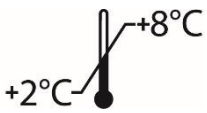
AESQC® Instructions for use

Human serum pool to be used:

- as precision control with ELISA methods
- as function control with Line Immunoassays

AESKU.Diagnostics GmbH & Co. KG
Mikroforum Ring 2
55234 Wendelsheim, Germany
Phone.: +49-6734-9622-0
Fax: +49-6734-9622-2222
www.aesku.com



V007: 2020-08-06

AESQC® multiparametric autoimmunity quality controls

Intended use

The AESQC quality controls are reagents obtained from pools of human sera available with different autoantibodies that allow a multi parametric control in autoimmune disease diagnosis.
The AESQC quality control multiparameter reagents should be used as unassayed precision control with ELISA/FARR procedures for determination of autoimmune antibodies.

Application

Quality Control materials and procedure are a useful method to help laboratories verifying the accuracy and precision of their analytical methods. These controls were developed to help lab managers ensure that analytical error stays within acceptable limits.
The AESQC controls were designed for monitoring the performance l of Enzyme linked immunosorbent assays (ELISA). Moreover, AESQC pool 2 and 3 can also be used in FARR assays for determination of dsDNA antibodies.
AESQC Pool 1 and 4 can be used as function controls of AESKUBLOTS® Line Immuno Assays (LIA).
These reagents are composed of a pool of sera available with different autoantibodies (detailed composition listed on table 1.). They can be used as multi parametric controls in autoimmune disease diagnosis.

AESQC controls are ready to use reagents which have to be used in the same way as patient's samples, according to the instructions for use supplied by the manufacturer of the respective assay system. They are designed to give positive results for the respective autoantibody according to the lot specific certificate of analysis but do not have assigned values since these depend on the test system used.
Based upon its own techniques and equipment each laboratory should establish its own target value for each marker and for each lot on a minimum of 20 determinations.

Contents

2 vials of 500 µl, ready to use reagents; human serum with 0.02 % ProClin as preservative.
For detailed composition please check table 1.

Storage and shelf life

Store all reagents at 2-8°C/35-46°F in their original containers.
Once opened reagents are stable for 60 days at 2-8°C/35-46°F.
Reagents shall be used within the expiry date indicated on each vial, only.
Do not freeze.
Never expose reagents to higher temperature than 37°C.
Adverse storage conditions or use of reagents beyond the expiration date may produce false results.

Precautions of Use

THIS PRODUCT IS FOR IN VITRO DIAGNOSTIC USE ONLY. Thus, only staff trained and specially advised in methods of in vitro diagnostics may use the reagent.

All human source material used has been tested by FDA approved methods and found negative for HbsAg, Hepatitis C and HIV-1. However, no test can guarantee the absence of viral agents in such material completely. Thus handle kit controls, standards and patient samples as if capable of transmitting infectious diseases and according to national requirements.
Do not eat or drink when using reagents, avoid contact with skin and eyes.

General directions for use

Do not mix or substitute reagents from different lot numbers and different REFs.

Reagents should be analysed in the same manner as patient's samples, according to the instructions for use supplied by the manufacturer of the test kit used.

Performances and levels of reactivity of AESQC may vary with different manufacturer's test kits

Do not use AESQC reagents as substitution for positive or negative control of tests and procedures.

Because AESQC reagents contain non human derived constituents, incompatibility between these components and test kits may occur.

Do not use AESQC reagents for calibration

Each laboratory should establish its own quality assurance program to determine the suitability of AESQC reagents for its particular use and should establish guidelines for interpretation of AESQC's results.

Table 1: AESQC available pools and composition

AESQC Pool 1 • Ref. Nr: **AESQCP1** • Presentation: **2x 500µl**

- SS-A 60 kDa
- SS-A 52 kDa
- SS-B
- Sm
- Sm / RNP
- Ribo
- CEN-P-B
- Jo-1
- Scl-70
- AMA

AESQC Pool 4 • Ref. Nr: **AESQCP4** • Presentation: **2x 500µl**

- TPO
- TG
- Glia IgA and IgG
- tTG IgA
- MPO
- PR3
- GBM

AESQC Pool 2 • Ref. Nr: **AESQCP2** • Presentation: **2x 500µl**

- aCL IgG
- aPL IgG
- β2GP1 IgG and IgM
- DNA (ELISA & FARR)

AESQC Pool 5 • Ref. Nr: **AESQCP5** • Presentation: **2x 500µl**

- hRF IgM isotype
- CCP IgG isotype
- LCP IgG isotype (Linear citrullinated peptides)

AESQC Pool 3 • Ref. Nr: **AESQCP3** • Presentation: **2x 500µl**

- aCL IgM
- aPL IgM
- β2GP1 IgG and IgM
- DNA (ELISA & FARR)

AESQC Pool Mix • Ref. Nr: **AESQCPM** • Presentation: **5x 500µl**

- 1x 500µl AESQC Pool 1
- 1x 500µl AESQC Pool 2
- 1x 500µl AESQC Pool 3
- 1x 500µl AESQC Pool 4
- 1x 500µl AESQC Pool 5