

Technical Data Sheet

Doc No – Ab/TDS/Cryo-22

Rev No: 01

TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

Cryo Vial External Threaded Sterile, PP

Valid for Cat. No. P60115, P60116, P60117, P60118

1. Description/Specification

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

1.2 Design:

1.2.1 Vials : Available in Star Foot, Round Bottom with External Thread

1.2.3 Cap: Separate Cap with threads.

1.3 Performance Specifications:

1.3.1 Vial Volume: 1.0 ml, 1.8 ml and 4.5 (\pm 0.1 ml)

1.3.2 Vial Size :

Code	Capacity (mm)	Outer Diameter (mm)	Height	No. Per Case	Self Standing	Bottom
P60115	1.0	12.00	41.00	1000	Yes	Star Foot
P60116	1.8	12.00	48.5	1000	Yes	Star Foot
P60117	1.8	12.00	47.5	1000	No	Round
P60118	4.5	11.36	86.5	500	Yes	Star Foot

1.4 Material:

1.4.1 Polypropylene (PP), 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.



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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

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

1.9. Basic Features

1.9.1 Temperature range : Tube : -196°C to $+121^{\circ}\text{C}$ (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 (Caps & Vials)

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

1.9.4 Large White frosted portion for easy writing & silk screen accurate graduation for sample identification.

1.9.5 These cryo vial are designed for mechanical freezing and screw cap reduces risk of contamination due to handling.

1.9.6 Star Foot Bottom base helps in single hand operation.

1.9.7 Secure tamper evident packaging along with self stand Zipper pouch.

1.9.8 No discolorization after re- sterilizing.

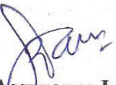
1.9.9 Chemical resistance: See website.

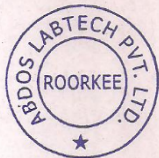


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Autoclaving Guideline for Plastics

All plastic consumables are autoclavable at 121⁰C 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 50⁰C before removing product.


Quality Assurance Incharge
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