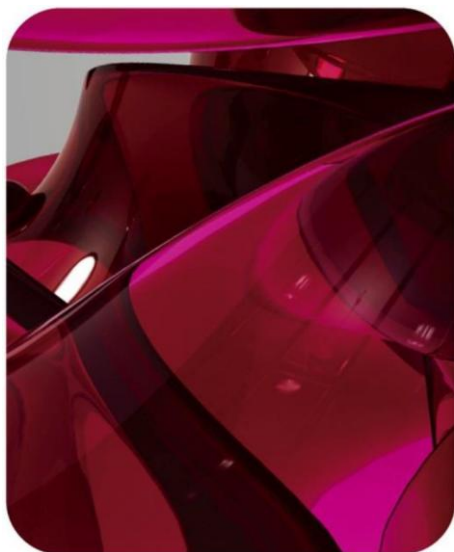




AESKU.DIAGNOSTICS

THE DIAGNOSTIC TOOL THAT WORKS



AESKUBLOTS®

THE DIAGNOSTIC TOOL THAT WORKS

INSTRUCTION MANUAL

AESKUBLOTS® Allergy CCD Blocker

Ref 420000

Ref 420000.BULK5



Instruction Manual

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1 Intended Use

AESKUBLOTS® Allergy CCD Blocker is an accessory for the **AESKUBLOTS® Allergy** product line. It binds to the variable region of anti-CCD IgE antibodies in human serum or plasma and inhibits their binding to CCDs of the allergens in the test system.

The product is used for sample preparation and does not detect diseases.

This product is for professional use only in laboratories.

2 Clinical Application and Principle of the Test

A type I allergy is caused by the formation of specific IgE antibodies against allergens. Most allergens are proteins with molecular weights between 9 - 200 kDa, but also small molecules like drugs can act as allergens if bound to a protein.

In eukaryotic organisms (usually plants), most proteins are glycosylated and therefore contain carbohydrate side chains. The immune system develops IgE antibodies also against these carbohydrate side chains (cross-reactive carbohydrate determinants, CCDs). IgE antibodies with CCDs as target molecules also cross react with clinically irrelevant proteins which do not cause allergic symptoms. However, these antibodies generate positive results in laboratory tests. These positive results must be considered false-positive. To distinguish true-positive results from false-positive results, the anti-CCD IgE antibodies must be inhibited in binding of the CCDs of allergens in the laboratory test. The occurrence of a positive result for the CCD-Marker or many positive reactions in the individual **AESKUBLOTS® Allergy** test system is an indication of cross-reactions that could be caused by anti-CCD IgE antibodies. In these cases, the serum or plasma needs to be treated with the **AESKUBLOTS® Allergy CCD Blocker**, and the test needs to be repeated. The **AESKUBLOTS® Allergy CCD Blocker** is used for the pretreatment of samples for **AESKUBLOTS® Allergy** tests.

Principle of the test

The **AESKUBLOTS® Allergy CCD Blocker** binds to the variable region of anti-CCD-IgEs, so these antibodies are inhibited. Thus, they cannot bind to the carbohydrate domain of the allergens in the test system.

3 Kit Contents

TO BE RECONSTITUTED					
Ref	Item	Quantity	Cap color	Reagent color	Description / Contents
420000	AESKUBLOTS® Allergy CCD Blocker	1 vial	transparent	yellow	44 µg freeze dried MUXF-HSA-conjugate per vial
420000.BULK5	AESKUBLOTS® Allergy CCD Blocker	5 vials	transparent	yellow	44 µg freeze dried MUXF-HSA-conjugate per vial
PRODUCT RELATED INFORMATION					
Quality Control Certificate			1 piece		
Kit Card: Electronic Instruction for Use			1 piece		
MATERIALS REQUIRED, BUT NOT PROVIDED					
Precision pipettes (10, 200 µl), sample tubes, absorbent or filter paper. Our tests are designed to be used with purified water according to the definition of the United States Pharmacopeia and the European Pharmacopeia.					

4 Storage and Shelf Life

Store the reagent at 2-8 °C / 35.6-46.4 °F in the original container. The shelf life of the product is 7 years from the date of the final quality control. Once prepared, reconstituted CCD Blocker is stable at 2-8 °C / 35.6-46.4 °F for two weeks. For longer time periods store below -20 °C / -4 °F. Do not shake. The reagent shall be used within the expiry date indicated. Don't use after the expiry dates.

5 Precautions of Use and General Introductions

5.1 Health hazard data

This product is for IN VITRO DIAGNOSTIC use only. Thus, only staff trained and specially advised in methods of in vitro diagnostics may perform the kit.

All kit components are classified according to Regulation (EC) No. 1272/2008 [CLP]. See the Materials and Safety Document (MSDS) for more information on ingredients.

