Doc No-Ab/TDS/Micro-84

Rev No: 00 Date 05/2024-25

TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

Contact Plate, PS- Gama Radiated Sterile

Valid for Cat. No. P10950, P10951, P10952, P10953, P10954, P10958, P10959, P10960, P10961, P10962, P10963, P10964, P10965

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

1. Description/Specification

1.1 Description: Contact Plate- Gama Radiated Sterile, DNase, RNase, Human DNA, ATP, Pyrogen Free, CE certified

1.2 Design: Shallow dish design

- **1.2.1** Abdos Contact plates offers the best solutions for surface monitoring for cleanliness of the cleanrooms and laboratories.
- **1.2.2** All Abdos contact plates are manufactured under Class 8 cleanroom facility to minimize the risk of contamination and are further sterilized by Gamma irradiation.
- **1.2.3** The contact plates are available in Flat and Dome bases and are also available in vent and non-vent variants. 10x10mm Grid base for easy cell counting. 25cm² growth area. Tight closure for better handling. All Abdos Sterile Contact Plates are validated according to ISO 11137.

Code	Sterile	Shape	Diameter (mm)	Height (mm)	Compartment	Vented	Packing	No. Per Case
P10950	Sterile	Flat	65	15	No	3 Vent	Sleeve of 10	400
P10951	Sterile	Flat	65	14.8	No	0 Vent	Sleeve of 10	400
P10952	Sterile	Dome	65	15	No	3 Vent	Sleeve of 10	400
P10953	Sterile	Dome	65	14.8	No	0 Vent	Sleeve of 10	400
P10954	Aseptic	Flat	65	15	NO	3 Vent	Sleeve of 10	400

1.3 Performance Specifications:



Abdos Labtech Private Limited (A Divison 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

Dual Wrap

Code	Sterile	Shape	Diameter (mm)	Height (mm)	Compartment	Vented	Packing	No. Per Case
P10958	Sterile	Flat	65	15	No	3 Vent	Sleeve of 10	300
P10960	Sterile	Flat	65	14.8	No	0 Vent	Sleeve of 10	300
P10962	Sterile	Dome	65	15	No	3 Vent	Sleeve of 10	300
P10964	Sterile	Dome	65	14.8	No	0 Vent	Sleeve of 10	300

Triple Wrap

Code	Sterile	Shape	Diameter (mm)	Height (mm)	Compartment	Vented	Packing	No. Per Case
P10959	Sterile	Flat	65	15	No	3 Vent	Sleeve of 10	300
P10961	Sterile	Flat	65	14.8	No	0 Vent	Sleeve of 10	300
P10963	Sterile	Dome	65	15	No	3 Vent	Sleeve of 10	300
P10965	Sterile	Dome	65	14.8	No	0 Vent	Sleeve of 10	300

1.4 Material:

1.4.1 Contact Plates are made up of Hydrophobic Polystyrene (PS), Confirm with 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 successfully 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, the 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: Transparent (Natural color)

1.6 Quality control:

Products 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.



Abdos Labtech Private Limited (A Divison 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

1.7 Other Information

- 1.7.1 Contact Plates are suitable for all bacteriological/Microbiological applications.
- 1.7.2 Vented dishes have an elevated lid that allows for superior gas exchange and evaporation.
- 1.7.3 Plates retain their shape up to 55°C.
- 1.7.4 Filled media with approx. 13 ml in Flat & approx. 10ml in Dome Plates.
- 1.7.5 Recommended for single use only
- 1.7.6 Available in Dual & Triple wrap also.

1.8 Basic Features

1.8.1 Temperature range: Stable up to 60°C.

1.8.2 Autoclavability: NO

1.8.3 Chemical resistance: See website (<u>www.abdoslifesciences.com</u>)

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

1.8.5 Intended use: Widely used in scientific studies of molecular biology, clinical chemistry, biochemistry and any type of scientific laboratory.

1.9 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

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 specimens.

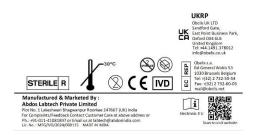
WARNING

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 Consult local fire codes prior to storage of flammable liquids.



Abdos Labtech Private Limited (A Divison 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





Rowi BTEC Quality Manager QUALITY DEPT. Abdos Labtech Private Limite **BB** Employee Code 30110 KET



Abdos Labtech Private Limited (A Divison 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