

ANALYSIS CERTIFICATE

APACOR

Product Name	CELLULOSE ACETATE MEMBRANE 5.7 x 14.4cm
Description	Cellulose Acetate Membrane
Part Number	82300
Lot Number	NSL293214
Date of Manufacture	12/2014
Expiry Date	10/2019
Pack Size	50
Storage	N/A
Country of Origin	UK
Date of Sterilization	N/A
BST/TSE Statement	N/A
Non-Pyrogenic	N/A
DNase & RNase Free	N/A
Cytotoxicity	N/A
Latex Free	Yes

1. Composition

Cellulose acetate membrane.

2. Intended Use

Used in the diagnosis of haemoglobinopathies including Sick Cell Diseases and Thalassemia.

3. Test Procedure

Allow the membrane to soak fully using Apacor High Resolution Buffer II. Dry with absorbent pads and then place the applicator block onto the membrane. Load a 25µl sample in a 15 second application. Remove the membrane from the Electrophoresis Chamber and transfer to vessel containing Ponceau S Solution. Remove the excess with 5% acetic acid solution. Place the membrane in clearing solution. The membrane will clear, giving high resolution banding. Ensure that the Electrophoresis Chamber is filled with High Resolution Buffer and that the polarity of the chamber is correct. Electrophorese for 20 minutes at 2-10 milliamps. Migrations patterns should be compared to a known control. For quantitative determination, use densitometry or elute separated fractions. When using Ponceau S Solution, the densitometric scan should be undertaken at 525nm.

4. Laboratories that it will be used in

Private and public medical analysis laboratories.

5. Dangerous Components/Radioactivity

N/A

6. Purpose of Product

For in vitro diagnostic use only.

7. Specifications

This product is Class I category device as defined by the FDA in 21CFR Parts 862-892.

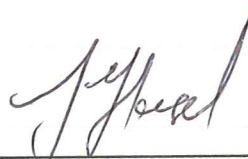
8. Quality System Compliance

This product is manufactured under ISO 9001 and ISO 13485 certified Quality Systems and is IVD CE registered.

The above stated product was analysed by our authorised quality control department on 25th April 2015.

and found to be consistent with the specifications.

This Analysis Certificate is valid for two years from the date of signature.



Quality Manager
25th April 2015

APACOR LIMITED, UNIT 5, SAPPHIRE CENTRE, FISHPONDS ROAD, WOKINGHAM, BERKSHIRE, RG41 2QL, ENGLAND



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