

# Technical Data Sheet

Doc No – Ab/TDS/Cryo-26

Rev No : 10 Date 04/2023-24

## TECHNICAL DATA SHEET

**Abdos Labtech Pvt. Ltd.**

**Storage Vial, PP**

**Valid for Cat. No. P60119, P60106, P60107, P60119A, P60119A1, P60106A, P60106A1, P60107A, P60107A1, P60120, P60107S**

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

### 1. Description/Specification

**1.1 Description:** Disposable Storage vials, DNase, RNase, Human DNA, ATP & Pyrogen Free, IVD certified

#### 1.2 Design:

1.2.1 Vials: Cylindrical External Threads with Self standing, Skirted Foot, without Printed

1.2.3 Cap: Separate Cap with threads

#### 1.3 Performance Specifications:

1.3.1 Vial Volume: 1.0 ml (P 60119 – Natural, P60119A- amber, P60119A1- Tr. Amber)

1.3.2 Vial Volume: 2.0 ml (P 60106 – Natural, P60106A- amber, P60106A1- Tr. Amber)

1.3.3 Vial Volume: 5.0 ml (P 60107 – Natural, P60107A- amber, P60107A1- Tr. Amber)

1.3.4 Vial Volume: 2.0 ml (P 60120 – Natural, Sterile)

1.3.5 Vial Volume: 5.0 ml (P 60107S – Natural, Sterile)

Code	Capacity (mm)	Outer Diameter (mm)	Height	No. Per Case	Sterile	Bottom	Brimful Capacity (Approx ml)
P60119	1.0	12.00	41.00	1000	NO	Star Foot	1.70
P60119A	1.0	12.00	41.00	1000	NO	Star Foot	1.70
P60119A1	1.0	12.00	41.00	1000	NO	Star Foot	1.70
P60106	2.0	11.80	47.2	1000	NO	Skirted	2.80
P60106A	2.0	11.80	47.2	1000	NO	Skirted	2.80
P60106A1	2.0	11.80	47.2	1000	NO	Skirted	2.80
P60107	5.0	11.80	86.5	1000	NO	Skirted	5.35



**Abdos Labtech Private Limited**  
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P60107A	5.0	11.80	86.5	1000	NO	Skirted	5.35
P60107A1	5.0	11.80	86.5	1000	NO	Skirted	5.35
P60120	2.0	11.80	47.2	1000 (2x500)	YES	Skirted	2.80
P60107S	5.0	11.80	86.5	1000 (4x250)	YES	Skirted	5.35

## 1.4 Material:

1.4.1 **Tube:** Polypropylene (PP), Hydrophobic **Cap**-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:

Translucent, For Light Sensitive material – Amber & Transparent Amber color

## 1.6 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.

## 1.7 Other Information:

Recommended for single use only, Without Printing.

### Vial Pack Size :

**For 5.0ml** 1000 pieces/case ( 4 Pouch x 250pcs tube + 1pouch x 1000pcs cap) = 1 case or Assembled with Cap & Tube (4x250pcs)

**For 2.0ml** 1000 pieces/case ( 2 Pouch x 500pcs tube + 1pouch x 1000pcs cap) = 1 case or Assembled with Cap & Tube (4x250pcs)



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For 1.0ml 1000 pieces/case ( 2 Pouch x 500pcs tube + 1pouch x 1000pcs cap) = 1 case or Assembled with Cap & Tube (2 x500pcs)

## 1.8. Basic Features

**1.8.1 Temperature range:** Tube : -80 °C to + 121 °C

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

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

**1.8.4 Manufactured in Clean room ISO Class 8 (100,000)**

**1.8.5 Chemical resistance:** see website (www.abdoslifesciences.com)

## 2.0 Sterilization: For P60120 & P60107S

**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. SAL  $10^{-6}$

## 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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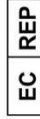
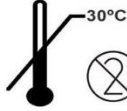
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Electronic IFU

Quality Manager

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P60107 P60106



P60119



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