

Technical Data Sheet

Doc No – Ab/TDS/PCR-103

Rev No: 03 Date 01/2021

TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

Strip Caps , PP

Valid for Cat. No. P10709, P10710, P10711, P10712

1. Description/Specification

1.1 Description:

Strip Caps, PP, DNase, RNase, Human DNA, ATP & Pyrogen Free, IVD & ISO
18385 certified

1.2 Design:

Strip Caps.

1.3 Performance Specification:

Code	Capacity (ml)	Type	No. per Case
P10709	0.2	8 Strip Cap Flat Optically Clear	125 Strips
P10710	0.2	12 Strip Cap Flat Optically Clear	80 Strips
P10711	0.2	8 Strip Cap Domed	125 Strips
P10712	0.2	12 Strip Cap Domed	80 Strips

1.4 Material:

1.4.1 Polypropylene (PP), Hydrophobic, confirm US FDA 21CFR

1.4.2 Complies with requirement accordance with article of regulation (EC) No. 1907/2006 and its amendments.

1.4.3 Complies with the requirement of European Pharmacopoeia, 7th edition (2011) & its supplements 7.5 (07/2012) monographs 3.2.2 Plastic Containers and closures for Pharmaceutical use.

1.4.4 The product has passed the USP testing including class VI tests & has been assigned the FDA Drug master file DMF 12123



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CIN : U85100WB2008PTC123903

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1.4.5 Materials has successful passed the biological tests according to ISO 10993 external communication devices for indirect blood contact for Prolonged period.

1.4.6 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

1.4.7 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:

Translucent (Natural)

1.6 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

1.7 Other information

1.7.1 DNase, RNase, DNA, Endotoxin and PCR inhibitor.

1.7.2 Recommended for Single use only

1.7.3 Have a longer length and even cap insertion that ensures tight fit eliminating the risk of sample evaporation.

1.8 Basic Features

1.8.1 **Temperature range:** -80 °C to + 121°C

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

1.8.3 **Manufactured in Aseptic Environment**

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

1.8.5 **Optically clear for real time qPCR**



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Autoclaving Guideline for Plastics

All plastic consumable are Autoclavable at 121⁰C for 20 minutes, 15 psi/1atm. Do not use dry cycle as this may cause deformation or weakening of plastic. Allow temperature within the autoclave to return to at least 50⁰C before removing product.



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