

HLA Testing Control Reagents

REF**Catalog # NS, ABSM, ABSG, AGSM, ATSG, ATSM, ATSMX, ALSG, ALSM**

For Research Use Only. Not for use in diagnostic procedures.

SUMMARY AND EXPLANATION

The Normal Serum Control (OLI Cat. #NS) is used to determine background cell death. The Normal Serum Control is human serum from non-transfused male donors with blood type AB negative.

The Anti-B Cell Controls (OLI Cat. #s ABSM, ABSG) are used to determine the purity of B lymphocytes. The anti-B lymphocyte controls are monoclonal antibodies that are strongly cytotoxic to B lymphocytes with no reactivity against granulocytes, T lymphocytes, platelets, monocytes and red blood cells.

The Anti-Granulocyte Control (OLI Cat. # AGSM) is used to determine the purity of granulocytes. The anti-granulocyte control consists of monoclonal antibodies that are strongly cytotoxic to granulocytes with no reactivity against B lymphocytes, T lymphocytes, platelets, monocytes and red blood cells.

The Anti-Monocyte Control (OLI Cat. # AMSM) is used to determine the purity of monocytes. The anti-monocyte control consists of monoclonal antibodies that are strongly cytotoxic to monocytes with no reactivity against granulocytes, B lymphocytes, T lymphocytes, platelets, and red blood cells.

The Anti-T Lymphocyte Controls (OLI Cat. #s ATSG, ATSM, ATSMX) are used to determine the purity of T lymphocytes. The anti-T lymphocyte controls are monoclonal antibodies that are strongly cytotoxic to T lymphocytes with no reactivity against granulocytes, monocytes, B lymphocytes, platelets and red blood cells. **Note:** ATSMX is the only anti-T control for use with FluoroBeads® T-isolated cells.

The Anti-Lymphocyte Controls (OLI Cat. #s ALSG, ALSM) are used to determine complement reactivity. The anti-Lymphocyte controls are monoclonal antibodies that are strongly cytotoxic to human lymphocytes with no reactivity against granulocytes, monocytes, platelets, and red blood cells.

Note: DTT is known to deactivate IgM, but not IgG. *Do not use ALSM, ALSG, ATSG, ATSM, or ATSMX as a control for testing with Dithiothreitol (DTT), 5Mm DTT used to deactivate human IgM does not deactivate ALSM, ATSM, and ATSMX because they are mouse monoclonal IgM antibodies and their disulfide bonds are not broken by DTT.*

Viable lymphocytes are incubated with complement-binding antibody. If the lymphocytes express an antigen recognized by a specific antibody, the Fab portion of the antibody binds to the antigen forming antigen-antibody complex. After these complexes have formed, rabbit complement is added. The C1q and Ca⁺⁺ from the complement bind to the FC portion of the antibody. One IgM antibody is required to bind one molecule of C1q or two IgG antibodies are required to bind one molecule of C1q. Binding of C1q with antigen-antibody complexes initiates the complement cascade that leads to cell lysis. In a negative reaction, the lymphocytes are alive. In a positive reaction, the lymphocytes are dead.

REAGENTS

A. Identification

Testing Control Reagents are supplied frozen (1ml). Specificity and dilution factors are determined by the microcytotoxicity test using NIH standard conditions. Subtypes: Catalog numbers with an "M" indicate the antibody is IgM, and those with a "G" indicate the antibody is IgG.



B. Warning or Caution

1. **Warning/Caution:** All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when tested in accordance with current FDA required tests. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents.
2. Refer to the Material Safety Data Sheet for detailed information.

**C. Preparing Reagents for Use**

1. See "Directions for Use."

D. Storage Instructions

Store reagents at temperature indicated on package. Use before printed expiration date. Avoid high temperature. ***Avoid repeated freezing and thawing of control reagents.***

E. Purification or Treatment Required for Use

See "Directions for Use."

F. Instability Indications

Do not use if antibody is not stored properly.

SPECIMEN COLLECTION AND PREPARATION

- A. Since viable lymphocytes are required for serological typing, blood should be received and processed immediately following procurement. Lymphocyte yield decreases with time and extreme temperature. Blood should be collected in acid citrate dextrose (ACD) or sodium heparin, stored horizontally at room temperature (20 - 25°C), and processed within 48 hours for maximum T and B lymphocyte yield.

PROCEDURE

A. Materials Provided

1. Vial of HLA Testing Control Reagent
2. Instructions for Use

B. Recommendations for Use

1. Frozen Reagents
 - a. Thaw in cold tap water.
 - b. Frozen control reagents are provided at cytotoxic working dilutions for immediate use.

RESULTS

None. Product is for Research Use Only.

LIMITATIONS OF THE PROCEDURE

- Erroneous results may occur when cell concentrations are above or below acceptable levels. Bacterial contamination or change in pH of the antisera may cause false negative reactions.
- Product is for research use only and not to be used in diagnostic procedures.

EXPECTED VALUES

None. Product is for Research Use Only.

SPECIFIC PERFORMANCE CHARACTERISTICS

None. Product is for Research Use Only.

EXPLANATION OF SYMBOLS

Symbol	Description
	Catalogue number
	Consult accompanying documents
	Temperature limitation
	Manufacturer

REVISION HISTORY

Revision	Date	Revision Description
11	2014/08	Update to new template. Updated Summary and Explanation section.
01	04/08/2019	Upgraded Internal Document Control System. No changes to the document content.
02	Current	Updated contact information and address to reflect change in legal manufacture site.