

Technical Data Sheet

Doc No – Ab/TDS/CT-01

Rev No: 09 Date- 04/2023-24

TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

Micro Centrifuge Tube, PP, Sterile/Non-Sterile

Valid for Cat. No. P10201, P10202, P10203, P10204, P10204A, P10207, P10201A, P10205, P10203A, P10202KT, P10201ST, P10202ST, P10203ST, P10201IS, P10202IS, P10203IS

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

1. Description/Specification

1.1 Description:

Micro Centrifuge tube PP, DNase, RNase, Human DNA, ATP & Pyrogen Free, CE & IVD certified.

1.2 Design:

1.2.1 Tube: Cylindrical upper and conical bottom

1.2.2 Tube cap: Attached Snap Cap with lid open force kgf

1.3 Performance Specification:

| Code | Capacity (ml) | OD (mm) | Height (mm) | Sterile | Colour | No./Case |
|-----------------|---------------|---------|-------------|---------|---------------------------|------------------|
| P10201 | 0.5 | 10 | 31.5 | NO | Natural | 1000 (1x1000pcs) |
| P10202 | 1.5 | 13 | 41 | NO | Natural | 500 (1x500pcs) |
| P10203 | 2.0 | 13 | 41 | NO | Natural | 500 (1x500pcs) |
| P10207 | 0.5 | 10 | 31.5 | NO | Red, Blue, Yellow & Green | 1000 (1x1000pcs) |
| P10201A | 0.5 | 10 | 31.5 | NO | Amber | 1000 (1x1000pcs) |
| P10204 | 1.5 | 13 | 41 | NO | Red, Blue, Yellow & Green | 500 (1x500pcs) |
| P10204A | 1.5 | 13 | 41 | NO | Amber | 500 (1x500pcs) |
| P10205 | 2.0 | 13 | 41 | NO | Red, Blue, Yellow & Green | 500 (1x500pcs) |
| P10205A | 2.0 | 13 | 41 | NO | Amber | 500 (1x500pcs) |
| P10202KT | 1.5 | 13 | 41 | NO | Natural | 500 (1x500pcs) |
| P10201ST | 0.5 | 10 | 31.5 | YES | Natural | 1000 (4x250pcs) |
| P10202ST | 1.5 | 13 | 41 | YES | Natural | 500 (4x125pcs) |
| P10203ST | 2.0 | 13 | 41 | YES | Natural | 500 (4x125pcs) |

Abdos Labtech Private Limited
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| | | | | | | |
|-----------------|-----|----|------|-----|---------|---------|
| P10201IS | 0.5 | 10 | 31.5 | YES | Natural | 100pcs |
| P10202IS | 1.5 | 13 | 41 | YES | Natural | 100 pcs |
| P10203IS | 2.0 | 13 | 41 | YES | Natural | 100pcs |

1.4 Material:

1.4.1 Polypropylene (PP) 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 (Natural), Coloured (Red, Blue, Yellow & Green) and Amber

1.6 Graduation and Writing Surface

1.6.1 Large Molded Graduation

1.6.2 Frosted Surface for easy writing on tube

1.6.3 These tubes come with integral snap cap.

1.6.4 Amber coloured micro centrifuge tubes are suitable for light-sensitive samples. do not allow any light to pass through the tubes.

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, Available in Non Sterile & Sterile with Individual.

1.9 Basic Features

1.9.1 Temperature range: Tube: -80 °C to + 121 °C

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



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1.9.3 Centrifugation: 14,000* to 20,000 RCF (* Rated with Phenol/ Chloroform)

1.9.4 Leak Test at 635 mm Hg: No leakage

1.9.5 Boiling test: Pass at 100°C for 30 minutes in water bath.

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

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

2.0 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 control-Radiation sterilization*. The product has been sterilized with Co-60 Gamma Radiation. SAL 10^{-6}

Autoclaving Guideline for Plastics

All plastic consumable is Autoclavable at 121°C for 20 minutes, 15 psi/1atm. Do not use dry cycle as this may cause deformation or weakening of 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.

Ensure all sample tubes are evenly filled

For each tube inserted in the rotor, add a tube of equal weight directly opposite it.

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

Wear a face shield and / or safety goggles if you have to work anywhere near a centrifuge that's in use.

Do not bump, jar, or move the centrifuge while the rotor is spinning. Make sure you don't have the cord dangling from a table edge where someone could catch their foot in it and pull down the centrifuge

Consult local fire codes prior to storage of flammable liquids.



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Quality Manager

Abdos Labtech Private Limited

Employee Code 30110



P10201



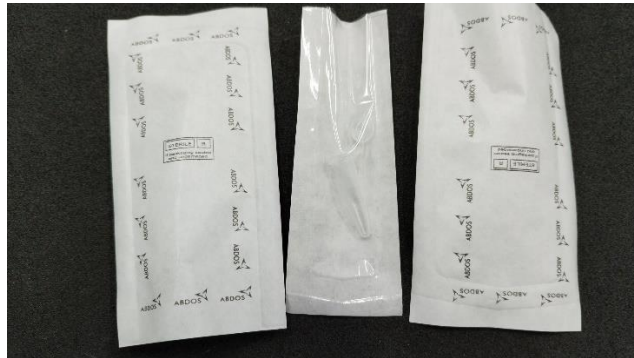
P10202



P10203



P10204A



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