

C
E
R
T
I
F
I
C
A
T
E

O
F

A
N
A
L
Y
S
I
S

Cat No: 12170501
Manf Date: 24/03/2015

Batch No: 121704201
Expiry Date: 23/03/2018

Size: 2mL

SPECIFICITY:

Blood Group S Antigen.

DESCRIPTION:

Human Monoclonal IgM Phenotyping Reagent.

PRESERVATIVE AND ADDITIVES:

Sodium Azide 0.1% w/v, Bovine Albumin and Macromolecular Potentiators.

SAFETY PRECAUTIONS:

For *in vitro* diagnostic use only. The material from which this product was derived was found to be non-reactive for specified markers for HIV 1 and 2, Hepatitis B and C, HTLV and Syphilis by currently approved methods. However no known method can assure that products derived from human blood will not transmit infectious agents.

Sodium Azide 0.1% w/v is added as a preservative. Users should be aware of the toxicity and cumulative explosive nature of Sodium Azide and take appropriate precautions when handling and discarding this reagent. This product should be clear; turbidity may indicate bacterial contamination. The reagent should not be used if a precipitate or particles are present.

STORAGE RECOMMENDATIONS:

Store at 2° to 8°C (Refrigerate. Do Not Freeze).

INTENDED USE:

For *in vitro* diagnostic use only. This product is not intended for therapeutic use.

RESULTS:

Test	Test Limits	Result
Potency	A score of ≥ 5 at a titre of 4.	Pass
Specificity	Score must be 0 with all antigen negative cells Score must be ≥ 8 with antigen positive cells.	Pass
Microbial Contamination Detection Test	Pass if no contamination detected.	Pass

Batch Release

Satisfactory Results, when tested by all methods recommended in the product leaflet:	Yes
Date of QA Approval:	26/02/2016

Signed: Dr. Leonora Pancho 
Director, Quality Control (QC), Seqirus Pty Ltd

Dated: 10 Mar 2016