Technical Data Sheet

Doc No – Ab/TDS/Cryo-24

Rev No: 01

TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

Cryo Coders for External & Internal Threaded Vials, HDPE Valid for Cat. No. P60114 W, P60114 B, P60114 R, P60114 Y, P60114 G

- 1. Description/Specification
- **1.1 Description:** Freezing Cryo vials, DNase, RNase and Pyrogen Free
- 1.2 Design:
- 1.2.1 Vials: Cylindrical Cryo Coders for External & Internal Threaded Vials.
- 1.2.3 Cap: These coders fit onto the top of Abdos skirted foot cryogenic vial closures.
- 1.3 Performance Specifications:
- 1.3.1 **Coders colour**: P60114 W White P60114 B Blue

P60114 R - Red P60114 Y - Yellow P60114 G - Green

1.3.2 These provide quick visual identification.

1.4 Material:

- 1.4.1 High Density Polyethylene (HDPE), 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:** White, Blue, Red, Yellow, Green.



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1.6 Sterilization:

Sterile catalog number from this lot have been pre-sterilizes 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 0 C to + 121 0 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 ^oC 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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