Dia.Pro
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Extracted from

Design Dossier

VCA IgM

Ref. VCAM.CE

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1. PRODUCT DESCRIPTION

The devise coded VCAM.CE is an In Vitro Diagnostic Device or IVDD and derives from the product name VCA IgM, code VCAM, manufactured by Dia.Pro Diagnostic BioProbes s.r.l. since 1999, adapted to match what required by the directive 98/79/EC.

The product is classified according to EDMA definitions as a devise for the determination of Viral Markers, code n° 15.04.04.07.

The product is not classified by the IVDD directive 98/79/EC (self-certification) .

Specifically, the device is an Enzyme Linked Immuno Sorbent Assay (or ELISA) intended to be used for the quantitative determination of class IgM antibody to Epstein Barr Virus Capsidic Antigen in human plasma and sera.

The kit is composed of a box that contains all the components and the instructions for use necessary for 96 tests.

In order to preserve the performances of the device, the kit has to be always stored and shipped at +2…8°C. At the customer site, the kit has to be stored at 2..8°C and returned to that temperature, after use.

The kit has to be used by skilled and qualified personnel in a laboratory of diagnostic analysis, under the control and supervision of a medical doctor, responsible of the management of the laboratory. The laboratory has to be qualified by a notified body to carry out in vitro diagnosis of human diseases.

The device contains the following components:

1. Antibody coated microwells (microplate)
2. Calibration Curve
3. Control Serum, lyophilised
4. Wash buffer concentrate
5. Enzyme conjugate 20x concentrate
6. Antigen diluent
7. Lyophilised VCA antigen
8. Chromogen/Substrate
9. Stop solution
10. Specimen Diluent
11. Plate sealing foils
12. Package insert

The kit has to be used in combination with the following essential tools, not supplied by Dia.Pro Diagnostic Bioprobes srl.:

- Automated ELISA Microplate washer
- ELISA Microplate reader
- ELISA Microplate incubator
- Precision micropipettes and disposable tips

Products of human origin are used in the formulation of the Calibration Curve and Control Serum.
The human plasma used is certified negative for HBsAg, HIV Ab and HCV Ab by the supplier (expired donations).
Bovine proteins are used in some components as a protein carrier and/or a stabilizing reagent.

As the product is intended to be used to test human sera and plasma, the package insert reports measures of personal and environmental safety (gloves, glasses and lab coats) to be used by the laboratory personnel when carrying out the assay.

Procedures of waste handling and disposal are also given to the end user.

No variants to the standard format of the device are present.

Should a Distributor want to put the name of its Company on the external box of the device, a specific label (see Annex for Labels) will take over for the one reporting the name of Dia.Pro Diagnostic BioProbes s.r.l.., positioned on the external box, upper label.
No modification of name, code, method of analysis and packaging has been introduced

Important Note:
No Common Technical Specifications have been elaborated by the European Community for VCA IgM testing and no International Standard has been defined, as well, for this assay.
Dia.Pro Diagnostic BioProbes s.r.l. has therefore defined internal Technical Specifications (ITS) for the present device taking into consideration:

a. *what reported by EC CTS for the markers of viral hepatitis B (not used for blood screening) concerning clinical specificity and sensitivity, as a reference of specifications ;*
b. *the specifications for Immunological Testing for Infectious Diseases – Approved Guideline – second Edition – code I/LA18-A2 – defined by NCCLS, USA.*

2. PRODUCT INFORMATION

2.1 Intended use

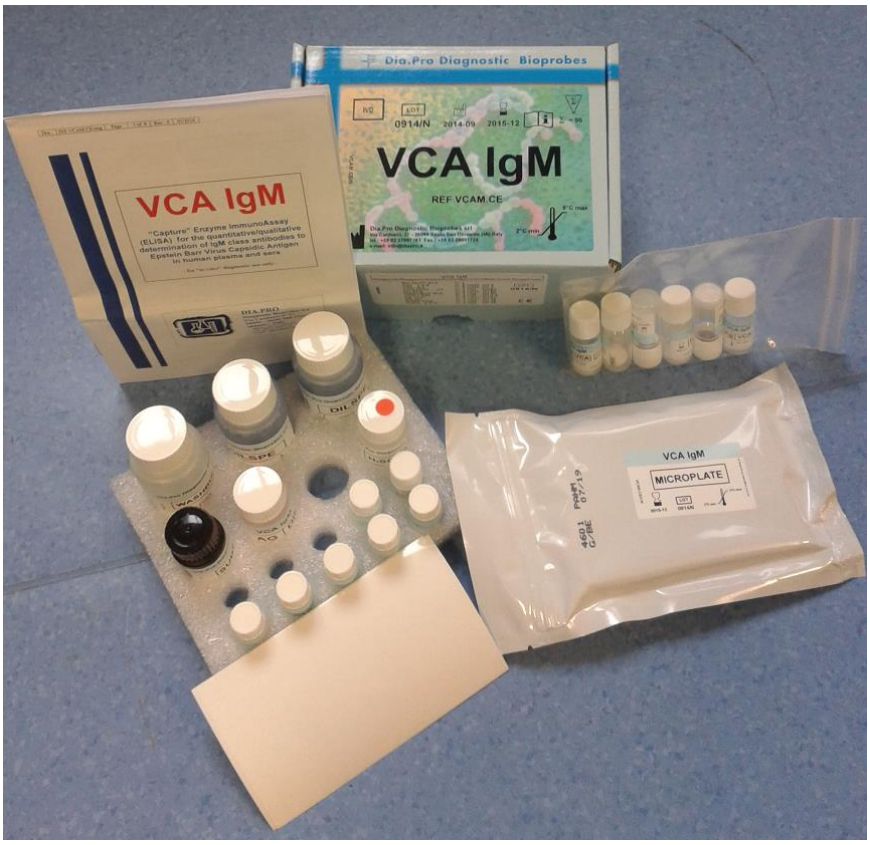
This device VCAM.CE is a quantitative/qualitative test to determinate IgM antibodies to Epstein Barr Virus Capsidic Antigen in human plasma and sera.
The VCAM.CE test can be used manually or automatically.
The VCAM.CE test is intended exclusively for *in vitro* diagnostic use.

