

Technical Data Sheet

Doc No – Ab/TDS/Cryo-29

Rev No : 06 Date 04/2023-24

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

SRN (Single Registration Number): IN-MF-000022272

1. Description/Specification

1.1 Description: 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), confirm US FDA 21CFR

1.4.2 Complies with the requirement of European Pharmacopoeia, Plastic Containers and closures for Pharmaceutical use.

1.4.3 The product has passed the USP testing including class VI tests ,Materials has successful passed the biological tests according to ISO 10993 external communication devices for indirect blood contact for Prolonged period.

1.4.4 Free from Heavy metals, RoHS Free according to meets relevant requirements of EU regulations 1935/2004/CE ,2002/95/EC as amended, UE 10/2011 as amended. EU CONEG & it's following amendments. It is safe use in contact with food stuff, Pharmaceuticals & drinking water

1.4.5 Product is manufactured without the use of Raw Materials of animal origin. Therefore BSE/TSE issue does not concern this product to the best of our Knowledge. No materials containing latex or natural rubber are used in the Manufacturing, handling & packaging process for this product.

1.5 Color: White, Blue, Red, Yellow, Green.



Abdos Labtech Private Limited
(A Division of Abdos Group)
(An ISO 9001,13485,14001,18385,GMP & CE certified company)
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1.6 Sterilization:

NA

1.7 Quality control:

Product are manufactured, inspected and found to be in compliance with product & quality specification requirements as documented in ISO 9001:2015 & 13485:2016 Quality Management System. Testing of various characteristics in accordance with the valid specification, inspection reviewed & signed for product release.

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: Can be Autoclave

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

1.9.4 Chemical resistance: see website (www.abdoslifesciences.com)

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.

Instruction for Use

Product can be used for food contact also.

Storage temp. Max 30°C

Before using the product check crackness, pouch punctured etc.

Check all the information printed on pouches or boxes.

Always wear gloves while handling specimen.

WARNING

DO NOT store strong oxidizing agents.

DO NOT place any plastic labware in a flame.

DO NOT mix any chemicals that may result in a thermic reaction, which can cause product failure

Consult local fire codes prior to storage of flammable liquids.

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Quality Manager

Abdos Labtech Private Limited

Employee Code 30110



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