

Technical Data Sheet

Doc No – Ab/TDS/Cryo-21

Rev No : 04

TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

Freezing Tubes Sterile, PP

Valid for Cat. No. P60102, P60103

1. Description/Specification

1.1 Description: Freezing Cryo vials, DNase, RNase and Pyrogen Free

1.2 Design:

1.2.1 Vials: Cylindrical External Threads with Self standing, Round Bottom (PP)

1.2.3 Cap: separate Cap with threads (HDPE)

1.3 Performance Specifications:

1.3.1 Vial Volume: 1.8 ml and 4.5 ± 0.1 ml

1.3.2 Vial Size : 11.36 x 45.7 mm (P60102), 11.36 x 86.5 mm (P60103),

Cap Size : 13.2 mm (φ)

1.4 Material:

1.4.1 Polypropylene (PP), Hydrophobic

1.4.2 This material meets the FDA criteria Regulation 21 CFR 177.1520. Olefin polymers.

1.4.3 Free from heavy metals according to ELV Direction 2000/53/EC and its following amendments.

1.4.4 This material is used for all devices for diagnostic (Class-1 medical devices) according to Directive 98/79/EC requirements. IVD Certified

1.4.5 This Material is Gamma-Ray sterilizable & Phthalates Free.

1.5 Color:

Translucent



Shiv Ganga Industrial Estate,
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1.6 Sterilization:

Sterile catalog number from this lot have been pre-sterilized and dosimetrically released based on ANSI/AAMI/ISO 11137 *Sterilization of healthcare products-Requirements for validation and routine control- Radiation sterilization*. The product has been sterilized with Co-60 Gamma Radiation.

1.7 Quality control:

DNase, RNase and Pyrogen Free

Testing of various characteristics in accordance with the valid Process.

1.8 Other information:

Recommended for single use only

Vial Pack Size: 1000 pieces/case (P60102) & 500 pieces/case (P60103)

2. Basic Features

2.1 Temperature range: Tube: -80°C to $+121^{\circ}\text{C}$ (Can withstand in liquid nitrogen with standard procedure, recommended to store in vapor phase of liquid nitrogen).

2.2 Autoclavability: Autoclavable at 15 psi and 121°C for 20 minutes


2.3 Leak Test at 635 mm Hg with Cap fitted: No leakage

2.4 Chemical resistance: see website.

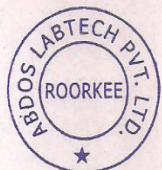
2.5 IVD Certified

Autoclaving Guideline for Plastics

All plastic consumables are autoclavable at 121°C for 20 minutes, 15 psi/1atm. Do not use a dry cycle as this may cause deformation or weakening of the plastic. Allow temperature within the autoclave to return to at least 50°C before removing product.


Quality Assurance Incharge

Abdos Labtech Pvt. Ltd.

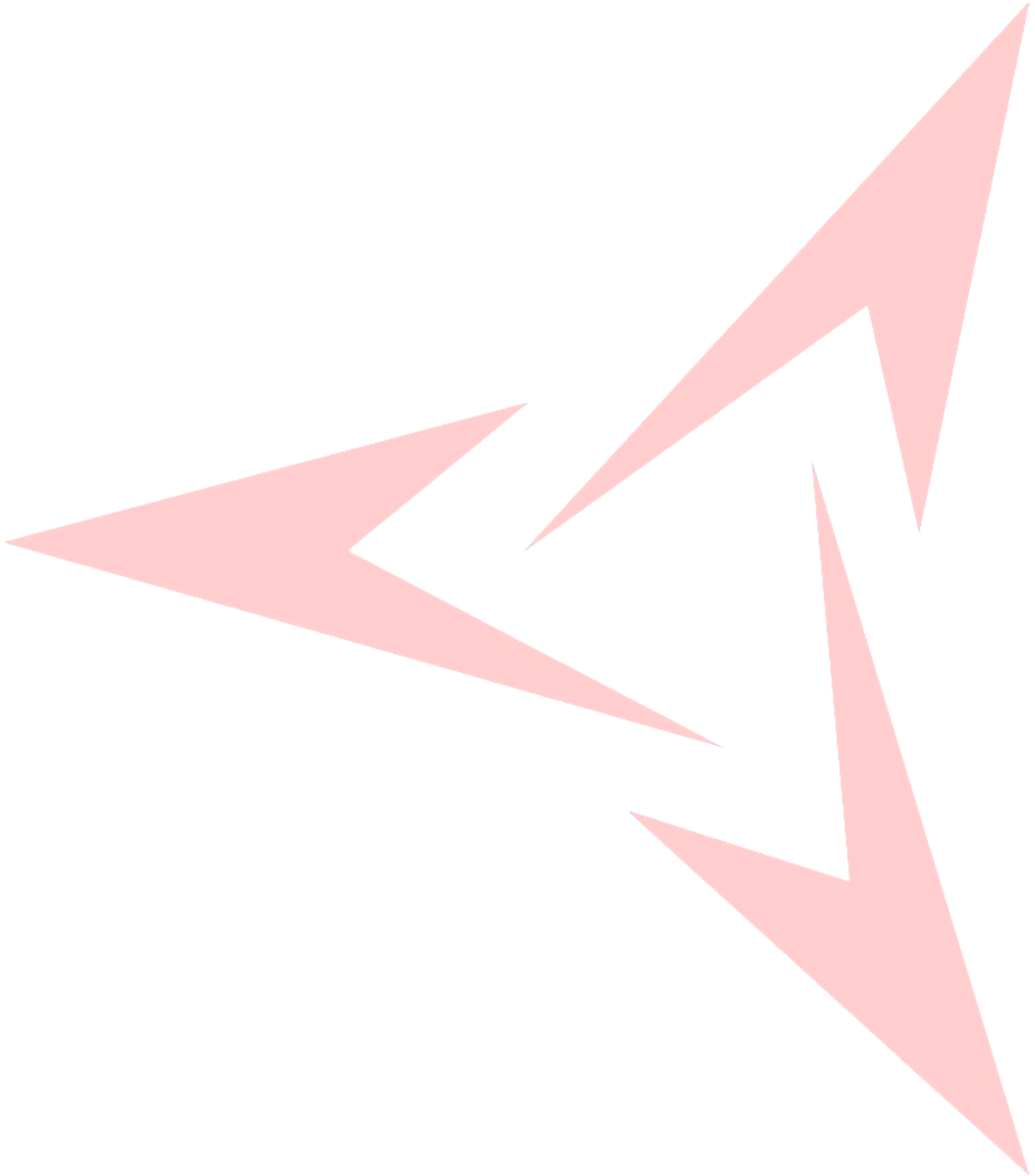


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