

Technical Data Sheet

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TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

PureRight Individually Wrap Centrifuge Tubes, PP/HDPE

Valid For Cat. No. P10425, P10426, P10427, P10451, P10452, P10453

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

1. Description/Specification

1.1 Description:

Disposable PP/HDPE centrifuge tube, DNase, RNase, Human DNA, ATP & Pyrogen Free, CE & IVD certified

1.2 Design:

1.2.1 Tube: Cylindrical Upper and conical Bottom with self-stand (skirted) & Conical Bottom

1.2.2 Tube Cap: Separate Threaded HDPE Cap

1.3 Performance Specifications:

Code	Capacity (ml)	OD (mm)	Height (mm)	Sterile	Colour	No./Case
P10425	15	16.5	121	YES	Blue	600
P10451	15	16.5	121	YES	Red	600
P10426	50	29.2	116	YES	Blue	350
P10452	50	29.2	116	YES	Red	350
P10427	50	29.2	117.3	YES	Blue	350
P10453	50	29.2	117.3	YES	Red	350

1.4 Material:

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.



Abdos Labtech Private Limited
(A Division of Abdos Group)
(An ISO 9001,13485,14001,18385,GMP & CE certified company)
Shiv Ganga Industrial Estate
Plot No-1, Lakheswari, Bhagwanpur,
Roorkee-247667, (UK) INDIA

Registered office
13A Government
Place East, 2nd Floor Kolkata
West Bengal – 700069
CIN: U85100WB2008PTC123903
Corporate Office
319, 3rd Floor, DLF Tower A, DDA Dist. Centre
Jasola, New Delhi - 110025

Ph. No: +91- (0) 1332235277
Email: labtech@abdosindia.com
Web: www.abdoslifesciences.com
GST: 05AAGCA8605A1Z7

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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 & its 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)

Cap color- Blue/Red

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 Freeze Level Indicator with Red Colour

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

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

2. Basic Features

2.1 Temperature range: Tube: -80°C to $+121^{\circ}\text{C}$

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

2.3 Centrifugation: 7000 RCF Self Stand & 18000 RCF Conical (Rated with Double Distilled water at 10°C for 30 minutes)

2.4 Leak Test at 635 mm Hg: No leakage

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

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

**Depending on the quality of Centrifuge and compatibility of Rotor.*



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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.

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.

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.



UKRP
Obelis UK LTD
Sandford Gate,
East Point Business Park,
Oxford OX4 6LB
United Kingdom
Tel: +44.1491.378012
info@obelis.co.uk

UK CA

STERILE R

30⁰C

CE

IVD

UC REP

Obelis s.a.
Bd General Wahis 53
1030 Brussels Belgium
Tel: +32) 2 732-59-54
Fax: +32) 2 732-60-03
mail@obelis.net

Abdos Labtech Pvt. Ltd.
Plot No. 1 Lakshewari Bhagwanpur Roorkee 247667 (UK) India
Email : labtech@abdosindia.com, www.abdoslifesciences.com
Ph: +(91) 11 41081897

Electronic #U

Quality Manager

Abdos Labtech Private Limited

Employee Code 30110



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