AESQC® IFA Instructions for use

Pre-diluted human serum to be used as unassayed function control with Immunofluorescence assay (IFA) methods

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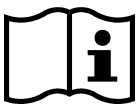

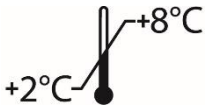

Intended use

The AESQC® IFA Quality Controls are intended for use as a ready to use, unassayed function control serum in the clinical laboratory to monitor the precision of in vitro testing procedures for the detection of some autoantibodies by IFA consistent with a specific pattern.

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 laboratory managers ensure that analytical error stays within acceptable limits.
The AESQC® IFA controls are designed for monitoring the performance of IFA methods.
These reagents are composed of pre-diluted human serum available with different autoantibody patterns (detailed composition listed on table 1.). They can be used as IFA controls in autoimmune disease diagnosis.

AESQC® IFA controls are pre-diluted and should be run neat (undiluted) or according to the instructions for use supplied by the manufacturer of the respective assay system. They are designed to give the defined results for the respective autoantibody IFA pattern 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.

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.
- 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 references.

Reagents should be run neat (undiluted) or according to the instructions for use supplied by the manufacturer of the respective assay system.

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

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

Do not use AESQC® IFA reagents for calibration!

We recommend each laboratory establishes its own quality assurance program to determine the suitability of AESQC® reagents for its particular use and establishes guidelines for interpretation of AESQC® IFA results.

For more information go to AESQC.com

Table 1: AESQC® IFA available pools and composition

AESQC IFA	Ref Number	Presentation	ICAP
IFA Negative	AESQCIFANEG	3 x 0.5 mL *	AC-0
ANA HEp-2 Homogeneous	AESQCANA01	3 x 0.5 mL *	AC-1
ANA HEp-2 Centromere	AESQCANA03	3 x 0.5 mL *	AC-3
ANA HEp-2 Speckled	AESQCANA04	3 x 0.5 mL *	AC-4, AC-5
ANA HEp-2 Nucleolar	AESQCANA09	3 x 0.5 mL *	AC-8, AC-9, AC-10
ANA HEp-2 Cytoplasmic	AESQCANA21	3 x 0.5 mL *	AC-21
ANA HEp-2 5 patterns Panel	AESQCIFANAP1	5 x 0.5 mL *	

**ready to use reagents; human serum with ProClin as preservative.*

For specific patterns see Certificate of Analysis.