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Certificate of Analysis

Product Name	Epiclone™ Anti-S Monoclonal Phenotyping Reagent
Catalogue No	12170501
Batch No	121705001
Manufacture Date	24/07/2018
Expiry Date	23/07/2021

This certifies that the Quality Control testing of this product (as represented by the attached certificate of analysis) has been performed by Seqirus on behalf of Immulab Pty Ltd.



WeeLing Lai
Regulatory & Quality Assurance Manager
Immulab Pty Ltd – A ParagonCare Company

Cat No: 12170501 **Batch No:** 121705001
Manf Date: 24/07/2018 **Expiry Date:** 23/07/2021

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

A. Prendegast
for Signed: Dr. Leonora Pancho *A. Prendegast*
Site Head, Quality Control (QC), Seqirus Pty Ltd

Dated: 05-DEC-18