Technical Data Sheet

Doc No – Ab/TDS/PCR-105

Rev No: 06 Date 04/2023-24

TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

AmpQlear™ PCR 8 Strip Caps, PP

Valid for Cat. No. P10709, P10711

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

1. Description/Specification

1.1 Description:

8 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)	Туре	No. per Case
P10709	0.2 & 0.1	8 Strip Cap Flat Optically Clear	125 Strips
P10711	0.2 & 0.1	8 Strip Cap Domed	125 Strips

1.4 Material:

1.4.1 Polypropylene (PP), Hydrophobic, 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.



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

Ph. No: +91- (0) 1332235277 Email:labtech@abdosindia.com Web: <u>www.abdoslifesiences.com</u> GST: 05AAGCA8605A1Z7

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 free.

1.7.2 Recommended for Single use only

1.7.3 Thin and uniform wall thickness to ensure optimal heat transfer reducing insulating effect.

1.7.4 Snap cap ensures tight fit eliminating risk of sample evaporation. Flat caps are optically clear for real time qPCR.

1.8 Basic Features

- **1.8.1 Temperature range:** $-80 \ {}^{0}C$ to $+ 121 \ {}^{0}C$
- 1.8.2 Autoclavability: Yes, Autoclavable at 15 psi and 121 ⁰C 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

Autoclaving Guideline for Plastics

All plastic consumable are Autoclavable at 121° C 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 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.



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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.





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