Assay.

REAGENTS AND MATERIALS PROVIDED

Catalog No. 2325:

#1	Non-infectious <i>N. gonorrhoeae</i> nucleic acid in a buffered solution	1 x 4 mL
#2	Non-infectious <i>N. gonorrhoeae</i> and <i>C. trachomatis</i> nucleic acid in a buffered solution	1 x 4 mL
#3	Non-infectious <i>C. trachomatis</i> 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 GEN-PROBE PACE 2 Tests or the APTIMA Combo 2 assay.

STORAGE AND HANDLING REQUIREMENTS

The reagents contained in the GEN-PROBE STD PROFICIENCY PANEL are to be stored at 2° to 25°C and are stable until the date indicated on the containers.

PACE 2 TEST PROCEDURE

1. Bring panel reagents to room temperature and vortex each vial 10 to 15 seconds prior to use.
2. Label tubes for each proficiency panel to be tested.
3. Pipette 100 µL of the corresponding proficiency panel into each tube to be tested.
4. Perform the GEN-PROBE test according to the procedure outlined in the appropriate PACE 2 package insert.

APTIMA COMBO 2 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.

PACE 2 TEST EXPECTED RESULTS

(RLU values are representative results)

STD Proficiency Panel	PACE 2 System for <i>C. trachomatis</i>	PACE 2 System for <i>N. gonorrhoeae</i>
#1	Negative (20 – 200 RLU)	Positive (2,000 - 6,000 RLU)
#2	Positive (500 - 1,500 RLU)	Positive (500 - 1,500 RLU)
#3	Positive (2,000 - 6,000 RLU)	Negative (20 - 200 RLU)

THESE DATA ARE INTENDED TO BE REPRESENTATIVE OF TYPICAL TEST RESULTS. THEY ARE NOT INTENDED TO REPRESENT PERFORMANCE SPECIFICATIONS OF THE STD PROFICIENCY PANEL. THESE VALUES SHOULD BE USED ONLY FOR INFORMATIONAL PURPOSES. EACH LABORATORY MUST ESTABLISH ITS OWN PERFORMANCE CHARACTERISTICS FOR THE STD PROFICIENCY PANEL.

Should values fall outside expected ranges, please contact Gen-Probe Technical Service for assistance.

APTIMA COMBO 2 ASSAY EXPECTED RESULTS

STD Proficiency Panel	APTIMA Combo 2 Result for <i>C. trachomatis</i>	APTIMA Combo 2 Result for <i>N. gonorrhoeae</i>
#1	Negative	Positive
#2	Positive	Positive
#3	Positive	Negative

Should results fall outside these expected results, please contact Gen-Probe Technical Service for assistance.

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2002-07
102450 Rev. J

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