Quality Certificate

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Quality System Compliance

This certificate confirms that the product listed conforms to written material specifications, was manufactured under our registered and audited **ISO 9001:2015** quality system, meets the requirements of **U.S. FDA Title 21, U.S. FDA**, and underwent testing as outlined in our laboratory procedures.

Labcon is a U.S. FDA registered medical device manufacturer with registration number **2916657**.

Quality Control Testing

These products come with our highest standard of quality assurance. Each lot of items is produced in a tightly controlled environment and subjected to our rigorous testing and performance procedures. Our products meet all stated standards for precision, clarity, warp, centrifugation and freedom from contamination. We stand behind these products, and will replace any that fail to meet our published standards.

Labcon Product Number: 3131-165-006-9

Country of Origin: USA

Lot Number: 12773 406CE 406C

Expiration Date: 2027-02

Sterilization Lot Information will appear below if this product is Sterile

Sterilization Date: 2024-02-13

Minimum Dose: 17.4

Range: 15.2 - 32.0 kGy

Maximum Dose: 26.5

Sterilization Processing & Validation to be labeled Sterile (If Applicable)

Labcon products are sterilized by beta radiation sterilization within a dose range of 15.2-32 kGy. The dose range necessary for the stated sterility assurance level is continuously audited through quarterly bio-burden and sterility validation studies performed according to the ANSI/AAMI/ISO 11137 standard by an independent laboratory. This dosage is sufficient to guarantee a sterility assurance level of 10^{-6}. Sterile products have a sterile shelf life of five years and non-sterile products have a suggested shelf life of six years.

Product Materials, Specifications, Standard Testing & Certification

Material:	Disposables are made of high quality 100% virgin polypropylene, polyethylene or polystyrene and are certified free of Bisphenol A (BPA), Oleamide, DiHEMDA, Phthalates, Nitrosamine, and cytoxic effects. Bovine Spongiform Encephalopathy/ Transmissible Spongiform Encephalopathy (BSE/TSE) compliant. Resins are USP Class-VI certified, RoHS Directive 2002/95/EC/-2011/65-2015/863 compliant, U.S.FDA regulation 21 CFR compliant, and are free of Substances of Very High Concern (SVHC). EU REACH Regulation (EC) No. 1907/2006 compliant, and are U.S.FDA approved for food contact. No disposables contain any of the "listed chemicals" as referenced in the California Safe Drinking Water and Toxic Enforcement Act of 1986, (Prop 65) as revised December 29, 2023.
Endotoxin (Pyrogen) Free:	Product samples are exposed to endotoxin-free water and the resulting extraction fluid is tested for contamination using the kinetic turbidimetric Limulus Amoebocyte Lysate (LAL) assay protocol and USP guidelines. All products tested must display less than 0.05 EU/ml to be certified free of endotoxin.
ATP Free:	Product sample surfaces are tested for the presence of adenosine triphosphate (ATP) using a controlled bioluminescence reaction to detect contamination. Luminescence data is compared to results generated by ATP-free surfaces and surfaces with known amounts of ATP as a positive control. The relative light units result must indicate less than 2×10^{-12} mg/µl of ATP for the product to be certified as ATP free.
Nuclease (DNase & RNase) Free:	Product samples are exposed to nuclease-free water and the resulting extraction fluid is tested for nuclease activity on commercially available fluorescence-quenched oligonucleotide probes with a one-hour 37°C incubation in appropriate buffers. Results are compared with appropriate positive and negative controls. Fluorescence signal must be below the level set by the positive control (1µL Enzyme; RNase 0.01U/mL, DNase 2U/uL, and 1 µM substrate) for the extraction fluid samples and products to be certified as RNase-free and DNase-free.
Heavy Metals Free:	Plastic resins used in product manufacturing have been tested for heavy metals using the prescribed USP method and confirmed to have levels lower than 1 part per million (1ppm).
Latex Free:	No Latex was used in the manufacturing of the product. This also includes all the packaging and shipping materials used in the production of all items. The only time the product or packaging may come in contact

with Latex would be from the Latex gloves that production employees are required to wear for the purpose of clean handling and to avoid biological contamination of the products.

BSE/TSE Free:	(Bovine Spongiform Encephalopathy/Transmissible Spongiform Encephalopathy) This product is free from and manufactured from materials that do not contain any raw materials or substances derived from animal origin as defined in EC Directive 97/534/EC and 76/768/EEC and Amendment 419 Annex II. EC Directive 90/385/EEC and 93/42/EEC, 98/8/EC and EC Directive 2007/47/EC. The manufacturer does not store any products of animal origin, including animal proteins, in any manufacturing areas of their facility or warehouses.

Additional special testing and certification for this Product Number 3131-165-006-9 Lot Number 12773 406CE - 406C appears below if applicable.

Transport Testing These products are pressure and temperature tested to confirm that they are suitable for use as collection and transport tubes for diagnostic and infectious specimens as defined by both domestic (US DOT HMR, 49 C.F.R., Parts 171-180) and international (IATA DGR UN3373 PI650) standards. Tubes were filled with a glycerol-water mix and incubated at 25°C in a vacuum chamber at -95kPa for 90 minutes, with no leakage of liquid content observed. Tubes were then incubated at -40°C for 90 minutes at the -95kPa differential, again with no leaking of liquid contents observed. The tubes were then incubated at +55°C for 90 minutes at the -95kPa differential, again with no leaking observed. These results show these products can structurally withstand the temperature range from -40°C to +55°C and an air pressure differential of 95 kPa, and therefore conform to accepted US Department of Transportation (DOT) and International Air Transport Association (IATA) specimen tube standards.

An important legal notice and disclaimer may appear on an additional page if it does not appear below.

labcon®

FDA REGISTERED FACILITY · GOOD MANUFACTURING PRACTICE GMP CERTIFIED · RESTRICTION ON THE USE OF CERTAIN HAZARDOUS SUBSTANCES RoHS COMPLIANT · ISO CERTIFIED ISO 9001 ISO CERTIFIED · ACT. The Environmental Impact Factor Label · ISO 11137 STANDARD · MADE IN USA

Important Legal Notice and Disclaimer

Labcon states that this certificate and declaration will not discharge the user from their obligation to ensure the product is suitable for the intended use. In all cases this product should be used by those familiar with laboratory procedures and trained in appropriate laboratory equipment. The use of these certificates is provided as a service and for documentation only. Labcon North America retains all rights to the information, procedures, and results of the testing and certificates as proprietary information. Any copying and distribution of these certificates, procedures, or results without prior written authorization is prohibited by law.

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