GEN-PROBE® APTIMA® Adapter Kit

For *in vitro* diagnostic use.

Intended Use

The GEN-PROBE® APTIMA® Adapter Kit is to be used to test male urethral specimens collected with the GEN-PROBE® PACE® Specimen Collection Kit for Urethral or Conjunctival Specimens or female endocervical specimens collected with the GEN-PROBE PACE Specimen Collection Kit for Endocervical Specimens in the APTIMA Assays.

Principles of the Procedure

The APTIMA Adapter Kit is specifically formulated to allow testing of specimens collected with PACE collection devices (catalog numbers 103300 and 103275) in the APTIMA Combo 2 Assay. The APTIMA Adapter Kit provides a diluent for PACE specimens. For more detailed information about the APTIMA Combo 2 Assay, refer to **PRINCIPLES OF THE PROCEDURE** in the APTIMA Combo 2 package insert. The APTIMA Adapter Kit can only be used in conjunction with the GEN-PROBE PACE Specimen Collection Kits for testing in the APTIMA Combo 2 Assay.

Reagents

Materials Provided

The GEN-PROBE APTIMA Adapter Kit provides the following reagents:

Catalog Number: 301087

Symbol	Component	Quantity	Description
STM	APTIMA Transport Medium	1 x 50 Tests	*110 mM LLS Buffered Solution*

Materials Required But Not Provided

GEN-PROBE PACE Specimen Collection Kits for Endocervical Specimens

GEN-PROBE PACE Specimen Collection Kits for Male Urethral and Conjunctival Specimens

APTIMA Combo 2 Assay for Chlamydia trachomatis and Neisseria gonorrhoeae

APTIMA Auto Detection Reagent Kit

Centrifuge capable of 420 RCF

Micropipettor: 200 µL to 1000 µL

Micropipettor: 20 µL to 200 µL

Pipette tips 20 µL to 200 µL

Pipette tips 200 µL to 1000 µL

Note: See APTIMA Combo 2 package insert for MATERIALS REQUIRED BUT NOT PROVIDED for the APTIMA Combo 2 Assay.

Materials Available from Gen-Probe

PACE Specimen Collection Kits for Endocervical Specimens (Cat. No. 103300)

PACE Specimen Collection Kits for Male Urethral and Conjunctival Specimens (Cat. No. 103275)

APTIMA Combo 2 Assay for Chlamydia trachomatis and Neisseria gonorrhoeae (Cat. No. 301032)

APTIMA Auto Detection Reagent Kit (Cat. No. 301048)

Micropipettor: 20 µL to 200 µL (Cat No. 103878)

Micropipettor: 200 µL to 1000 µL (Cat No. 104216)

Warnings and Precautions

A. For *in vitro* diagnostic use.

B. See **WARNINGS AND PRECAUTIONS** in the APTIMA Combo 2 package insert for running the APTIMA Combo 2 Assay.

C. Use only supplied or specified disposable laboratory ware.

D. Use routine laboratory precautions. Do not eat, drink or smoke in designated work areas. Wear disposable, powderless gloves, and laboratory coats when handling specimens and kit reagents. Wash hands thoroughly after handling specimens and kit reagents.

E. Do not use the APTIMA Adapter Kit on specimens previously tested in the PACE Assay.

F. Take care to avoid cross-contamination during the specimen handling steps. Specimens can contain extremely high levels of organisms. Ensure that specimen containers do not contact one another, and discard used materials without passing over open containers. If gloves come in contact with specimen, change gloves to avoid cross-contamination.

G. Do not use this kit after its expiration date.

H. If the lab receives a specimen transport tube with no swab, two swabs, or a swab not supplied by Gen-Probe, the specimen must be rejected.

I. Maintain proper storage conditions during specimen shipping to ensure the integrity of the specimen. Specimen stability under shipping conditions other than those recommended has not been evaluated.

Storage and Handling Requirements

Store the APTIMA Transport Medium at 2°C to 30°C.

Specimen Collection and Storage

Specimens are collected according to the appropriate instructions supplied with the PACE Specimen Collection Kits for Endocervical Specimens and PACE Specimen Collection Kits for Male Urethral and Conjunctival Specimens.

