

## Bacterial Vaginosis and Candida Vaginitis Controls

For *in vitro* diagnostic use

### Intended Use

The Hologic *Lactobacillus crispatus*, *Gardnerella vaginalis*, *Candida albicans* and *Candida glabrata*, *in Vitro* transcript (IVT) controls are controls intended to be used with molecular assays that detect RNA from these organisms.

### Product Description

*Lactobacillus crispatus* IVT control (PRD-04519)

Component	Quantity	Description
Tube	1x1.7 mL	<i>In vitro</i> transcript of <i>Lactobacillus crispatus</i> 16s rRNA

*Gardnerella vaginalis* IVT control (PRD-04520)

Component	Quantity	Description
Tube	1x1.7 mL	<i>In vitro</i> transcript of <i>Gardnerella vaginalis</i> 16s rRNA

*Candida albicans* IVT control (PRD-04521)

Component	Quantity	Description
Tube	1x1.7 mL	<i>In vitro</i> transcript of <i>Candida albicans</i> RNaseP

*Candida glabrata* IVT control (PRD-04522)

Component	Quantity	Description
Tube	1x1.7 mL	<i>In vitro</i> transcript of <i>Candida glabrata</i> RNaseP

### Instructions for Use

The Hologic *Lactobacillus crispatus*, *Gardnerella vaginalis*, *Candida albicans* and *Candida glabrata* IVT controls 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 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 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 that are 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 Bacterial Vaginosis and Candida Vaginitis Controls are unassayed controls. Each laboratory should establish their own Quality Control ranges and frequency of QC testing based on applicable local laws, regulations and standard good laboratory practice.



Hologic, Inc.

10210 Genetic Center Drive

San Diego, CA 92121 USA

Customer Support      +1 800 442 465 9892  
customersupport@hologic.com

Technical Support      +1 888 484 4747  
molecularsupport@hologic.com

For more contact information visit [www.hologic.com](http://www.hologic.com).

Hologic and Progensa are trademarks and/or registered trademarks of Hologic, Inc. and/or its subsidiaries in the United States and/or other countries.

All other trademarks that may appear in this package insert are the property of their respective owners.

©2017 Hologic, Inc. All rights reserved.

AW-17240 Rev. 001  
2017-10