



CERTIFICATE OF COMPLIANCE

Part Number: SR-0050-BC
Lot Number: 208923
Expiration date, if applicable, is printed on the product label.

Biotix products are manufactured and packaged under an 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 San Diego, CA.

Traceability:

Products are manufactured with a printed 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:

Tips considered "pre-sterile" undergo an irradiation process to destroy DNA, microorganisms, and other potential biological contaminants. The irradiation process is validated to achieve a minimum SAL level of 10^{-3} .

Contaminant tested For	Limit of Detection
RNase/DNase	$<10^{-7}$ Kunitz units/uL
Nucleic Acid	10 ng
Endotoxin/Pyrogens	< 0.06 EU/mL
PCR inhibitors	Pass/Fail using PCR amplification and gel electrophoresis analysis
ATP	$<7.3^{-9}$ mg/uL

Materials 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.


Quality Control Director

