

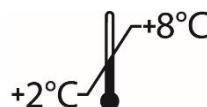
AESQC® Instructions for use

Human serum pool to be used as function
control **AESKUBLOTS®** Borrelia

REF AESQCP6 Function Control IgG
REF AESQCP7 Function Control IgM
For Aeskublots REF 4006 and 4007



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AESQC® parametric infection serological controls

Intended use

The **AESQC®** quality controls are reagents obtained from pools of human sera available with different antibodies that allow an additional control in Borrelia infections diagnosis.

The **AESQC®** quality control reagents should be used as unassayed function control for determination of immune 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 of **AESKUBLOT®** Borrelia. These reagents are composed of a pool of sera available with different antibodies and allow a parametric control in Borrelia 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 antibody 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

1 vials of 200 µl, ready to use reagents; human serum with 0.02 % ProClin as preservative

Storage and shelf life

Store all reagents at 2-8 °C/35,6-46,4 °F in their original containers.

Once opened reagents are stable for 28 days at 2-8 °C/35,6-46,4 °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/98,6 °F.

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

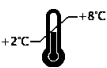
Do not use **AESQC®** reagents as substitution for positive or negative control of tests and procedures.

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.

Regulatory Symbols

	- Diagnosi in vitro	- For in vitro diagnostic use
	- Pour diagnostic in vitro	- Para uso diagnóstico in vitro
	- In-vitro-Diagnostikum	- In Vitro Διαγνωστικό μέσο
	- Para uso Diagnóstico in vitro	
	- Numero d'ordine	- Catalogue number
	- Référence Catalogue	- Numéro de catálogo
	- Katalognummer	- Αριθμός παραγγελίας
	- Número de catálogo	
	- Descrizione lotto	- Lot
	- Lot	- Lote
	- Chargen Bezeichnung	- Χαρακτηρισμός παρτίδας
	- Lote	
	- Identificatore univoco del dispositivo	- Unique device identifier
	- Identifiant unique de l'appareil	- Identificador único del dispositivo
	- eindeutige Produktidentifizierung	- Μοναδικό αναγνωριστικό συσκευής
	- Identificador único do dispositivo	
	- Conformità europea	- EC Declaration of Conformity
	- Déclaration CE de Conformité	- Declaración CE de Conformidad
	- Europäische Konformität	- Ευρωπαϊκή συμφωνία
	- Declaração CE de conformidade	
	- Rispettare le istruzioni elettroniche per l'uso	- See electronic instructions for use
	- Voir les instructions d'utilisation électronique	- Sigla las instrucciones electrónicas de uso
	- Elektronische Gebrauchsanweisung beachten	- Ακολουθήστε τις ηλεκτρονικές οδηγίες χρήσης
	- Seguir as instruções electrónicas de utilização	
	- Da utilizzarsi entro	- Use by
	- Utiliser 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	
	- Non riutilizzare	- Do not reuse
	- Ne pas réutiliser	- No reutilizar
	- Nicht wiederverwenden	- Μην επαναχρησιμοποιείτε
	- Não reutilizar	
	- Proteggere dall'esposizione alla luce	- Protect from exposure to light
	- Protéger de l'exposition à la lumière	- Proteger de la exposición a la luz
	- Vor Sonnenlicht schützen	- Προστασία από την έκθεση στο φως
	- Proteger da exposição à luz	
	- Conservare all'asciutto	- Store dry
	- Stocker au sec	- Almacenar en seco
	- Trocken aufbewahren	- Αποθηκεύστε ξηρά
	- Armazenar em local seco	
	- Non utilizzare se la confezione è danneggiata e consultare le istruzioni per l'uso	- Do not use if package is damaged and consult instructions for use
	- Ne pas utiliser si l'emballage est endommagé et consulter le mode d'emploi.	- No utilizar si el envase está dañado y consultar las instrucciones de uso
	- Nicht verwenden, wenn die Verpackung beschädigt ist, und Gebrauchsanweisung beachten	- Μην χρησιμοποιείτε εάν η συσκευασία έχει υποστεί ζημιά και συμβουλευτείτε τις οδηγίες χρήσης.
	- Não utilizar se a embalagem estiver danificada e consultar as instruções de utilização	
	- Rischi biologici	- Biological risks
	- Risques biologiques	- Riesgos biológicos
	- Biologische Risiken	- Βιολογικοί κίνδυνοι
	- Riscos biológicos	