

Diluent Universal



REF 03183971 122

2 x 36 mL

For USA: Elecsys Diluent Universal

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

Assay	REF	cobas e 411	MODULAR ANALYTICS E170	cobas e 601, cobas e 602
Prolactin II	03203093	•	•	•
Cortisol	11875116	•	•	•
HCG STAT	03300811	•	—	•
total P1NP	03141071	•	•	•
Troponin T STAT	04660307	•	—	•
Troponin T	04491815	•	•	•
Myoglobin	12178214	•	•	•
Myoglobin STAT	11820788	•	—	•
Digitoxin	03002659	•	•	•
proBNP II	04842464	•	•	•
proBNP II STAT	05390109	—	—	•
CEA	11731629	•	•	•
CEA	04491777	—	•	•
AFP	04481798	•	•	•
AFP	04491742	—	•	•
total PSA	04641655	•	•	•
total PSA	04491734	—	•	•
CA 15-3 II	03045838	•	•	•
CA 125 II	11776223	•	•	•
CA 19-9	11776193	•	•	•
CA 72-4	11776258	•	•	•
CYFRA 21-1	11820966	•	•	•
Ferritin	03737551	•	•	•
Ferritin	04491785	•	•	•
Anti-HBs	11820524	•	•	•
Elecsys Anti-HBs II	05894816	•	•	•
Elecsys Anti-HBs II	06771823	•	•	•
Anti-HBc IgM	11820567	•	•	•
Anti-HAV IgM	11820591	•	•	•
Toxo IgG	04618815	•	•	•
Toxo IgM	04618858	•	•	•
Rubella IgG	04618793	•	•	•
Rubella IgM	04618831	•	•	•
Digoxin	11820796	•	•	•
IgE II	04827031	•	•	•
N-MID Osteocalcin	12149133	•	•	•
Tg	05118921	•	•	•
HCG+β	03271749	•	•	•

Assay	REF	cobas e 411	MODULAR ANALYTICS E170	cobas e 601, cobas e 602
free βhCG	04854071	•	•	•
PAPP-A	04854098	•	•	•
CMV IgG	04784596	•	•	•
CMV IgM	04784618	•	•	•
PTH (1-84)	05608546	•	•	•
SCC	07126972	•	•	•

• Autodilution possible

— Autodilution not possible

Reagents - working solutions

Diluent Universal is labeled as Dil. Uni.

2 bottles each containing 36 mL

Contents: Protein matrix; preservative ≤ 0.1 %

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.

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

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

Reagent handling

Diluent Universal 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	3 months

Materials provided

- Diluent Universal

Materials required (but not provided)

- MODULAR ANALYTICS E170 or 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 Method Sheet.

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.

Diluent Universal









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, 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 (for USA: see <https://usdiagnostics.roche.com> for definition of symbols used):

	Contents of kit
	Analyzers/Instruments on which reagents can be used
	Reagent
	Calibrator
	Volume after reconstitution or mixing
	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.

COBAS, COBAS E and ELECSYS are trademarks of Roche.

All other product names and trademarks are the property of their respective owners.

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

© 2016, Roche Diagnostics



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



Distribution in USA by:

Roche Diagnostics, Indianapolis, IN

US Customer Technical Support 1-800-428-2336