2.2 Intended users

The kit VCAM.CE has to be used by skilled and qualified personnel in a laboratory of diagnostic analysis, under the control and supervision of a medical doctor, responsible of the management of the laboratory. The laboratory has to be qualified by a notified body to carry out in vitro diagnosis of human diseases.

2.3 Photographs of kit

The standard device is intended as 96 tests format code VCAM.CE.
A picture of the Product is reported in the Figure below:



2.4 Principle of the assay

The method of analysis used is based on the following principle.
The assay is based on the "IgM Capture" method.
Microplates are coated with a polyclonal anti-hIgM antibody that in the 1st incubation "captures" specifically this class of antibodies.
After washing out all the other components of the sample, in the 2nd incubation bound anti EBV-VCA IgM are detected by the addition of a complex formed by biotinilated affinity purified VCA antigen and Streptavidine, labelled with peroxidase (HRP).
The enzyme captured on the solid phase, acting on the substrate/chromogen mixture, generates an optical signal that is proportional to the amount of IgM antibodies present in the sample and can be detected by an ELISA reader.
Quantification of IgM is made possible by a standard curve calibrated in arbitrary units, in absence of an international standard to refer to.

2.5 Specimen collection

The device has been validated for use with serum and plasma that are prepared using standard techniques of preparation of samples for clinical laboratory analysis.

2.5.1 Serum and plasma collection and transport

Blood is drawn aseptically by venipuncture and plasma or serum is prepared using standard techniques of preparation of samples for clinical laboratory analysis. No influence has been observed in the preparation of the sample with citrate, EDTA and heparin.
Samples have to be clearly identified with codes or names in order to avoid misinterpretation of results.
Haemolysed (red) and visibly hyperlipemic ("milky") samples have to be discarded as they could generate false results. Samples containing residues of fibrin or heavy particles or microbial filaments and bodies should be discarded as they could give rise to false results.
Sera and plasma can be stored at +2°..8°C for up to five days after collection. For longer storage periods, samples can be stored frozen at –20°C for several months. Any frozen samples should not be frozen/thawed more than once as this may generate particles that could affect the test result.
If particles are present, centrifuge at 2.000 rpm for 20 min or filter using 0.2-0.8um filters to clean up the sample for testing.
Do not use heat inactivated samples as they could give origin to false reactivity.

2.6 For instruments of automated assays: a description of the appropriate assay characteristics or dedicated assays

Any ELISA automated work station can be used following some recommendations:

- When using an ELISA automated work station, all critical steps (dispensation, incubation, washing, reading, data handling) have to be carefully set, calibrated, controlled and regularly serviced in order to match the values reported in the IFU (sections "Internal Quality Control"). The assay protocol has to be installed in the operating system of the unit and validated as for the washer and the reader. In addition, the liquid handling part of the station (dispensation and washing) has to be validated and correctly set. Particular attention must be paid to avoid carry over by the needles used for dispensing and for washing. This must be studied and controlled to minimize the possibility of contamination of adjacent wells. The use of ELISA automated work stations is recommended for blood screening when the number of samples to be tested exceed 20-30 units per run.
- It is strongly recommended to check that the time lap between the dispensation of the first and the last sample will be calculated by the instrument and taken into consideration by delaying the first washing operation accordingly.

2.7 Product workflow

The time required to perform the test after clinical specimen collection is about 3h 20' considering that:

1- The components of the kit have to reach room temperature (about 1 hour) before their use in the assay (pre-assay operations)

2- The time required to perform the Assay procedure is about 2h 20' (washing steps excluded) according to the following Assay Scheme:

Calibrators Control Serum (*) Samples diluted 1:101	100 ul 100 ul 100 ul
1st incubation	**60 min**
Temperature	+37°C
Enzyme Conjugate	100 ul
2nd incubation	**60 min**
Temperature	+37°C
TMB/H2O2 mix	100 ul
3rd incubation	**20 min**
Temperature	r.t.
Sulphuric Acid	100 ul
Reading OD	450nm & 620nm

(*) Important Notes:

- *The Control Serum (CS) it does not affect the test's results calculation.*
- *The Control Serum (CS) used only if a laboratory internal quality control is required by the Management.*