

PRODUCT DESCRIPTION:

Each frozen aliquot contains 1 mL of a pure, titered culture of a recombinant strain of *Saccharomyces cerevisiae*. A gene specific to *Histoplasma capsulatum* was inserted as a single copy into the genome of *S. cerevisiae* using standard recombinant techniques. *S. cerevisiae* was confirmed by rDNA sequencing. The insert was detected with a specific in-house real-time PCR assay. The purity of the culture was monitored by additional culturing and Gram staining to detect any contaminating bacteria. The titer was performed on a minimum of two aliquots 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.

*This reagent contains a recombinant construct that may not represent the targeted genetic region for all possible assays analyzing for *Histoplasma capsulatum*. We have evidence of utility with assays designed by Luminex Molecular Diagnostics; however, the performance characteristics of this reagent should be determined by the end-user.

BIOSAFETY:

H. capsulatum-S. cerevisiae is a biosafety level 1. Please consult your institution's regulations regarding the use of this organism. For a detailed discussion on biological safety see the current edition of Biosafety in Microbiological and Biomedical Laboratories (BMBL), published by the CDC.

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.

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Effective Date: 07/18/2022

 REF	Catalog Number		Temperature Limitation
 LOT	Batch Code		Expiration Date
 RUO	For Research Use Only		Biological Risk
	Manufacturer		

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

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