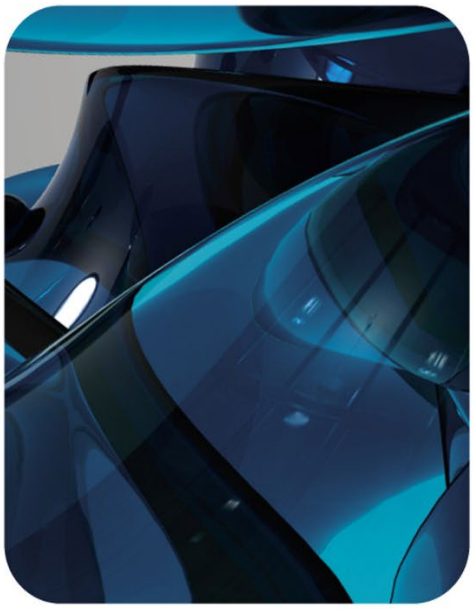
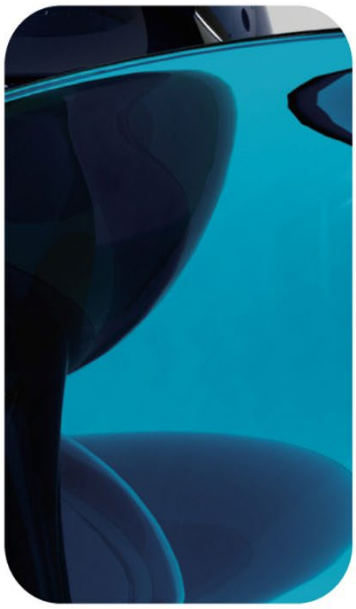
AESKU.DIAGNOSTICS
THE DIAGNOSTIC TOOL THAT WORKS


AESQC® IFA

INSTRUCTIONS FOR USE

IVD

+2°C +8°C

AESQC® IFA autoimmunity quality controls

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

The ***AESQC***® IFA Controls are reference material for Internal Quality Control purposes.
The controls were developed to aim laboratories to achieve Quality Control procedures for assessment the validity of tests.
The ***AESQC***® IFA Controls are designed for assessment the performance of immunofluorescence testing.

Reagent

The ***AESQC***® IFA Controls are prepared from human serum, available with different autoantibodies, pre-diluted with sample diluent and a preservative.
These reagents are provided in liquid form.

Table 1: *AESQC*® IFA Controls available pools and composition

AESQC®	Ref Number	Presentation	ICAP
AESQC® IFA Negative Control	AESQCIFANEG	3 x 500µl	AC-0
AESQC® ANA HEp-2 Homogeneous	AESQCANA01	3 x 500µl	AC-1
AESQC® ANA HEp-2 Centromere	AESQCANA03	3 x 500µl	AC-3
AESQC® ANA HEp-2 Speckled	AESQCANA04	3 x 500µl	AC-4, AC-5
AESQC® ANA HEp-2 Nucleolar	AESQCANA09	3 x 500µl	AC-8, AC-9, AC-10
AESQC® ANA HEp-2 Cytoplasmic	AESQCANA21	3 x 500µl	AC-21
AESQC® ANA HEp-2 Panel 1	AESQCIFANAP1	5 x 500µl	AC-1, AC-3, AC-4, AC-9, AC-21

For specific patterns see Certificate of Analysis

Storage and stability

- Store all reagents at 2-8°C/35.6-46.4°F in their original containers.
- Once opened reagents are stable for 60 days at 2-8°C/35.6-46.4°F.
- Reagents shall be used within the expiry date indicated on each vial.
- Never expose reagents to higher temperature than 37°C/ 98.6°F.
- Adverse storage conditions or use of reagents beyond the expiration date may produce false results.

Procedure

The ***AESQC***® IFA Controls are pre-diluted and should be run **undiluted** or according to the instructions for use supplied by the manufacturer of the respective assay system.
Prior to use let the reagent reach room temperature (18-25°C/64.4-77°F) and mix gently to ensure homogeneity.
After usage return the reagents to 2-8°C/35.6-46.4°F storage.
These qualitative controls shall give a result according to the lot specific certificate of analysis.

Precautions of Use

THIS PRODUCT IS FOR *IN VITRO DIAGNOSTIC USE* ONLY.
Immunofluorescence testing must be performed by authorized and trained staff.

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 completely guarantee the absence of viral agents in such material. 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.
- Performances and levels of reactivity of ***AESQC***® IFA Controls may vary with different test kits.
- Do not use ***AESQC***® IFA Controls as substitution for positive or negative control of tests and procedures.
- Do not use ***AESQC***® IFA Controls 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 Controls results.

Expected Results

- Negative result: shows no specific pattern of fluorescence on the substrate.
- Positive result: shows a specific pattern of fluorescence on the substrate (**see Table 2**).

