

Technical Data Sheet

Doc No – Ab/TDS/CT-09

Rev No : 09 Date 04/2023-24

TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

Racked Centrifuge Tube Conical Bottom, Paper

Valid for Cat. No. Paper Rack: P10409 (15ml), P10410 (50ml)

Racked Non-Sterile: P10411, P10413, P10415, P10417

Racked Sterile: P10412, P10414, P10416, P10418, P10462, P10463, P10455

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

1. Description/Specification

1.1 Description:

Disposable PP/PS Tube, HDPE Cap & Paper rack, 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: Separate Threaded HDPE Cap

1.2.3 Rack: These racks are made of eco-friendly paper to hold 25 Abdos 15 ml & 50 ml Conical Bottom Centrifuge Tubes.

1.3 Performance Specifications:

| Code | Capacity (ml) | OD (mm) | Height (mm) | Sterile | Tube | Cap Colour | No./Case |
|---------------|---------------|---------|-------------|---------|---------|------------|--------------------|
| P10409 | 15 | NA | 47 | NO | NA | White | 10 |
| P10410 | 50 | NA | 48 | NO | NA | White | 10 |
| P10411 | 15 | 16.5 | 121 | NO | Natural | Blue | 500(25pcsx20racks) |
| P10412 | 15 | 16.5 | 121 | YES | Natural | Blue | 500(25pcsx20racks) |
| P10462 | 15 | 16.5 | 121 | YES | Natural | White | 500(25pcsx20racks) |
| P10413 | 15 | 16.5 | 121 | NO | Amber | Blue | 500(25pcsx20racks) |
| P10414 | 15 | 16.5 | 121 | YES | Amber | Blue | 500(25pcsx20racks) |
| P10455 | 15 | 16.5 | 121 | YES | Natural | Red | 500(25pcsx20racks) |
| P10415 | 50 | 29.2 | 116 | NO | Natural | Blue | 500(25pcsx20racks) |



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|---------------|----|------|-----|-----|---------|-------|--------------------|
| P10416 | 50 | 29.2 | 116 | YES | Natural | Blue | 500(25pcsx20racks) |
| P10417 | 50 | 29.2 | 116 | NO | Amber | Blue | 500(25pcsx20racks) |
| P10418 | 50 | 29.2 | 116 | YES | Amber | Blue | 500(25pcsx20racks) |
| P10463 | 50 | 29.2 | 116 | YES | Natural | White | 500(25pcsx20racks) |

1.4 Material:

Rack- Paper

1.4.1 Tube - Polypropylene (PP) & Cap- 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:

Tube color- Translucent (Natural), and Amber

Cap color- Blue/White/Red

Paper Racked Color: White

1.6 Graduation and writing surface:

1.6.1 Large Printed Graduation

1.6.2 White Patch for easy writing on the tube

1.6.3 Printed Max Freze Level Indicator with Red Colour

1.7 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, SAL 10^{-6}



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1.8 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.

1.9 Other Information:

Recommended for single use only

Pack Size: P10409 & P10410- 10 pcs/case

P10411, P10413, P10415, P10417, P10463– **500 Pcs (25X 20 Racks) case**

P10412, P10414, P10416, P10418, P10462, P10455– **500 Pcs (25X 20 Racks) case**

2. Basic Features

2.1 Temperature range: Tube: -80⁰C to +121⁰C (PP), -10⁰C to + 70⁰C (PS)

2.2 Autoclavability: Only PP is Autoclavable at 15 psi and 121⁰C for 20 minutes

2.3 Centrifugation: 18,000 RCF (Rated with Double Distilled water at 25⁰C for 30 minutes)

(Only PP Tubes)

2.4 Leak Test at 635 mm Hg: No leakage

2.5 These racks are made of eco-friendly paper to hold 25 pieces of CT 15 & 50ml.

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

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

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.

Instruction for Use

Product can be used for food contact also.

Storage temp. Max 30⁰C

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.



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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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