

**Cat No:** 12170501

**Batch No:** 121704801

**Manf Date:** 05/09/2017

**Expiry Date:** 04/09/2020

**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 $\geq 5$ at a titre of 4.	Pass
Specificity	Score must be 0 with all antigen negative cells Score must be $\geq 8$ 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:	19/01/2018

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

Dated: 31-Jan-18