Dia.Pro
*Dia*gnostic
Bio*Pro*bes

Extracted from

Design Dossier

VCA IgG

Ref. VCAG.CE

DIA.PRO Diagnostic Bioprobes S.r.l.
Sede legale e lab.: Via G.Carducci, 27 – 20099 Sesto S.Giovanni (MI) – Italia
Tel. +39 02 27007161/6450 • Fax +39 02 44386771 • http://www.diapro.it • E-mail: info@diapro.it
Capitale sociale €50.000,00 I.V. – P.IVA: 11924660159 – Reg. Imp. 11924660159 – REA 1509959

1. PRODUCT DESCRIPTION

The devise named VCA IgG, coded VCAG.CE, is an In Vitro Diagnostic Device or IVDD, manufactured by Dia.Pro srl 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° 15.04.04.08.

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 both the qualitative and the quantitative determination of class IgG antibody to Epstein Barr Virus Viral Antigen (VCA IgG) 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. Antigen coated microwells
2. Calibration curve (arbitrary U/ml)
3. Control serum
4. Wash buffer concentrate
5. Enzyme conjugate
6. Chromogen/Substrate
7. Stop solution
8. Specimen Diluent
9. Plate sealing foils
10. 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 standard curve (human IgG).
The VCA IgG positive plasma used there is certified negative for HBs Ag, HIV Ab and HCV Ab by the supplier (expired donations).
Serum bovine albumin is used in some components as a carrier and a stabilizing product.

Foetal bovine serum is used as protein carrier in the lyophilised control serum.

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 EBNA IgG determination. Dia.Pro Diagnostic BioProbes s.r.l. has therefore defined the internal technical specifications, or ITS for the present device taking into consideration:

a. *what reported by EC CTS for the markers of viral hepatitis, not used for blood screening, concerning clinical specificity and sensitivity;*
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 VCAG.CE is a quantitative/qualitative test to determinate IgG antibodies to Epstein Barr Virus Capsidic Antigen in human plasma and sera.
The VCAG.CE test can be used manually or automatically.
The VCAG.CE test is intended exclusively for *in vitro* diagnostic use.

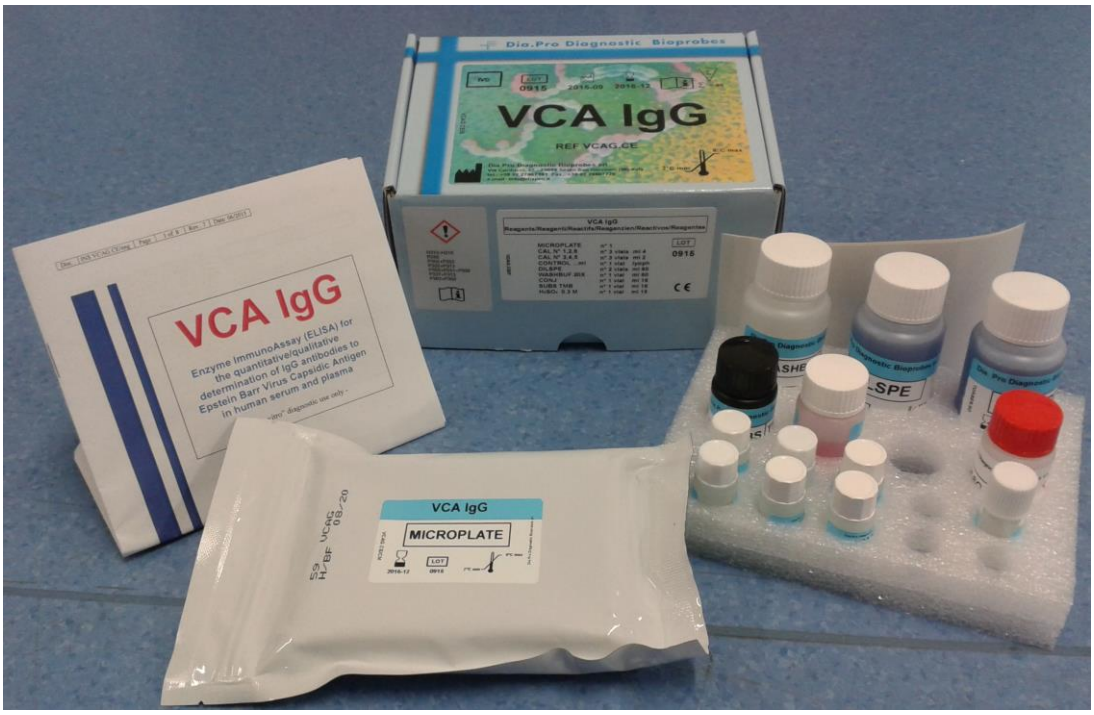
2.2 Intended users

The kit VCAG.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 VCAG.CE.
A picture of the Product is reported in the Figure below:

Figure 2-1: Illustration of the VCAG.CE with all components out of the kit



2.4 Principle of the assay

The method of analysis used is based on the following principle.
Microplates are coated with affinity purified native VCA antigen, to provide the assay with the highest specificity and sensitivity.
In the 1st incubation, the solid phase is treated with diluted samples and anti-VCA IgG are captured, if present, by the antigens.
After washing out all the other components of the sample, in the 2nd incubation bound anti-VCA IgG are detected by the addition of anti hIgG antibody, labeled 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 anti-VCA IgG antibodies present in the sample.
IgG in the sample may therefore be quantitated by means of a standard curve calibrated in arbitrary units per milliliter (arbU/ml) as no international standard is available.

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:

Method	**Operations**
Calibrators	100 µl
Control Serum (*)	100 µl
Samples diluted 1:101	100 µl
1st incubation	**60 min**
Temperature	+37°C
Wash step	4-5 cycles
Enzyme conjugate	100 µl
2nd incubation	**60 min**
Temperature	+37°C
Wash step	4-5 cycles
TMB/H2O2	100 µl
3rd incubation	**20 min**
Temperature	r.t.
Sulphuric Acid	100 ul
Reading OD	450nm

(*) 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.*