Anti-HLA Control Reagents
for the microlymphocytotoxicity test

Package size
Kontroll-HLA pos.  REF  824 101  0,5 ml
Kontroll-HLA neg.  REF  824 106  0,5 ml

Reagent Description
Kontroll-HLA pos. is a lyophilized anti-human lymphocyte globulin (IgG) from rabbit which reacts cytotoxic with activated and non-activated lymphocytes. 0.095% sodium azide is added to Kontroll-HLA pos. as a preservative.

Kontroll-HLA neg. is a lyophilized reagent consisting of a serum pool from different healthy male donors of blood group AB which shows no cytotoxic reactions in the microlymphocytotoxicity test with randomly selected donor lymphocytes. 0.095% sodium azide is added to Kontroll-HLA neg. as a preservative.

Statement of Precautions
All materials of human origin used in this product have been tested and found to be non-reactive for HBsAg, anti-HCV and anti-HIV-1/2. However, all products of human origin should be considered to be potential transmitters of hepatitis, HIV or other infectious agents. Appropriate safety measures are recommended.

Storage
Lyophilized anti-HLA control reagents should be stored at 2...8°C. They are stable up to the date stated on their individual label. Reconstituted anti-HLA control reagents have to be stored in aliquots at −20°C or below. Reconstituted anti-HLA control reagents are stable up to 18 months but maximal up to the date stated on the label if stored at −20°C or below.

Repeated thawing and freezing of the Kontroll-HLA pos. is to avoid, this may cause decrease in reactivity!

Procedure
Anti-HLA control reagents have to be reconstituted with 0.5 ml distilled water before use.

The use of the reagents with the Biotest Lymphoscreen product line is described in the instructions for use (art.no. REF 823 300 and 823 350). 2 µl control reagent is pipetted per well.

Expected Values
Kontroll-HLA pos. is made to control the correct usage of the microlymphocytotoxicity test. The reactions of lymphocytes with Kontroll-HLA pos. should lyse 81-100 % of the lymphocytes. The determination using Kontroll-HLA neg. indicates the vitality of the lymphocytes. The reactions of lymphocytes with Kontroll-HLA neg. should end up with less than 20% lysed lymphocytes.

Quality Control
Every batch of Kontroll-HLA neg. is tested with at least thirty T-lymphocyte suspensions and twenty B-lymphocyte suspensions of different blood donors.

Maximal 20% lysed lymphocytes (score 2) should be detected in each well. Every batch of Kontroll-HLA pos. is tested with at least thirty T-lymphocyte suspensions and twenty B-lymphocyte suspensions of different blood donors.

A score 8 value (81 – 100% lysed lymphocytes) is guaranteed one titer dilution below the working solution.

Specific Performance Characteristics
Kontroll-HLA pos. reacts positive with human lymphocytes (Score 8). Kontroll-HLA neg. reacts non-cytotoxic with human lymphocytes (negative).

Limitations
1. Kontroll-HLA pos. reacts weak positive or negative:
- The activity of complement is too low.
- Unproper storage of HLA trays (e.g. with dry ice, wrong temperature, HLA trays thawed and frozen again).
- Incubation times in the microlymphocytotoxicity test are too short.
- Incubation temperature in the microlymphocytotoxicity test is too low.

2. Kontroll-HLA neg. reacts doubtful negative, weak positive or positive:
- Prior damage of the lymphocytes (storage of the lymphocyte suspension too long or not in accordance with the rules).
- Carry over by using Hamilton syringes.
- Incubation times in the microlymphocytotoxicity test are too long.
- Incubation temperature in the microlymphocytotoxicity test is too high.
- Failure to add fixative.

Intended Use
Kontroll-HLA pos. and Kontroll-HLA neg. are used as positive and negative anti-HLA control reagents for in vitro diagnostic of human HLA antibodies in the complement-dependent microlymphocytotoxicity test.

Principle of the Microlymphocytotoxicity Test

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