



CMV Control slides

CMV pp65 positive and negative cytopots

REF⁹ VIR-CMV CS05 ▾ 5 slides **i** Product Information File (PIF)

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

Control slides – CMV Brite™ Turbo kit

At this time, the Control slides - CMV Brite™ Turbo Kit are 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

The CMV control slides are a component of the CMV Brite™ Turbo kit which can be used as a control in the fluorescence staining in the test procedure of the CMV Brite Turbo kit. Slides are provided in a sealed pouch with desiccant and are ready to use.

Form

Microscope slides with a positive and negative cytospot. Positive cytospot contains pp65 positive sf9 cells. Cells are fixated.

Applications

Slides can be used as a control in the fluorescence staining in the test procedure of the CMV Brite Turbo™ kit.

Usage

The positive and negative control slides are provided with the CMV Brite Turbo™ kit. The slides are only used to check the staining procedure and do not influence the diagnostic value of the kit. The positive control must demonstrate appropriate staining before patient specimens can be evaluated. The positive control should exhibit homogeneous yellow-green staining of positive cells with round morphology (nucleus is not visible). The negative control should show no yellow-green staining. Despite the fact that the quality procedures are followed strictly, single positive cells could be observed in the negative control. In such cases the staining run should not be considered invalid. The single positive cells on the negative control do not mean that the slide with patient material cannot be interpreted.



Handling and Storage

Control slides are stable for the period shown on the box 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, each batch of CMV control slides is tested for conformance.

Warning Product contains glass.



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Current version + release date	Version 4 February 2025
Previous version	Version 3
Changes	Added Australia, Peru and Saudi-Arabiaas country in which this product is registered as IVD.
Justification	Registration in these countries is complete.

Current version + release date	Version 3 January 2025
Previous version	Version 2
Changes	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 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 2023
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 March 2019
Previous version	N/A
Changes	N/A
Justification	N/A