Substances listed on the so-called "Candidate List of Substances of very High Concern (SVHCV) for authorization" of the European Chemicals Agency (ECHA) are not intentional components of this product. It is therefore not to be expected that these substances are contained in amounts ≥ 0.1 % in the product.

Reagents should be stored safely and be inaccessible to children.

In particular, the mixture does not contain any substances in concentrations ≥ 0.1 % to be classified as PBT or vPvB.

Patient samples should be considered potentially infectious and handled according to national laws. Patient samples and other potentially infectious material should be decontaminated after the test run.

 AESKU.DIAGNOSTICS THE DIAGNOSTIC TOOL THAT WORKS	Product Ref.	420000 & 420000.BULK5
	Product Desc.	Allergy CCD Blocker
	Manual Rev. No.	002a: 2025-06-12

5.2 General directions for use

In case that the product information, including the labeling, is incorrect please contact the manufacturer or the supplier of the test kit.

If the vial with the product is damaged, do not use the product.

AESKUBLOTS® Allergy CCD Blocker can be used for all **AESKUBLOTS® Allergy** test panels (ONE to THIRTEEN).

Allow the reagent to reach room temperature (20-32 °C / 68-89.6 °F) before use. Avoid mixing after reconstitution and follow the recommended procedure for an optimum inhibition of IgE antibodies to CCD-motifs.

Never expose the product to higher temperature than 40 °C / 104 °F.

Always pipette the reagent solution with brand new tips only. Never pipette the reagent with tips priorly used with other samples.

If the patient sample also contains IgE antibodies specific for the protein backbone, positive results will be reduced but not completely inhibited after treatment with CCD Blocker.

A definite clinical diagnosis should not only be based on the results of the performed test. The diagnosis should be made by a physician after all clinical and laboratory findings have been evaluated. The diagnosis is to be verified using different diagnostic methods.

6 Sample Collection, Handling and Storage

Use preferentially freshly collected serum and plasma samples. Blood withdrawal must follow national requirements. Do not use icteric, lipemic, hemolyzed or bacterially contaminated samples. Sera with particles should be cleared by low-speed centrifugation (< 1000 x g). Blood samples should be collected in clean, dry and empty tubes.

After separation, the samples should be used during the first 8 h. Alternatively, the samples should be stored in tightly closed vials at 2-8 °C / 35.6-46.4 °F for up to 48 h, or frozen at -20 °C / -4 °F for longer periods. Avoid freezing and thawing samples repeatedly. (Thomas: Labor und Diagnose; CLSI Guideline GP44-A4) Do not use thermally inactivated samples (56 °C / 132.8 °F).

7 Assay Procedure

7.1 Preparations prior to starting

Before use, bring the reagents to room temperature (20-32 °C / 68-89.6 °F). Remove the test tube from the refrigerator and let it sit for approximately 30 minutes until it reaches room temperature (RT).

Pipette 44 µl purified H₂O into the reagent tube. Do not shake or vortex!

7.2 Test Procedure

Add 1 part reconstituted **AESKUBLOTS® Allergy CCD Blocker** to 50 parts plasma, serum, or serum-dilution, e.g., 10 µL of CCD Blocker to 500 µL of plasma, serum, or serum-dilution

Mix and incubate at room temperature (20–32 °C / 68-89.6 °F) for 10 min.

The treated serum or plasma must be tested on **AESKUBLOTS® Allergy** test immediately after incubation.

8 Qualitative Interpretation

AESKUBLOTS® Allergy CCD Blocker is intended for sample preparation. Evaluation and interpretation are done using **AESKUBLOTS® Allergy**.

For CCD-positive samples, the signal of the CCD lines on the **AESKUBLOTS® Allergy** test must be reduced by more than 1.00 Class. For allergens without known CCD cross-reactivity the result should not deviate by more than 1.0 class after addition of the CCD Blocker.

The following technical issues should as well be checked: expiry date of (prepared) reagents, storage conditions, pipettes, equipment and incubation conditions.

9 Technical Data

Active compound:	MUXF-HAS-conjugate
Reagent volume:	44 µl after reconstitution
Total incubation time:	10 minutes at 20-32 °C / 68-89.6 °F
Storage:	at 2-8 °C / 35.6-46.4 °F; use original vials only.

10 Performance Data

Performance of **AESKUBLOTS® Allergy CCD Blocker** was tested for 10 CCD positive samples (qualified by ImmunoCAP) on the **AESKUBLOTS® Allergy** panels. The results showed that **AESKUBLOTS® Allergy CCD Blocker** reduces the signals in the different **AESKUBLOTS® Allergy** panels according to the acceptance criteria.

11 Disposal

Please observe the relevant statutory requirements!