Table 2: *AESQC*® IFA Control Patterns

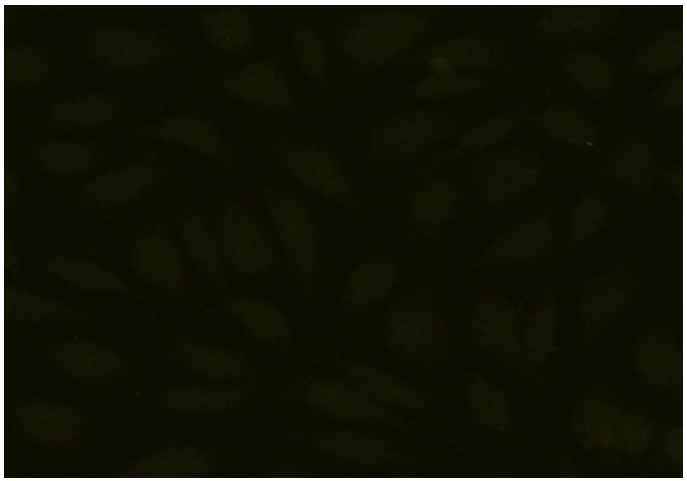
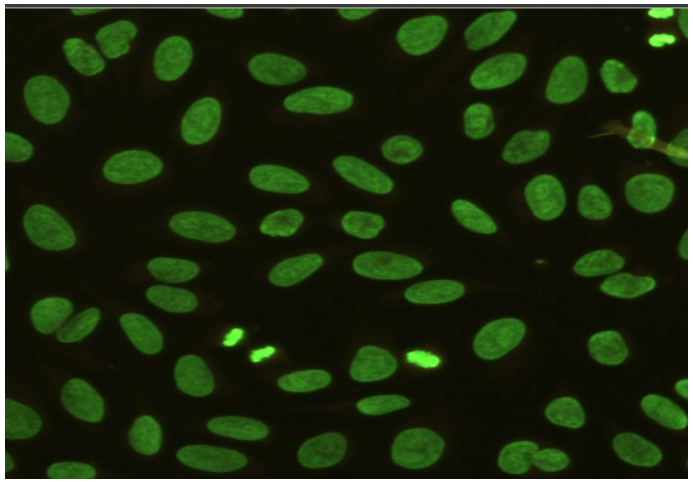
AESQC®	Reference	ICAP	Pattern	Description
AESQC® IFA Negative Control	AESQCIFANEG 3 x 500µl	AC-0		Negative on: ▪ HEp-2 ▪ Crithidia luciliae ▪ ANCA ▪ r/m LKS ▪ EMA
AESQC® ANA HEp-2 Homogeneous	AESQCANA01 3 x 500µl	AC-1		Interphase: Uniform diffuse staining of the nucleoplasm. Nucleoli: Nucleolar staining is variable, can be positive or negative. Mitosis: In all phases, a homogeneous or peripheral chromatin staining can be seen.

Table 2: *AESQC*® IFA Control Patterns

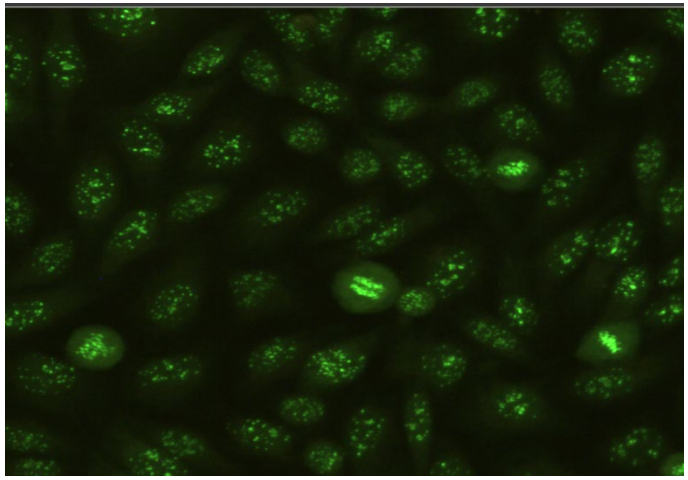
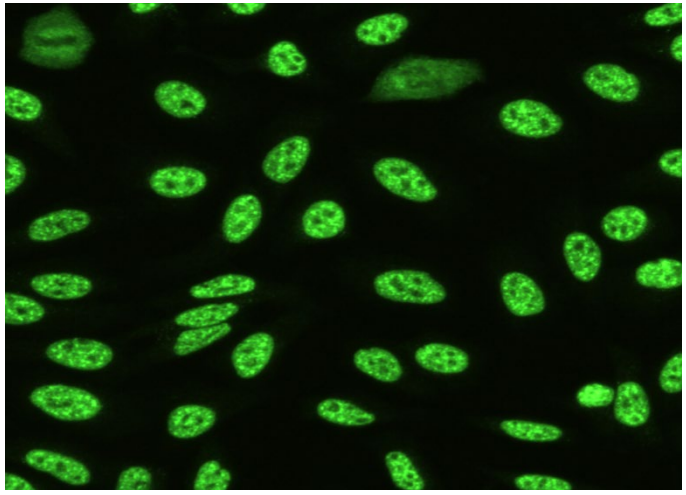
***AESQC*®**	**Reference**	**ICAP**	**Pattern**	**Description**
***AESQC*®** ANA HEp-2 Centromere	AESQCANA03 3 x 500µl 	AC-3		Interphase: 23-46 speckles distributed throughout the entire nucleus. Nucleoli: Negative. Mitosis: A block of closely associated speckles is found in the condensed nuclear chromatin of the metaphase, anaphase, and telophase cells.
***AESQC*®** ANA HEp-2 speckled	AESQCANA04 3 x 500µl 	AC-4		Interphase: Fine speckles (granular). Granules are distinct in the nucleus. Nucleoli: Negative. Mitosis: No staining of the condensed chromatin in mitotic cells.