After collection, transport and store the swab in the swab specimen transport tube at 2°C to 30°C until tested. Specimens must be assayed with the APTIMA Combo 2 Assay within 60 days of collection.

Note: Federal requirements for packaging must be met when specimens are transported by common land and air carriers. Refer to 42 CFR, Part 72. The most current requirements may be obtained from the Centers for Disease Control and Prevention Office of Health and Safety in Atlanta, GA at (404) 636-3883.

Test Procedure

1. Follow the **TEST PROCEDURE** section of the APTIMA Combo 2 Assay package insert.
2. To test swab specimens collected in the PACE collection devices use the following protocol:
   a. Add 400 µL APTIMA Transport Medium (STM) to each tube in the TTU in which a PACE sample will be tested.
   b. Centrifuge PACE specimen for 5 minutes at 420 RCF. Do not vortex or mix the samples after the centrifugation step.
   c. Uncap PACE swab specimen. **DO NOT REMOVE OR EXPRESS THE SWAB**. Pipette 40 µL of the specimen into the appropriate TTU tube.
   d. After all the specimens have been added to the TTUs, mix by gently shaking rack by hand. Do not vortex.
3. Proceed with the APTIMA Combo 2 Assay as described in the APTIMA Combo 2 package insert.

Validation Study Report

A validation study using clinical samples was conducted to establish the equivalence between APTIMA Combo 2 Assay results using the GEN-PROBE PACE Specimen Collection Kits with the APTIMA Adapter Kit and the APTIMA Combo 2 Unisex Swab Collection Kit. Assay performance was assessed by comparing the results from PACE male urethral and female endocervical swab specimens, diluted using the Transport Medium supplied in the APTIMA Adapter Kit, to the results from swab specimens collected with the APTIMA Combo 2 Unisex Swab Collection Kit. The study evaluated paired swab specimens from 154 male subjects and 231 female subjects attending STD and Family Planning clinics. A total of 770 *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoea* (GC) test results were used in the data analysis.

The percent agreement between the APTIMA Combo 2 Assay CT results using specimens collected with the PACE Swab Specimen Collection Kit and with the APTIMA Combo 2 Swab Specimen Collection kit was 97.7% (95% C.I.: 95.6% - 98.9%). The percent agreement between the APTIMA Combo 2 Assay GC results using specimens collected with the PACE Swab Specimen Collection Kit and with the APTIMA Combo 2 Swab Specimen Collection kit was 98.7% (95% C.I.: 97.0% - 99.6%). Further, agreement between the two collection kits was evaluated based on the CT and GC outcomes of the Combo 2 swab specimen that included CT+/GC+, CT+/GC-, CT-/GC+ and CT-/GC-. Among all specimens, CT+/GC+ results were obtained by 20 PACE swab and 20 Combo 2 swab paired specimens (100%, 95% C.I.: 83.2%-100%); among female specimens, 6/6 (100%, 95% C.I.: 54.1%-100%); and among male specimens, 14/14 (100%, 95% C.I.: 76.8%-100%). Similarly, CT+/GC- results were obtained by 35 PACE swab and 39 Combo 2 swab paired specimens (89.7%, 95% C.I.: 75.8%-97.1%); among female specimens, 19/21 (90.5%, 95% C.I.: 69.6%-98.8%); and among male specimens, 16/18 (88.9%, 95% C.I.: 65.3%-98.6%). Of those specimens with CT-/GC+ results, PACE swab specimens had 22 and Combo 2 swab specimens had 28 (78.6%, 95% C.I.: 59.0%-91.7%); among female specimens, 5/9 (55.6%, 95% C.I.: 21.2%-86.3%); and among male specimens, 17/19 (89.5%, 95% C.I.: 66.9%-98.7%). Finally, CT-/GC- results were obtained by 295 PACE swab specimens and 297 Combo 2 swab specimens (99.3%, 95% C.I.: 97.6%-99.9%); among female specimens, 193/195 (99.0%, 95% C.I.: 96.3%-99.9%); and among male specimens, 102/102 (100%, 96.4%-100%).

The results of this study demonstrate that using the APTIMA Adapter Kit with specimens collected in the PACE Specimen Collection Kits yield equivalent APTIMA Combo 2 Assay results when compared to specimens collected with the APTIMA Combo 2 Assay, Unisex Swab Specimen Collection Kits.

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