Dia.Pro
Diagnostic
BioProbes

Extracted from

Device Master File

HAV Ab

Ref. AVAB.CE

DIA.PRO Diagnostic Bioprobes S.r.l.
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Capitale sociale €50.000,00 I.V. – P.IVA: 11924660159 – Reg. Imp. 11924660159 – REA 1509959

2. PRODUCT INFORMATION

2.1. Product description including variants (configuration) and accessories

2.1.1. Product description

Specifically, the device is an Enzyme Linked Immuno Sorbent Assay (or ELISA) intended to be used for the qualitative determination of total antibody to Hepatitis A Virus HAV Ab in human plasma and sera derived from HAV infected patients.

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

1. Antigen coated microwells
2. Negative Control
3. Positive Control
4. Calibrator
5. Wash buffer concentrate
6. Enzyme conjugate
7. Chromogen/Substrate
8. Specimen diluent
9. Stop solution
10. Plate sealing foils
11. 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

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The method of analysis used is based on the following principle.

2.1.2. Intended use

This device AVAB.CE is a qualitative test to determinate antibodies to Hepatitis A Virus in human plasma and sera. The kit is used for the follow-up of patients infected by HAV in human plasma and sera.
The AVAB.CE test is intended exclusively for *in vitro* diagnostic use.

2.1.3. Intended users

The kit AVAB.CE hasto be used by skilled and properly trained technical personnel only, under the supervision of a medical doctor responsible of the laboratory.
The kit 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.

2.1.4. Photographs of kit

The standard device is intended as 96 tests format code AVAB.CE.
A picture of the Product is reported in the Figure 2-1

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

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2.1.5. Principle of the assay

The method of analysis used is based on the following principle.
The assay is based on the principle of competition where the antibodies in the sample compete with a polyclonal antibody for a fixed amount of antigen on the solid phase.
A purified inactivated HAV is coated to the microwells.
The patient's serum/plasma is added to the well.
Then a polyclonal antibody, conjugated with Horseradish Peroxidase (HRP) and specific to HAV is added and binds to the free HAV coated on the plastic.

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After incubation, microwells are washed to remove any unbound conjugate and then the chromogen/substrate is added. In the presence of HRP the colourless substrate is hydrolysed to a coloured end-product.
The colour intensity is inversely proportional to the amount of antibodies to HAV present in the sample.

2.1.6. Components of the kit

The device HAV Ab consists of the following dedicated components, shown in Table 2-2.

Table 2-2: Description of components of the device

Number of tests	**96**
Code	**AVAB.CE**
1.Microplate	n°1
2.Negative Control	1x4ml/vial
3.Positive Control	1x4ml/vial
4.Calibrator	n°1 vial
5. Wash buff conc	1x60ml/bottle
6.Enzyme Conjugate	1x16ml/vials
7.Chrom/Substrate	1x16ml/vial
8. Specimen Diluent	1x6ml/vial
9.Sulphuric Acid	1x15ml/vial
10.Plate seal foils	n° 2
11.Pack. insert	n° 1

Note: upon request, a Calibration Curve ranging: 0-5-10-50-100 WHOmIU/ml is supplied. The calibration curve contains diluted human HAV Ab positive plasma certified negative for HBsAg, HIV Ab and HCV Ab by the supplier (expired donations).

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

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