12 Note to the User (European Union)

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

13 Literature

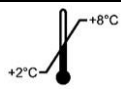
Aberer, W, F Holzweber, W Hemmer, L Koch, D Bokanovic, W Fellner, and F Altmann (2017). Inhibition of Cross-Reactive Carbohydrate Determinants (CCDs) Enhances the Accuracy of in Vitro Allergy Diagnosis." *Allergologie Select* 1 (2): 141–49

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Hemmer, Wolfgang, Friedrich Altmann, Friedrich Holzweber, Clemens Gruber, Felix Wantke, and Stefan Wöhrle (2018). ImmunoCAP Cellulose Displays CrossReactive Carbohydrate Determinant (CCD) Epitopes and Can Cause False Positive Test Results in Patients with High Anti-CCD IgE Antibody Levels. *The Journal of Allergy and Clinical Immunology* 141 (1): 372-381.e3.

14 Regulatory Symbols

IVD	- Diagnosi in vitro - Pour diagnostic in vitro - In Vitro Diagnostikum - Para uso Diagnóstico in vitro	- For in vitro diagnostic use - Para uso diagnóstico in vitro - In Vitro Διαγνωστικό μέσο
REF	- Numero d'ordine - Référence Catalogue - Bestellnummer - Número de catálogo	- Catalogue number - Numéro de catálogo - Αριθμός παραγγελίας
LOT	- Descrizione lotto - Lot - Chargen Bezeichnung - Lote	- Lot - Lote - Χαρακτηρισμός παρτίδας
UDI	- Identificatore univoco del dispositivo - Identifiant unique de l'appareil - eindeutige Produktidentifizierung - Identificador único do dispositivo	- Unique Device Identifier - Identificador único del dispositivo - Μοναδικό αναγνωριστικό συσκευής
CE	- Conformità europea - Déclaration CE de Conformité - Europäische Konformität - Declaração CE de Conformidade	- EC Declaration of Conformity - Declaración CE de Conformidad - Ευρωπαϊκή συμφωνία
eIFU  WWW.AESKU.COM	- Rispettare le istruzioni elettroniche per l'uso - Voir les instructions d'utilisation électronique - Elektronische Gebrauchsanweisung beachten - Seguir as instruções electrónicas de utilização	- See electronic instructions for use - Sigla las instrucciones electrónicas de uso - Ακολουθήστε τις ηλεκτρονικές οδηγίες χρήσης
	- Da utilizzarsi entro - Utilise avant le - Verwendbar bis - Utilizar antes de	- Use by - Utilizar antes de - Χρήση μέχρι
CCD BLOCK	- AESKUBLOTS® Allergy CCD Blocker - AESKUBLOTS® Allergy CCD Blocker - AESKUBLOTS® Allergy CCD Blocker - AESKUBLOTS® Allergy CCD Blocker	- AESKUBLOTS® Allergy CCD Blocker - AESKUBLOTS® Allergy CCD Blocker - AESKUBLOTS® Allergy CCD Blocker - AESKUBLOTS® Allergy CCD Blocker
	- Conservare a 2-8°C (35,6-46,4°F) - Conserver à 2-8°C (35,6-46,4°F) - Lagerung bei 2-8°C (35,6-46,4°F) - Conservar entre 2-8°C (35,6-46,4°F)	- Store at 2-8°C (35,6-46,4°F) - Conserver a 2-8°C (35,6-46,4°F) - Φυλάσσεται στους 2-8°C (35,6-46,4°F)
	- Conservare a -20 °C (-4 °F) - Conserver à -20 °C (-4 °F) - Lagerung bei -20 °C (-4 °F) - Conservar entre -20 °C (-4 °F)	- Store at -20 °C (-4 °F) - Conserver a -20 °C (-4 °F) - Φυλάσσεται στους -20 °C (-4 °F)
	- Prodotto da - Fabriqué par - Hergestellt von - Fabricado por	- Manufactured by - Fabricado por - Κατασκευάζεται από
	- Non riutilizzare - Ne pas réutiliser - Nicht wiederverwenden - Não reutilizar	- Do not reuse - No reutilizar - Μην επαναχρησιμοποιείτε
	- Conservare all'asciutto - Stocker au sec - Trocken aufbewahren - Armazenar em local seco	- Store dry - Almacenar en seco - Αποθηκεύστε ξηρά
	- Non utilizzare se la confezione è danneggiata e consultare le istruzioni per l'uso - Ne pas utiliser si l'emballage est endommagé et consulter le mode d'emploi. - Nicht verwenden, wenn die Verpackung beschädigt ist, und Gebrauchsanweisung beachten - Não utilizar se a embalagem estiver danificada e consultar as instruções de utilização	- Do not use if package is damaged and consult instructions for use - No utilizar si el envase está dañado y consultar las instrucciones de uso - Μην χρησιμοποιείτε εάν η συσκευασία έχει υποστεί ζημιά και συμβουλευτείτε τις οδηγίες χρήσης.