Mycoplasma genitalium Controls

For in vitro diagnostic use.

Intended Use

The Hologic *Mycoplasma genitalium in vitro* transcript (IVT) controls are controls intended to be used with molecular assays that detect rRNA from *Mycoplasma genitalium*.

Product Description

Mycoplasma genitalium Controls Kit (PRD-04940) (store at 2°C to 8°C upon receipt)

Symbol	Component	Quantity
Control-	Mycoplasma genitalium Negative Control Buffered solution.	5 x 1.7 mL
Control+	Mycoplasma genitalium Positive Control Non-infectious nucleic acid in buffered solution.	5 x 1.7 mL

Storage Condition

Store at 2-8°C.

Warnings and Limitations

A. Use routine laboratory precautions. Do not pipette by mouth. Do not eat, drink or smoke in designated work areas. Wear disposable, powderless gloves, protective eye wear, and laboratory coats when handling specimens and kit reagents. Wash hands thoroughly after handling specimens and kit reagents.

Note: As in any reagent system, excess powder on some gloves may cause contamination of opened tubes. Powderless gloves are required.

- B. Dispose of all materials that have come in contact with specimens and reagents in accordance with applicable national, international, and regional regulations.
- C. Avoid cross-contamination during the IVT handling steps. Be especially careful to avoid contamination by the spread of aerosols when loosening or uncapping the IVTs. Controls contain extremely high levels of IVT. Ensure that specimen containers do not contact one another, and discard used materials without passing over open containers. Change gloves if they come in contact with the controls.

Quality Control

Each laboratory should establish their own frequency of Quality Control testing based on applicable local laws, regulations, and standard good laboratory practice.





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