

# Technical Data Sheet

Doc No – Ab/TDS/CC-99

Rev No : 02 Date 02/2022-23

## TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

### Bio Reaction Tubes, PP/HDPE

Valid For Cat. No. P21070, P21071, P21072

#### 1. Description/Specification

##### 1.1 Description:

Disposable PP/HDPE Bio Reaction Tubes, DNase, RNase, Human DNA, ATP & Pyrogen Free, CE & IVD certified

##### 1.2 Design:

1.2.1 Tube: Cylindrical Upper, conical & self –stand bottoms

1.2.2 Tube Cap: Separate Threaded HDPE Cap with vent & membrane filters

##### 1.3 Performance Specifications:

| Code          | Capacity (ml) | OD (mm) | Height (mm) | Bottom     | No./Case |
|---------------|---------------|---------|-------------|------------|----------|
| <b>P21070</b> | 15            | 16.5    | 121         | Conical    | 100      |
| <b>P21071</b> | 50            | 29.2    | 116         | Conical    | 100      |
| <b>P21072</b> | 50            | 29.2    | 117.3       | Self-stand | 100      |

##### 1.4 Material:

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

1.4.2 Poly Propylene (PP), Hydrophobic, confirm US FDA 21CFR & High Density poly Ethylene (HDPE), Hydrophobic, confirm US FDA 21CFR

1.4.3 Complies with the requirement of European Pharmacopoeia, Plastic Containers and closures for Pharmaceutical use.

1.4.4 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.

1.4.5 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



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1.4.6 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-** Green

## 1.6 Graduation and writing surface:

1.6.1 Large Printed Graduation

1.6.2 White Patch for easy writing on the tube

## 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 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

1.9.1 Recommended for single use only

1.9.2 ABDOS Bio-Reaction tubes are manufactured with high purity virgin Class VI Medical grade polypropylene (PP) conforming to US FDA 21 CFR, free from natural rubber & heavy metal.

1.9.2 Bioreaction tubes are convenient and economical option for small scale, high density suspension cell culture and are ideal for biological reaction experiments that require aseptic conditions with free gas exchange.

1.9.3 These tubes consist of ultrasonically welded 0.22um hydrophobic membrane to allow gas exchange.

1.9.4 These tubes come with a large unerasable frosting white printed writing area and engraved graduation.

## 2. Basic Features

**2.1 Temperature range:** Tube:-80<sup>0</sup>C to +121<sup>0</sup>C

**2.2 Autoclavability:** Yes, Autoclavable at 15 psi and 121<sup>0</sup>C for 20 minutes

**2.3 Centrifugation:** 12,000 RCF (15ml), 16,000 RCF (50ml conical) & 6,000 RCF (50ml Self-stand)

**2.4 Leak Test :** No leakage



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

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

## Autoclaving Guideline for Plastics

All plastic consumables are autoclavable at 121<sup>0</sup>C for 20 minutes, 15 psi/1atm. Do not use cycle as this may cause deformation or weakening of the plastic. Allow temperature within the autoclave to return to at least 50<sup>0</sup>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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