

Corning Incorporated - Life Sciences
Avenida Industrial del Norte S/N
Parque Industrial del Norte
Reynosa TAMP 88736 MEX
www.corning.com/lifesciences
Refer to website for regional contact information.

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Product Name	: TGOLD,PCR 8WL,CAP,RTPCR,CLR,PP,NS,BK,125/1250		
Catalog Number	: 3742	Manufacture Date	: 2019-02-24
Lot ID	: 05019016		
Expiration Date	: 2019-02-24		

Quality Management System - Complies with the current version of the ISO 9001 Standard and the FDA CFR 21 Part 820, current Good Manufacturing Practices (cGMP).

Non-Pyrogenic - Tested and met the criteria established in the current version of ANSI/AAMI ST 72, "Bacterial Endotoxins - Test methodologies, routine monitoring, and alternatives to batch testing" and USP <85>, "Bacterial Endotoxins Test". The acceptance level for product is ≤ 0.10 EU/ml or ≤ 4 EU/device.

USP Class VI Testing - All material resin is tested, qualified and shown to be non-toxic as established in the Standards USP Class VI Chapter<87>, "Biological reactivity Tests, in Vitro" and Chapter<88>, "Biological Reactivity Tests, in vivo".

DNase/RNase Free - Tested by nuclease assay method and found to be free of detectable DNase/RNase contamination. The assay detection limit is 10^{-7} Kunitz units/uL for DNase and 10^{-9} Kunitz units/uL for RNase.

Quality Control Testing - Representative production samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and approved by qualified personnel for product release. Key inspections and inline tests are listed below:

- Visual Inspection - Pass
- Packaging Inspection - Pass

- This product met Corning Incorporated - Life Sciences' high standards of quality at the time of batch/lot release.



JOSE DOMINGUEZ
Quality Manager