

GEN-PROBE® APTIMA® Controls Kit

For *in vitro* diagnostic use

Intended Use

The GEN-PROBE® APTIMA® Controls Kit is for use with the GEN-PROBE APTIMA Assays for the detection of *C. trachomatis* and/or *N. gonorrhoeae*. These quality control reagents are to be used according to the instructions in the package insert of the appropriate GEN-PROBE APTIMA Assay to establish run validity.

Reagents

Materials Provided

APTIMA Controls Kit (Cat. No. 1110)

Symbol	Component	Quantity	Description
PCT/NGC	APTIMA Positive Control, CT/ Negative Control, GC	5 x 1.7 mL	Non-infectious CT nucleic acid in a buffered solution containing < 5% detergent. Each 400 µL sample contains the estimated rRNA equivalent of 1 CT IFU (5 fg/assay*).
PGC/NCT	APTIMA Positive Control, GC/ Negative Control, CT	5 x 1.7 mL	Non-infectious GC nucleic acid in a buffered solution containing < 5% detergent. Each 400 µL sample contains the estimated rRNA equivalent of 50 GC cells (250 fg/assay*).

*The rRNA equivalents were calculated based on the genome size and estimated DNA:RNA ratio/cell of each organism.

Warnings and Precautions

For use with APTIMA Assays for the detection of *C. trachomatis* and/or *N. gonorrhoeae*. The Positive Control CT (Negative Control GC) serves as the negative control for GC Assays/test results. The Positive Control GC (Negative Control CT) serves as the negative control for CT Assays/test results.

Storage and Handling Requirements

The reagents contained in the GEN-PROBE APTIMA Controls Kit are to be stored at 2°C to 8°C and are stable until the date indicated on the vials.

Upon warming to room temperature, some control tubes may appear cloudy or contain precipitates. Cloudiness or precipitation associated with controls does not affect control performance. The controls may be used whether they are clear or are cloudy/precipitated. If clear controls are desired, solubilization may be expedited by incubating them at the upper end of the room temperature range (15°C to 30°C).

APTIMA Assay Procedure

Please reference the test procedure section of the GEN-PROBE APTIMA Assay package insert or the instrument Operator's Manual for procedural instructions.

APTIMA Assay Expected Results

Control	CT Result*	GC Result*
Positive Control CT/Negative Control GC	Positive	Negative
Positive Control GC/Negative Control CT	Negative	Positive

*Refer to the APTIMA Assay package insert for specific RLU values associated with the APTIMA Controls.
Should results fall outside these expected results, please contact Gen-Probe Technical Service for assistance.



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