

PRODUCT DESCRIPTION:

Each frozen aliquot contains 1 mL of a pure, titered culture *Gardnerella vaginalis*. The identification of this organism was confirmed by 16S sequencing. The purity of the culture was monitored by Gram staining and by additional culturing. The titer was performed on one aliquot after freezing. The freezing medium contains 15% glycerol as a cryoprotectant. Please see the Certificate of Analysis for the specific freezing medium used.

INTENDED USE:

Live, titered microorganisms can be used to determine a limit of detection (LOD), in diagnostic assay development or cross-reactivity studies. When used as a control for nucleic acid tests, the same protocols as those used to amplify clinical specimens should be employed.

BIOSAFETY:

Gardnerella vaginalis is a biosafety level 2 microorganism and must be used within Biological Safety Level 2 facility or cabinet. Please consult your institution's regulations regarding the use of this organism. For a detailed discussion on biological safety see the 5th edition of Biosafety in Microbiological and Biomedical Laboratories (BMBL), published by the CDC at <http://www.cdc.gov/biosafety/publications/bmbl5/index.htm>.

PRECAUTIONS:

- Use Universal Precautions, this organism is **potentially biohazardous**.
- Repetitive freezing and thawing is not recommended (aliquot material if necessary). Titer will be altered by a single freeze-thaw.
- To avoid cross-contamination, use separate pipette tips for all reagents.




RECOMMENDED STORAGE:

Titered material should be stored at -65°C or below.

DO NOT USE IN HUMANS. FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.

These products are intended for research, product development, or quality assurance. These products are NOT intended for use in the manufacture or processing of injectable products subject to licensure under section 351 of the Public Health Service Act or for any other product intended for administration to humans.

This product was manufactured in a facility which has a Quality Management System that is ISO 13485 certified.

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| REF | Catalog Number |  | Temperature Limitation |
| LOT | Lot Number |  | Expiration Date |
| RUO | For Research Use Only |  | Biological Risk |

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