

PRODUCT DESCRIPTION:

Each aliquot contains 1 µg of DNA extracted from a pure culture of a recombinant strain of *Saccharomyces cerevisiae*. A gene specific to *Pneumocystis jirovecii* 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 DNA was extracted from the cells following a protocol based on the yeast protocol provided in the Qiagen® Genomic DNA Handbook and using Qiagen® Genomic DNA Buffers with a 500/G genomic tip. DNA concentration and A_{260/280} ratios were determined by testing a minimum of two aliquots on a NanoDrop®. The extracted DNA also tested positive on an in-house real time PCR assay.

INTENDED USE*:

Purified Genomic DNA is designed for use as an amplification and/or detection control for nucleic acid testing of *Pneumocystis jirovecii*. It can also be used to determine a limit of detection (LOD), in diagnostic assay development, cross-reactivity studies or genomic sequencing. Controls should be run using the same protocols as those used to amplify extracted clinical specimens.

***This reagent contains a recombinant construct that may not represent the targeted genetic region for all possible assays analyzing for *Pneumocystis jirovecii*. 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.**

PRECAUTIONS:

- Use Universal Precautions when handling Genomic DNA.
- The material may be re-frozen after thawing. Repetitive freezing and thawing is not recommended (aliquot material if necessary).
- To avoid cross-contamination, use separate pipette tips for all reagents.

RECOMMENDED STORAGE:








This control is supplied in TE Buffer and should be frozen at -20°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 manufacturing use only. 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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PI0801698DNA-1µg
Revision: 03
Effective Date: 07/14/2021

	Catalog Number		Temperature Limitation
	Batch Code		Expiration Date
	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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