CMV C10/C11 cocktail

Mouse monoclonal antibody C10/C11 mix specific for CMV pp65

REF[9] VIR-CMVC10-C11 200 Tests Product Information File (PIF)

IVD CE 0344 ***In Vitro Diagnostic medical device***

Other languages of this Product's Instruction for Use (IFU) / Product Insert can be found at the World Wide Web at www.iqproducts.nl. Copies may also be requested by sending an email request to marketing@iqproducts.com or by contacting your local product distributor.

Monoclonal antibody, C10/C11 mix against CMV lower matrix protein pp65

At this time, the CMV C10/C11 cocktail- CMV Brite™ Turbo Kit is registered as "in vitro diagnostic medical device" in Australia, Brasil, Peru, Saudi Arabia, Singapore, South Korea, the United States of America and in the countries that belong to the European Community. In all other countries it should be labeled "for research use only". Please be aware that this product is not approved for use in testing (i.e. screening) of blood or plasma donors. All obligatory and necessary information as specified in Directive 98/79/EC needed to use this product safely and properly, can be found in the package insert of the CMV Brite™ Turbo kit (please see www.iqproducts.nl).

Description

Clone	C10 : 1-5-12 / C11 : 1-5-17
Isotype	IgG1 / IgG1
Specificity	Anti-CMV; pp65 antigen
Applications	The cocktail of two monoclonal antibodies (C10/C11) is directed against the CMV lower matrix protein pp65, an early antigen in virus replication which is abundantly present in antigen positive polymorphonuclear. The cocktail can be used in an indirect immunofluorescence staining in combination with VIR-FITC of cytospin preparations of peripheral blood leukocytes
Usage	Ready-to-use solution

Immunofluorescence staining with VIR-CMV C10/C11 and VIR-FITC

1. Prepare cytocentrifuge slides (according to laboratory procedures).
2. During immunofluorescence staining do not allow the cell preparations to dry out.
3. For controlling the immunofluorescence staining you can use control slides (VIR-CMV CS05) produced by IQ Products.
4. Rehydrate control slide in PBS for 1 - 2 minutes.
5. Remove the slide from the washing solution. Carefully dry the area surrounding the cell spot. (Remove one slide at the time to prevent the cells from drying.)
6. Apply 35 µl of C10/C11 (VIR-CMV C10/C11) moab solution and incubate for 20 minutes at 37 °C in a humid chamber.
7. Dip slides 3 times in washing solution PBS for 3 minutes.
8. Remove one slide at a time from the washing solution. Carefully dry the area surrounding the cell spot.
9. Apply 35 µl of FITC-conjugated sheep anti-mouse immunoglobulins with Evans Blue (VIR-FITC).
10. Incubate for 20 minutes at 37 °C in a humid chamber.
11. Wash twice in fresh PBS and carefully rinse with tap water (3 times). Mount with mounting medium and a micro cover glass.
12. Perform reading as soon as possible. Cover the slides tightly in order to minimize fading.

Handling and Storage

Antibodies are supplied as 200 tests per vial (7 mL). They are supplied as tissue culture supernatant containing 8% (v/v) FBS 0.09% sodiumazide (NaN_3). Store the vials at 2-8 °C. Reagents are stable for the period shown on the vial label when stored properly

Warranty Products sold hereunder are warranted only to conform to the quantity and contents stated on the label at the time of delivery to the customer. There are no warranties, expressed or implied, which extend beyond the description on the label of the product. IQ Products is not liable for property damage, personal injury, or economic loss caused by the product

Characterization

To ensure consistently high-quality reagents, each batch of monoclonal antibody is tested for conformance with characteristics of a standard reagent.

Warning All products contain sodiumazide. This chemical is poisonous and hazardous. Handling should be done by trained staff only

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Current version + release date	Version 4 February 2025
Previous version	Version 3
Changes	1. Added sentence: Other languages of this Product's Instruction for Use (IFU) / Product Insert can be found at the World Wide Web at www.iqproducts.nl. Copies may also be requested by sending an email request to marketing@iqproducts.com or by contacting your local product distributor. 2. Added Australia, Peru and Saudi-Arabiaas country in which this product is registered as IVD.
Justification	1. Clarification for customers. 2. Registration in these countries is complete.

Current version + release date	Version 3 January 2025
Previous version	Version 2
Changes	1. Attachment Package Insert CMV Brite Turbo (CMV-Kit) and the reference to this attachment was removed. Reference to the CMV-Kit package insert on IQ Products website was added. 2. Fax number was deleted. 3. Added that the product is not approved for use in testing (i.e. screening) of blood or plasma donors. 4. Replaced sentence on 'RUO' labeling by the following sentence: At this time, the Control slides - CMV Brite™ Turbo Kit is registered as "in vitro diagnostic medical device" in Brasil, Singapore, South Korea, the United States of America and in the countries that belong to the European Community. In all other countries it should be labeled "for research use only". 5. All translations except for the English version were deleted.
Justification	1. Prevention of the attached package insert is not the currently active version. 2. Fax number is no longer used. 3. Required for registration in Singapore. 4. Mention the same information as in the Package Insert of the CMV-Kit. 5. Specific information in several translations can be found on the CMV-Kit Package Insert.

Current version + release date	Version 2 November 2024
Previous version	Version 1
Changes	Updated the attached version of the CMV Brite Turbo Package Insert.
Justification	A new version of the package insert was activated.

Current version + release date	Version 1 January 2018
Previous version	N/A
Changes	N/A
Justification	N/A