Aptima® Controls Kit

Instructions for Use

For *in vitro* diagnostic use

Rx only

Intended Use

The Aptima® Controls Kit is for use with the 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 Aptima Assay to establish run validity.

Reagents

Materials Provided

Aptima Controls Kit (Cat. No. 301110)

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

A. 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.

B. For professional use.

Note: *Hazard communication information for labeling of globally marketed products reflects the US and EU Safety Data Sheets (SDS) classifications. For hazard communication information specific to your region, refer to the region specific SDS on the Safety Data Sheet Library at www.hologic.com/safety-data-sheets. For more information on the symbols, refer to the symbol legend on www.hologic.com/package-inserts.*

Storage and Handling Requirements

The reagents contained in the 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 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 falls outside these expected results, please contact Hologic Technical Support for assistance.

Contact Information and Revision History

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

IVD

CE 2797

EC REP
Hologic BV
Da Vincilaan 5
1930 Zaventem
Belgium

Australian Sponsor
Hologic (Australia & New Zealand) Pty Ltd.
Macquarie Park NSW 2113

For country-specific Technical Support and Customer Service email address and telephone number, visit www.hologic.com/support.

Serious incidents occurring in relation to the device in the European Union should be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

AW-28283-001 Rev. 002
2025-10

Revision History	Date	Description
AW-28283 Rev. 001	March 2023	• Created Aptima Controls Kit IFU AW-28283 Rev. 001 based on IN0114-01-IFU-PI Rev. 005 for regulatory compliance with IVDR. • Added Instruction for use on the first page • Updated note about hazard communication for globally marketed assays. • Updated contact information including: EC Rep, CE Mark, Australian Rep information, and serious incidents.
AW-28283 Rev. 002	October 2025	• Updated SDS URL. • Added for professional use statement. • Added trademark statement.