



## ISOTYPIC CONTROL

### For In Vitro Diagnostic Use

### INTENDED USE

COULTER CLONE MslgG1 Isotypic Control Reagent is intended for use as a quality control reagent to monitor the levels of nonspecific antibody binding in cell surface staining procedures which use COULTER CLONE monoclonal antibody reagents of the mouse IgG1 subclass.

COULTER CLONE MslgG1 is intended "For In Vitro Diagnostic Use" when used with COULTER CLONE monoclonal antibody reagents labeled "For In Vitro Diagnostic Use." All other uses are "For Research Use Only. Not For Use In Diagnostic Procedures."

### ANTIBODY SPECIFICITY

The MslgG1 antibody is used to monitor the level of nonspecific staining in cell staining procedures which use antibodies of the mouse IgG1 subclass.<sup>1-3</sup>

### REAGENT

Coulter Clone MslgG1

PN 6602872 - 100 tests (0.5 mL)

**CLONE:** 2T8-2F5 was derived from the hybridization of mouse NS-1 cells with spleen cells from BALB/c mice.

**lg CHAIN:** Mouse IgG1 heavy and kappa light chains

**SOURCE:** Conditioned media

**PURIFICATION:** Affinity chromatography

### REAGENT CONTENTS

The final concentration of nonantibody reagents when reconstituted is 0.2% BSA, 0.01 M potassium phosphate, 0.15 M NaCl, 0.1% NaN<sub>3</sub>.

### STATEMENT OF WARNINGS

1. This reagent contains 0.1% sodium azide. Sodium azide under acid conditions yields hydrazoic acid, an extremely toxic compound. Azide compounds should be flushed with running water while being discarded. These precautions are recommended to avoid deposits in metal piping in which explosive conditions can develop. If skin or eye contact occurs, wash excessively with water.
2. Specimens, samples and all material coming in contact with them should be handled as if capable of transmitting infection and disposed of with proper precautions.
3. Never pipet by mouth and avoid contact of samples with skin and mucous membranes.
4. Do not use reagent beyond the expiration date on the vial label.
5. Minimize exposure of reagent to light during storage or incubation.

6. Avoid microbial contamination of reagent or erroneous results may occur.
7. Use Good Laboratory Practices (GLP) when handling this reagent.
8. Harmful if swallowed.
9. After contact with skin, wash immediately with plenty of water.

### STORAGE CONDITIONS AND STABILITY

Lyophilized reagent is stable to the expiration date on the vial label when stored at 2-8°C. Do not freeze. Minimize exposure to light.

Reconstituted stock solution of lyophilized reagent is stable as follows:

- 6 months when stored at 2-8°C or 0 to -20°C when reconstituted using the Reconstitution Procedure described in the REAGENT PREPARATION section. If all of a reconstituted reagent is not to be used within 6 months, follow the Freezing Procedure.
- 1 year when stored at -70°C using the Freezing Procedure.

### Freezing Procedure

#### MATERIALS REQUIRED BUT NOT SUPPLIED:

PBS - Phosphate Buffered Saline (pH=7.2)

PN 6603369

PBS containing 2% heat-inactivated fetal or new born calf serum (FCS). Dilute 2 mL of calf serum to 100 mL with PBS.

1. Dilute the reconstituted stock solution of the COULTER CLONE reagent with PBS containing 2% FCS prior to freezing as follows:  
Add 5 µL of reconstituted stock solution (1 test\*) to 100 µL PBS with 2% FCS\*\*.  
\*These may be frozen in multiple test volume aliquots.  
\*\*This yields 2X the concentration of the working solution.
2. Prior to use, allow the frozen aliquot to reach 20-25°C.
3. The frozen aliquot, at 2X the final concentration, must be further diluted to equal the total volume as calculated in the REAGENT PREPARATION section. Dilute each aliquot with the appropriate volume of PBS without 2% FCS and mix well.
4. Avoid repeated freeze/thaw cycles. This will denature the antibody protein.
5. Do not store in a self-defrosting freezer.

### EVIDENCE OF DETERIORATION

Any change in the physical appearance of this reagent\*, or any major variation in values obtained for control samples may indicate deterioration and the reagent should not be used. If the lyophilized material appears moist, do not use.

#### \*Normal Appearance of Reagents

Lyophilized-white plug

Reconstituted-clear, colorless liquid

### REAGENT PREPARATION

Reconstitute the lyophilized COULTER CLONE reagent by adding 500 µL of distilled water to the vial. This is the stock solution. Centrifuge the stock solution at 20-25°C at 100,000 x g for 10 minutes to optimize staining results. Use this liquid reagent directly from the vial as the stock solution. The reagent working solution\* is prepared as follows (volume listed is on a per test basis):

Add 5 µL of stock solution to 195 µL PBS\*\*.

\*Diluted reagent working solution is good for day of preparation only.

\*\*PBS - Phosphate Buffered Saline (pH=7.2).

Bring reagent to 20-25°C prior to use.

### USAGE

This reagent is for use with standard flow cytometry methodologies using whole blood lysis or mononuclear

cell preparation techniques. Refer to the COULTER CLONE monoclonal antibody reagent package insert for instructions on how to use this control reagent.

### SELECTED RESEARCH REFERENCES

1. ASHI Standards For Clinical Flow Cytometry and Cell Surface Phenotyping Laboratories. 1987. ASHI Quarterly 11(1).
2. National Committee For Clinical Laboratory Standards: Clinical Applications of Flow Cytometry: Quality Assurance and Immunophenotyping of Peripheral Blood lymphocytes; Tentative Guideline. 1992. NCCLS Document H42-T, pp. 12, 13, 37, 38.
3. Flow Cytometry Inspection Checklist. Fall 1988. College of American Pathologists, Commission on Laboratory Accreditation, p.9.

### PRODUCT AVAILABILITY

COULTER CLONE MslgG1

PN 6602872 - 100 tests (0.5 mL)

For additional information in the USA, call 800-526-7694. Outside the USA, contact your local Beckman Coulter Representative.

### TRADEMARKS

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