

Diluent Universal 2

REF 05192943190

2 x 36 mL

English

For use in the USA only

Intended use

Diluent Universal 2 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 test method. In addition, general predilution of samples is specified for some Elecsys assays.

Assay	REF	cobas e 411	cobas e 601, cobas e 602
Elecsys hGH	05390125190	•	•
Elecsys Cortisol II	06687733160	•	•
Elecsys AFP	09015060160	•	•
Elecsys AFP	09015086160	•	•
Elecsys AMH	06331076160	•	•
Elecsys AMH	08819319160	•	•
Elecsys IGF-1	07475896190	•	•
Elecsys Androstenedione	07679831190	•	•
Elecsys Anti-SARS-CoV-2 S	09289267190	•	•
Elecsys HCG STAT	08890587190	•	•
Elecsys proBNP II	09315268160	•	•
Elecsys proBNP II STAT	09315276160	-	•

- Autodilution possible
- Assay not available on analyzer

Reagents - working solutions

Diluent Universal 2 is labeled as Dil. Uni. 2.

2 bottles each containing a usable volume of 36 mL

Contents: Protein matrix; preservative ≤ 0.1 %

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.

For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

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 mist or vapours.

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: 1-800-428-2336

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

Reagent handling

Diluent Universal 2 is ready for use.

Bring the cooled diluent to approximately 20 °C and place on the reagent disk of the analyzer.

Opening and closing of the bottle is performed automatically by the analyzer.

Storage and stability

Store at 2-8 °C.

Stability:	
unopened at 2-8 °C	up to the stated expiration date
on the analyzers at 20-25 °C	12 weeks

Materials provided

- Diluent Universal 2

Materials required (but not provided)

cobas e immunoassay analyzers and assay reagents

See the appropriate 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 kit.

Dilutions can be performed either manually by the operator or, if requested, automatically by the analyzers via the instruments' 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.

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

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

Diluent Universal 2



SYSTEM	Analyzers/Instruments on which reagents can be used
REAGENT	Reagent
CALIBRATOR	Calibrator
→	Volume for reconstitution
GTIN	Global Trade Item Number

FOR US CUSTOMERS ONLY: LIMITED WARRANTY



Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

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