

Diluent Universal

REF 07299001190

07299001500

36 mL

English

Intended use

Diluent Universal is used as a sample diluent in conjunction with Elecsys assay reagents.

Summary

Dilution of samples is necessary when the analyte concentrations exceed the measuring range of the respective Elecsys assay method. In addition, general predilution of samples is specified for some Elecsys assays.

For further information, please refer to the electronically available note.

Reagents - working solutions

Diluent Universal is labeled as Dil Uni.

3 bottles containing a total usable volume of 36 mL

Contents: Protein matrix; preservative

Precautions and warnings

For in vitro diagnostic use for health care professionals. Exercise the normal precautions required for handling all laboratory reagents.

Infectious or microbial waste:

Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards:

Apply all relevant local disposal regulations to determine the safe disposal.

Safety data sheet available for professional user on request.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:



Warning

H317 May cause an allergic skin reaction.

Prevention:

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves.

Response:

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

P362 + P364 Take off contaminated clothing and wash it before reuse.

Disposal:

P501 Dispose of contents/container to an approved waste disposal plant.

Product safety labeling follows EU GHS guidance.

Contact phone: all countries: +49-621-7590

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

Reagent handling

Diluent Universal is ready for use.

Place the cooled (stored at 2-8 °C) diluent on the reagent manager. The system automatically regulates the temperature of the reagents and the opening/closing of the bottles.

Storage and stability

Store at 2-8 °C.

Stability:

unopened at 2-8 °C	up to the stated expiration date
on the analyzers	16 weeks

Materials provided

- Diluent Universal

Materials required (but not provided)

- cobas e 402 and cobas e 801 analyzers and Elecsys assay reagents

See the appropriate Elecsys assay Method Sheet and the operator's manual for additionally required materials.

Assay

For general predilution and for analyte concentrations above the measuring range, see dilution recommendation in the respective Elecsys assay Method Sheet.

Dilutions can be performed either manually by the operator or, if requested, automatically by the analyzer via the instrument's software.

Elecsys test results

The analyte content of the diluent is in the vicinity of the lower detection limit for the Elecsys assays and can be ignored.

For manual dilutions, the measured concentration must be multiplied by the dilution factor to obtain the actual value in the sample. When dilution is performed by the analyzer, this factor is automatically included in the calculation of the sample concentration.

The concentration in the diluted sample may not be less than the stated minimum concentration in the respective Elecsys assay Method Sheet.

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.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see dialog.roche.com for definition of symbols used):

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

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Additions, deletions or changes are indicated by a change bar in the margin.

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