Mycoplasma genitalium IVT WT Control

For *in vitro* Diagnostic Use

Intended Use

The *Mycoplasma genitalium* (MG) Wild Type (WT) In vitro transcript (IVT) Control is a control intended to be used with molecular assays that detect RNA from this organism.

Materials Provided

MG IVT WT (Cat. No. PRD-06727)

Component	Quantity	Description
Tube	1 x 0.25 mL	*In vitro* transcript of *Mycoplasma genitalium* 23S RNA

Instructions for Use

The Hologic *Mycoplasma genitalium* IVT control should be diluted in buffer that prevents RNA degradation (e.g., Progensa PCA3 Specimen Diluent Kit, Specimen Transport Medium, cat. no. 302351) to a concentration determined by the user.

Storage and Handling

Store at -15°C to -25°C. Multiple freeze/thaw cycles should be minimized by appropriate aliquoting and should not exceed 4 freeze/thaw cycles.

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 recommended.*

B. Dispose of unused controls and human specimens according to local, state and federal regulations.

C. Stability of the controls may be affected if diluted in buffers not validated for use with RNA.

D. 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

The *Mycoplasma genitalium* WT IVT control is unassayed control. Each laboratory should establish its own Quality Control ranges and frequency of QC testing based on applicable local laws, regulations and standard good laboratory practice.

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AW-23000-001 Rev. 001
2021-02