Table 2: *AESQC*® IFA Control Patterns

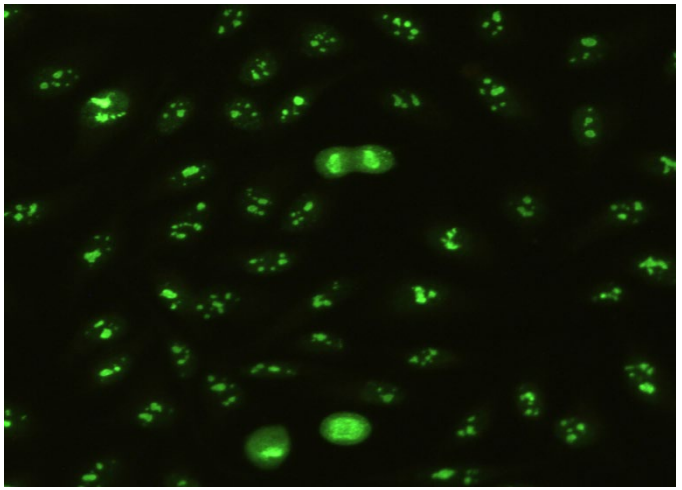
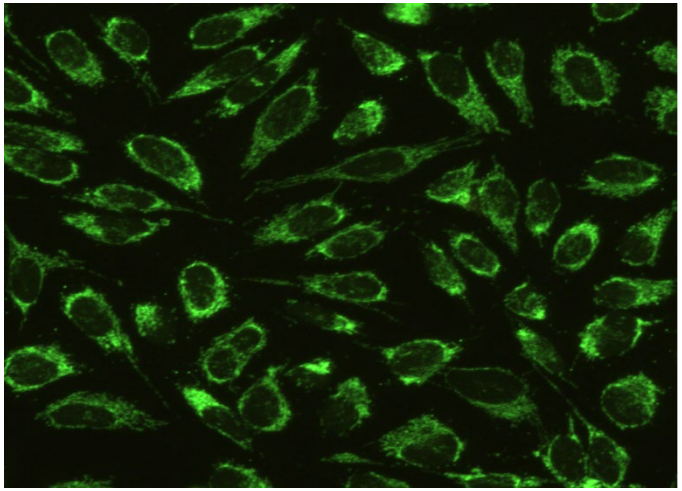
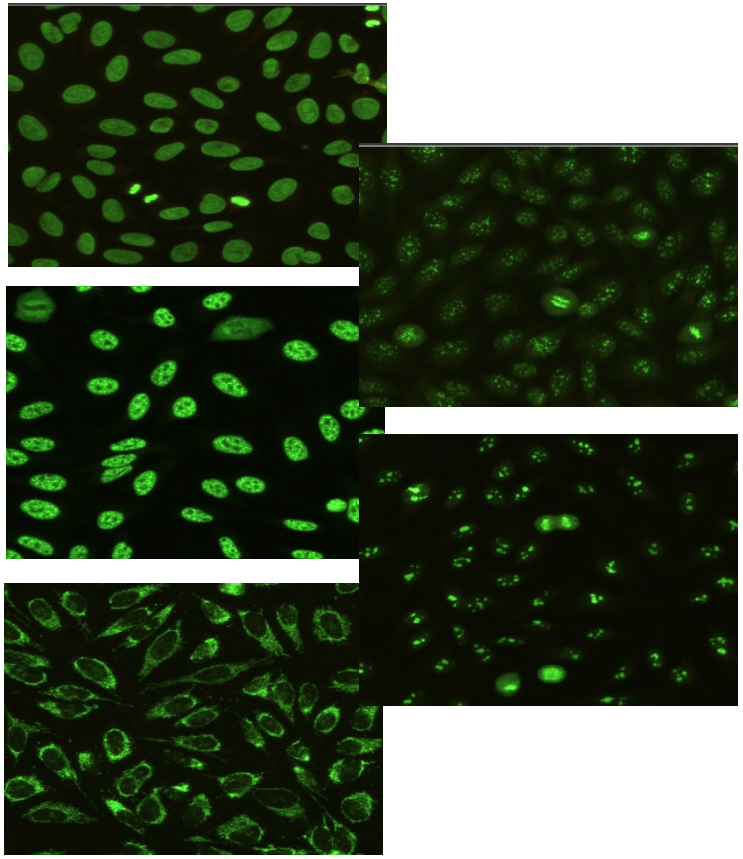
AESQC®	Reference	ICAP	Pattern	Description
AESQC® ANA HEp-2 Nucleolar	AESQCANA09 3 x 500µl	AC-9		Interphase: Granular fluorescence of the nucleoli. The nucleoplasm is dark. Nucleoli: Positive “clumpy”. Mitosis: Metaphase and telophase plates show reticular staining.
AESQC® ANA HEp-2 Cytoplasmic	AESQCANA21 3 x 500µl	AC-21		Interphase: Fluorescence of large irregular granules organized as a network of filaments extending around the nucleus and throughout the cytoplasm. No staining of the nucleus. Nucleoli: Negative. Mitosis: Chromosomal material in metaphase cells is negative.

