

Technical Data Sheet

Doc No – Ab/TDS/Cryo-21

Rev No : 01

TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

Freezing Tubes Coders, HDPE

Valid for Cat. No. P60104 W, P60104 B, P60104 R, P60104 Y, P60104 G

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: These coders fit onto the top of Abdos Freezing tube closure.

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 (1.8ml), 11.36 x 86.5 mm (4.5ml),

Cap Size : 13.2 mm (ϕ)

1.3.3 These coders are suitable for P60102, P60103 and P60118

1.3.4 Coders are available in wide range of colors.

1.3.5 These provide quick visual identification.

1.4 Material:

1.4.1 **HDPE** (High Density Polyethylene), Hydrophobic

1.4.2 This material meets the FDA criteria Regulation 21 CFR 177.1520. olefins 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: P60104 W- White P60104 B- Blue P60104 R- Red

P60104 Y- Yellow P60104 G- Green



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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 : 100 pieces/case

1.9 Basic Features

1.9.1 Temperature range : Tube : -196 °C to + 121 °C (Can withstand in liquid nitrogen with standard procedure, recommended to store in vapor phase of liquid nitrogen).

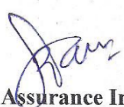
1.9.2 Autoclavability: Autoclavable at 15 psi and 121 °C for 20 minutes

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

1.9.4 Chemical resistance: see website.

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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