CERTIFICATE OF COMPLIANCE

Part Number: 63300015
Lot Number: 1008538045
Expiration: 2028/07

Biotix products are manufactured and packaged under ISO 9001:2015 quality management system. Biotix certifies that the product is free of any detected defects and has passed our quality control standards and testing outlined below.

Biotix products are manufactured and packaged in our Tijuana MX facility and shipped from USA.

Traceability:
Products are manufactured with a Lot number, Part number and expiration date, clearly printed on the pack and case box labels. Pipette tip racks are labeled with the Lot number, Part number and tip size, on the front of the lid for an extra level of traceability.

Functional Testing:
Each product is inspected at regular intervals to our set specifications to ensure the proper form, fit and function. Functional testing for tips include a test for leaking and an accuracy test using the maximum volume of the tip. Accuracy and precision are then printed on the pack boxes in the form of the CV value.

Bio contamination Testing:
Sterilized Biotix products undergo an irradiation process damaging the DNA and destroying the reproductive capabilities of the microorganisms. The irradiation process is in compliance with procedures outlined in ISO 11137-2:2013, including quarterly audits and bioburden testing to validate a minimum SAL level of 10^{-3}.
Biotix certifies that no Bio contaminants were found to be above the limits of detection stated below:

Prueba	Limites de Detección	Especificación
RNase/DNase, via electrophoretic detection	10^{-7} Kunitz U/µL	< 10^{-7} Kunitz U/µL
Nucleic Acid, via electrophoretic detection	10 ng	No amplicons detected
Endotoxins/Pyrogens, via LAL	0.06 EU/mL	Levels < 0.06 EU/mL
PCR inhibitors, via gel electrophoresis anlysis	Pass/Fail, using PCR amplification and gel electrophoresis	Successful PCR amplification
ATP, via luminescence detection	$2.5x10^{-10}$ mg/µL	Luminescence detected in the $2.5x10^{-10}$ - $7.2x10^{-9}$ mg/µL range

Material Statement:
Biotix uses no plasticizers, mold release agents, latex or GMOs in the manufacture of our laboratory products. The raw material resin used to make our products undergoes hydrogenation, alkaline hydrolysis and distillation ensuring the product is BSE (bovine spongiform encephalopathy) and TSE (transmissible spongiform encephalopathy) free. Biotix has performed an extractable study using a third party laboratory on our polypropylene finished goods. No heavy metals were found to be above the instrument quantitation limit for any metals.

Rafael Flores
Senior Director of Quality

Biotix, Inc.
10636 Scripps Summit Court, Suite 130
San Diego, CA 92131