Dia.Pro
Diagnostic
BioProbes

Extracted from

Device Master File

HDV Ag

Ref. DAG.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

1.6 Status of pending request for market clearance

Not applicable.

1.7 Safety and Performance

1.7.1 Biological safety

Information on materials of human and animal origin is shown in Table 1-3.

Table 1-3: Information on materials of human and animal origin

Material	Origin	Steps to decrease risk of transmission on infection
Bovine Serum Albumin (BSA)	Animal	All BSA used in the reagents contained in the DAG.CE kit originate from herds in countries declared free of Transmissible Spongiform Encephalopathies (TSE) and are obtained from TSE-free certified manufacturers.

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2. PRODUCT INFORMATION

2.1. Product description including variants (configuration) and accessories

2.1.1. Product description

Specifically, the devise is an Enzyme Linked Immuno Sorbent Assay (or ELISA) intended to be used for the qualitative determination of Hepatitis Delta Virus specific Antigen or HDV Ag in human plasma and sera derived from patients suspected of bearing infection.

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

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The device contains the following components:

1. Microplate
2. Negative Control
3. Positive Control
4. Calibrator
5. Wash buffer concentrate
6. Enzyme conjugate
7. Specimen Diluent
8. Chromogen/Substrate
9. Sulphuric Acid
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

2.1.2. Intended use

This device DAG.CE is a qualitative test for determination of Hepatitis Delta Virus or HDV in human plasma and sera.
The DAG.CE test is intended exclusively for *in vitro* diagnostic use.

2.1.3. Intended users

The kit DAG.CE has to 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.

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2.1.4. Photographs of kit

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

Figure 2-1: Illustration of the DAG.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.
HDV Ag, if present in the sample, is captured by a specific monoclonal antibody, in the 1st incubation. A detergent is added to the sample in order to dissolve the specific antigen from HDV particles. In the 2nd incubation, after washing, a tracer, composed of a second anti HDV Ag antibody, labeled with peroxidase (HRP), is added to the microplate and binds to the captured HDV Ag. The concentration of the bound enzyme on the solid phase is proportional to the amount of HDV Ag in the sample and its activity is detected by adding the chromogen/substrate in the 3rd incubation. The presence of HDV Ag in the sample is determined by means of a cut-off value that allows for the semi quantitative detection of the antigen.

2.1.6. Components of the kit

The device HDV Ag 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	**DAG.CE**
1.Microplate	n°1
2.Negative Control	1x2ml/vial
3.Positive Control	1x2ml/vial
4.Calibrator	n°1 vial
5. Wash buff conc	1x60ml/bottle
6.Enzyme Conjugate	1x16 vial
7.Chrom/Substrate	1x16ml/vial
8.Specimen Diluent	1x16ml/vial
9.Sulphuric Acid	1x15ml/vial
10.Plate seal foils	n° 2
11.Pack. insert	n° 1

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

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