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 regulations1935/2004/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:

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: -80° C to $+121^{\circ}$ C (PP), -10° C to $+70^{\circ}$ C (PS)

2.2 Autoclavability: Only PP is Autoclavable at 15 psi and 121^oC for 20 minutes

2.3 Centrifugation: 18,000 RCF (Rated with Double Distilled water at 25°C 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 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.

Ensure all sample tubes are evenly filled

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

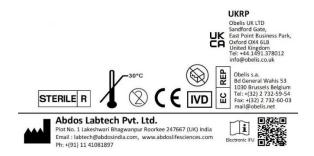


WARNING

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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