Class I and Class II Complement

REF **Catalog #s CABC-5, CABC-50, CDR5, CDR50, CABC-1D, and CDR-1D**

Important: *Instructions in this product insert must be used in conjunction with the product insert for Terasaki HLA Tissue Typing Trays. Complement is used in the preparation of cytotoxicity assays.*

IVD For In Vitro Diagnostic Use.

INTENDED USE

For use in complement dependent cytotoxicity assays for determining HLA Class I and Class II cell surface antigens.

SUMMARY AND EXPLANATION

Rabbit serum is a source for complement for the microcytoxicity test. ABC complement is used for HLA Class I typing and DR complement is used for Class II typing. Each complement has been titrated against a panel of Class I or Class II typing reagents for potency and non-cytotoxicity against T and B lymphocytes.

PRINCIPLE(S)

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 binds 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

Rabbit complement is frozen or lyophilized. Frozen complement is packaged in 5 ml and 50 ml volumes. Lyophilized complement volume is 1 ml reconstituted

IVD **B. Warning or Caution**

1. FDA Designation: IVD
2. Refer to the Material Safety Data Sheet for detailed information.

C. Preparing Reagents for Use

See “Directions for Use.”

D. Storage Instructions

Frozen complement should be stored at a temperature of -65º degrees or colder. Lyophilized complement can be stored at 2 - 5º C until used. Use before expiration date printed on package.

E. Purification or Treatment Required for Use

See “Directions for Use.”

F. Instability Indications

Complement stability is affected by heat. Therefore, if frozen complement is received thawed, discard complement. Complement that has brown discoloration should not be used.

SPECIMEN COLLECTION AND PREPARATION

See product insert for Terasaki HLA Tissue Typing Trays.

PROCEDURE

A. Materials Provided

1. HLA Class I or Class II complement, frozen or lyophilized.

B. Materials Required, But Not Provided

1. Terasaki Tissue Typing Trays

C. Directions for Use

1. See “Directions for Use” below.

DIRECTIONS FOR USE

A. Frozen Complement

1. Before use, frozen complement should be thawed in a water bath at a temperature of 20º C or in cool tap water. Remove thawed complement immediately and place in a container filled with crushed ice.
2. Do not freeze/thaw more than once after initial thaw.

B. Lyophilized Complement Reconstitution

1. Add 1 ml sterile water at 2 -5º C to each vial of lyophilized complement.
2. Mix gently until full dissolved.
3. Store at 2 –5º C until use.
4. Unused complement must be aliquoted and immediately stored at -20º C or below. Do not freeze-thaw more than once after reconstitution.

LIMITATIONS OF THE PROCEDURE

Refer to product insert for Terasaki HLA Tissue Typing Trays.

EXPECTED VALUES

Refer to product insert for Terasaki HLA Tissue Typing Trays.

SPECIFIC PERFORMANCE CHARACTERISTICS

Refer to product insert for Terasaki HLA Tissue Typing Trays.

BIBLIOGRAPHY

Refer to product insert for Terasaki HLA Tissue Typing Trays

EUROPEAN AUTHORIZED REPRESENTATIVE

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EXPLANATION OF SYMBOLS *(reference EN ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied)*

Symbol	Description
REF *ISO 7000 Reg No. 2493*	Catalog number
IVD	In vitro diagnostic medical device
 *ISO 7000 Reg No. 1641*	Consult instructions for use
 *ISO 7000 Reg No. 0434A*	Caution, consult accompanying documents
 *ISO 7000 Reg No. 0659*	Biological risks
 *ISO 7000 Reg No. 0632*	Temperature limitation
CE	CE mark
CE 0197	CE mark of medical quality
 *ISO 7000 Reg No. 3082*	Manufacturer
EC REP	Authorized representative in the European Community

REVISION HISTORY

Revision	Date	Revision Description
3	08/25/2017	Addition of discoloration statement, Update template.
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.

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