EN

RUO

INSTRUCTIONS FOR USE

ANTI-HLA CONTROL SERA

Electronic instructions for use see www.bag-diagnostics.com

REF 61100, **Anti-HLA Positive Control RUO, 2 ml, liquid, frozen**

REF 61101, **Anti-HLA Negative Control RUO, 2 ml, liquid, frozen**

For research use only – not for diagnostic purposes

1. APPLICATION

Anti-HLA Positive and Anti-HLA Negative Control are used as control sera in the microlymphocytotoxicity test applied in the serological detection of HLA antigens on the lymphocyte surface or of HLA antibodies in human serum. **For research use only – not for diagnostic purposes.**

2. PRODUCT DESCRIPTION

Anti-HLA Positive Control consists of anti-human T-lymphocyte globulin from rabbit pooled with human HLA antisera. Anti-HLA Negative Control consists of a serum pool from donors of blood group AB, which has no HLA antibodies.

3. TEST PRINCIPLE

HLA-antisera react with the corresponding membrane-bound antigens on human lymphocytes. The addition of rabbit complement results in a structural change of the cell membrane which leads to a penetration of an indicator dye. Stained lymphocytes = positive reaction. In case of missing antigen-antibody reaction, the cell membrane is intact. No penetration of indicator dye takes place and the cells remain unstained = negative reaction.

4. TEST PROCEDURE

The frozen anti-HLA control sera are thawed at room temperature, mixed by gently swirling the tubes and can then be used in the microlymphocytotoxicity test. It is recommended to aliquot and refreeze the anti-HLA control sera as needed after the initial thawing.

5. PERFORMANCE CHARACTERISTICS

Each batch of Anti-HLA Positive or Anti-HLA Negative Control was tested in the microlymphocytotoxicity test with at least 40 lymphocyte suspensions from different donors and reacted positively or negatively according to the specifications.

6. WARNINGS AND PRECAUTIONS

Human source material for the production of the test reagents has been tested by serological or molecular genetic methods for HIV, HBV and HCV. Only negative material was used for production. Nevertheless, all used biological material should be handled as potentially infectious, because no test method can guarantee that material derived from biological sources is free from infectious agents. When handling biological material appropriate safety precautions are recommended (do not pipet by mouth; wear disposable gloves while handling biological material and performing the test; disinfect hands when finished the test).

Biological material should be inactivated before disposal (e.g. in an autoclave). Disposables should be autoclaved or incinerated after use. Spillage of potentially infectious materials should be removed immediately with absorbent paper tissue and the contaminated areas swabbed with a suitable standard disinfectant or 70% alcohol. Material used to clean spills, including gloves, should be inactivated before disposal (e.g. in an autoclave). Anti-HLA sera contain NaN_3 as a preservative. The reagents contain < 0.1% NaN_3 which is not considered to be harmful to health. Nevertheless, avoid contact with the skin and mucous membranes. The copper and lead used in some plumbing systems can react with azides to form explosive salts. The quantities of azide contained in the reagents are small; nevertheless, when disposing azide-containing material, it should be flushed away with a large volume of water.

Disposal of all samples, unused reagents and waste should be in accordance with country, federal, state and local regulations. When used in accordance with the principles of Good Laboratory Practice, good standards of occupational hygiene and the instructions stated in this direction, the reagent supplied should not present a hazard to health.

A declaration on Material Safety Data Sheets (MSDS) can be downloaded at www.bag-diagnostics.com.

7. SHELF LIFE: until the expiration date indicated on the label

8. STORAGE: ≤-20°C

9. EXPLANATION OF SYMBOLS USED ON LABELLING

	Use by			Storage temperature / Upper limit of temperature
LOT	Batch code			Consult Instructions for use
REF	Catalogue number			Manufacturer
RUO	Research use only		IFU	Instructions for use

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