ms_11361252122V8.0

Diluent Hepatitis A

cobas®

REF **11361252** 122 **2 x 15 mL**

English

Intended use

Diluent Hepatitis A is used as a sample diluent in conjunction with the Elecsys Anti-HAV assay.

Summary

Dilution of samples is necessary when the anti-HAV concentrations of the samples exceed the measuring range of the Elecsys Anti-HAV assay.

Reagents - working solutions

2 bottles each containing 15 mL

Contents: Human serum matrix; preservative

Precautions and warnings

For in vitro diagnostic use.
Exercise the normal precautions required for handling all laboratory reagents.
Disposal of all waste material should be in accordance with local guidelines.
Safety data sheet available for professional user on request.

All human material should be considered potentially infectious. All products derived from human blood are prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV and HIV. The testing methods applied were FDA-approved or cleared in compliance with the European Directive 98/79/EC, Annex II, List A.

However, as no testing method can rule out the potential risk of infection with absolute certainty, the material should be handled with the same level of care as a patient specimen. In the event of exposure, the directives of the responsible health authorities should be followed.[1,2]

Avoid foam formation in all reagents and sample types (specimens, calibrators and controls).

Reagent handling

Diluent Hepatitis A is ready for use.

Bring to 20-25 °C before use.

Avoid contamination!

Storage and stability

Store at 2-8 °C.

Stability:	
unopened at 2-8 °C	up to the stated expiration date
after opening at 2-8 °C	6 weeks

The possible occurrence of precipitate does not impair the performance of the assay.

Materials provided

- Diluent Hepatitis A

Materials required (but not provided)

- Elecsys 2010, MODULAR ANALYTICS E170 or **cobas e** immunoassay analyzers and Elecsys Anti-HAV assay reagents

See the assay Method Sheet and the operator's manual for additionally required material.

Assay

For analyte concentrations above the measuring range, see dilution recommendation in the Elecsys Anti-HAV Method Sheet. Perform dilutions manually. Label diluted samples as such at the sample identification stage and analyze in the same way as undiluted samples.

Elecsys test results

The analyte content of the diluent is in the vicinity of the lower detection limit of the Elecsys Anti-HAV assay and is not taken into account. Multiply the measured concentrations by the dilution factor.

The concentration in the diluted sample may not be less than the stated minimum concentration in the Elecsys Anti-HAV assay.

References

1 Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register.

2 Directive 2000/54/EC of the European Parliament and Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.

For further information, please refer to the appropriate operator's manual for the analyzer concerned, the respective application sheets, the product information and the Method Sheets of all necessary components (if available in your country).

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard.

CONTENT	Contents of kit
SYSTEM	Analyzers/Instruments on which reagents can be used
REAGENT	Reagent
CALIBRATOR	Calibrator
→	Volume after reconstitution or mixing
GTIN	Global Trade Item Number

CE

Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim
www.roche.com

Roche