Table 2: *AESQC*® IFA Control Patterns

AESQC®	Reference	ICAP	Pattern	Description
AESQC® ANA HEp-2 Panel 1	AESQCANAP1 5 x 500µl 	AC-1 AC-3 AC-4 AC-9 AC-21		See pattern specific descriptions above.

References

- B.M. Simonet, Quality control in qualitative analysis. Trends in Analytical Chemistry, Vol. 24, No. 6, 2005. doi:10.1016/j.trac.2005.03.011
- von Muhlen, et al.How to report the antinuclear antibodies (anti-cell antibodies) test on HEp-2 cells: guidelines from the ICAP initiative. *Immunologic Research(2021)*, *69*(6), 594-608.https://doi.org/10.1007/s12026-021-09233-0

IVD	- Diagnosi in vitro	ro diagnostic use
	- Pour diagnostic in vitro	- Para uso diagnóstico in vitro
	- In Vitro Diagnostikum	- In Vitro Διαγνωστικό μέσο
	- Para uso Diagnóstico in vitro	
REF	¨ Numero d'ordine	¨ Cataloge number
	¨ Référence Catalogue	¨ Numéro de catálogo
	¨ Bestellnummer	¨ Αριθμός παραγγελίας
	¨ Número de catálogo	
LOT	¨ Descrizione lotto	¨ Lot
	¨ Lot	¨ Lote
	¨ Chargen Bezeichnung	¨ Χαρακτηρισμός παρτίδας
	¨ Lote	
CE	¨ Conformità europea	¨ EC Declaration of Conformity
	¨ Déclaration CE de Conformité	¨ Declaración CE de Conformidad
	¨ Europäische Konformität	¨ Ευρωπαϊκή συμφωνία
	¨ Déclaracão CE de Conformidade	
	¨ Rispettare le istruzioni per l'uso	¨ See instructions for use
	¨ Voir les instructions d'utilisation	¨ Ver las instrucciones de uso
	¨ Gebrauchsanweisung beachten	¨ Λάβετε υπόψη τις οδηγίες χρήσης
	¨ Ver as instrucões de uso	
	¨ Da utilizzarsi entro	¨ Use by
	¨ Utilise avant le	¨ Utilizar antes de
	¨ Verwendbar bis	¨ Χρήση μέχρι
	¨ Utilizar antes de	
	¨ Conservare a 2-8°C (35.6-46.4°F)	¨ Store at 2-8°C (35.6-46.4°F)
	¨ Conserver à 2-8°C (35.6-46.4°F)	¨ Conservar a 2-8°C (35.6-46.4°F)
	¨ Lagerung bei 2-8°C (35.6-46.4°F)	¨ Φυλάσσεται στους 2-8°C (35.6-46.4°F)
	¨ Conservar entre 2-8°C (35.6-46.4°F)	
	¨ Prodotto da	¨ Manufactured by
	¨ Fabriqué par	¨ Fabricado por
	¨ Hergestellt von	¨ Κατασκευάζεται από
	¨ Fabricado por	
	- Rischio biologico	- Biological Risk
	- Risque biologique	- Peligro biológico
	- Biogefährdung	- Βιολογικός κίνδυνος
	- Risco biológico	

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