

Cat No: 11980501 **Batch No:** 119802401
Manf Date: 02/09/2014 **Expiry Date:** 01/09/2017

Size: 2mL

SPECIFICITY:

Blood Group C^w 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
Avidity	Time for agglutination to commence < 60 secs with a score of ≥ 8 at 3 minutes.	Pass
Specificity	Score must be 0 with all antigen negative cells Score must be ≥ 8 with antigen positive cells.	Pass
Sterility	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: 23/07/2015

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

Dated: 30th July 2015