



Elecsys BRAHMS PCT

cobas®

REF			SYSTEM
08828679190	08828679500	300	cobas e 402 cobas e 801

English

System information

Short name	ACN (application code number)
PCT	10161

Intended use

Immunoassay for the in vitro quantitative determination of PCT (procalcitonin) in human serum and plasma.

The Elecsys BRAHMS PCT assay can be used to aid in the early detection of clinically relevant bacterial infections.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on **cobas e** immunoassay analyzers.

Summary

Procalcitonin (PCT) is a 116 amino acid prohormone with a molecular weight of approximately 12.7 kDa. PCT is expressed by neuroendocrine cells (C cells of the thyroid, pulmonary and pancreatic tissues) and successively enzymatically cleaved into (immature) calcitonin, katacalcitonin, and an N-terminal region. The blood of healthy individuals contains only low levels of PCT.^{1,2} It was discovered that PCT increases during bacterial infection.

It is probable that multiple tissues express PCT throughout the body in response to sepsis as was shown in an animal model.³ PCT circulating in septic patients consists of only 114 amino acids lacking the N-terminal dipeptide Ala-Pro.⁴

Increased PCT levels are often found in patients suffering from bacterial sepsis, especially severe sepsis and septic shock.^{5,6,7,8,9,10} PCT is considered as a prognostic marker to support outcome prediction in sepsis patients.^{8,11,12,13}

In acute pancreatitis PCT was found to be a reliable indicator of severity and of major complications.^{14,15}

In patients suffering from community-acquired respiratory tract infections or ventilator-induced pneumonia PCT has been proposed as a guide for the decision of antibiotic treatment necessity and to monitor treatment success.^{16,17}

Test principle

Sandwich principle. Total duration of assay: 18 minutes.

- 1st incubation: Antigen in the sample (18 µL), a biotinylated monoclonal PCT-specific antibody, and a monoclonal PCT-specific antibody labeled with a ruthenium complex^{a)} react to form a sandwich complex.
- 2nd incubation: After addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin.
- The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell II M. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier.
- Results are determined via a calibration curve which is instrument-specifically generated by 2-point calibration and a master curve provided via the **cobas** link.

a) Tris(2,2'-bipyridyl)ruthenium(II)-complex (Ru(bpy)₃²⁺)

Reagents - working solutions

The **cobas e** pack (M, R1, R2) is labeled as PCT.

M Streptavidin-coated microparticles, 1 bottle, 12.4 mL:
Streptavidin-coated microparticles 0.72 mg/mL; preservative.

R1 Anti-PCT-Ab~biotin, 1 bottle, 18.8 mL:
Biotinylated monoclonal anti-PCT antibody (mouse) 2.0 µg/mL;
phosphate buffer 95 mmol/L, pH 7.5; preservative.

R2 Anti-PCT-Ab~Ru(bpy)₃²⁺, 1 bottle, 18.8 mL:
Monoclonal anti-PCT antibody (mouse) labeled with ruthenium complex 5.6 µg/mL; phosphate buffer 95 mmol/L, pH 7.5; preservative.

PCT Cal1 PCT calibrator 1 (lyophilized), 1 bottle for 4 mL:
PCT (recombinant) approximately 0.10 ng/mL in a human serum matrix; preservative.

PCT Cal2 PCT calibrator 2 (lyophilized), 1 bottle for 4 mL:
PCT (recombinant) approximately 54 ng/mL in a human serum matrix; preservative.

PC PCT1 PreciControl PCT 1 (lyophilized), 2 bottles each for 4 mL:
PCT (recombinant) approximately 0.50 ng/mL in a human serum matrix; preservative.

PC PCT2 PreciControl PCT 2 (lyophilized), 2 bottles each for 4 mL:
PCT (recombinant) approximately 10 ng/mL in a human serum matrix; preservative.

Calibrators: The exact lot-specific calibrator values are available via the **cobas** link.

Controls: The exact lot-specific target values and ranges are available via the **cobas** link.

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.

H412 Harmful to aquatic life with long lasting effects.

Prevention:

P261 Avoid breathing dust.

P273 Avoid release to the environment.

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.

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

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 use assays that have been approved or cleared by the FDA or that are in compliance with the legal rules of the European Union (IVDR 2017/746/EU, IVDD 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.^{18,19}

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

Reagent handling

The reagents (M, R1, R2) in the kit are ready-for-use and are supplied in **cobas e** packs.

Calibrators and controls:

Carefully dissolve the contents of one bottle by adding exactly 4.0 mL of distilled or deionized water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding foam formation. Transfer the reconstituted calibrators/controls into empty labeled snap-cap bottles.

Unless the entire volume is necessary for calibration and quality control on the analyzer, transfer aliquots of the freshly reconstituted calibrators and controls into empty snap-cap bottles (CalSet Vials/ControlSet Vials). Attach the supplied labels to these additional bottles. Store the aliquots at -20 °C (± 5 °C) for later use. Perform **only one** calibration or control procedure per aliquot.

Note: Do not combine bottles from different lots. Use only control bottles out of one lot with each other.

All information required for correct operation is available via the **cobas** link.

Storage and stability

Store at 2-8 °C.

Do not freeze.

Store the **cobas e** pack **upright** in order to ensure complete availability of the microparticles during automatic mixing prior to use.

Stability of the cobas e pack:	
unopened at 2-8 °C	up to the stated expiration date
on the analyzers	16 weeks

The lyophilized calibrators and controls are stable up to the stated expiration date.

Stability of the reconstituted calibrators/controls:	
at -20 °C (± 5 °C)	3 months (freeze only once)
on the analyzers at 20-25 °C	2 hours (use only once)

Store the calibrators and controls **upright** in order to prevent the solution from adhering to the snap-cap.

Specimen collection and preparation

Only the specimens listed below were tested and found acceptable.

Serum collected using standard sampling tubes or tubes containing separating gel.

Li-heparin, K₂-EDTA and K₃-EDTA plasma.

Plasma tubes containing separating gel can be used.

Criterion: Slope 0.9-1.1 + intercept within ± 0.06 ng/mL + coefficient of correlation ≥ 0.95 .

Stable for 24 hours at 20-25 °C, 48 hours at 2-8 °C, 13 months at -20 °C (± 5 °C). Freeze only once.

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.

Centrifuge samples containing precipitates before performing the assay.

Do not use samples and controls stabilized with azide.

Ensure the samples and calibrators are at 20-25 °C prior to measurement.

Due to possible evaporation effects, samples and calibrators on the analyzers should be analyzed/measured within 2 hours.

Materials provided

See "Reagents – working solutions" section for reagents.

- 2 x 8 bottle labels (calibrators)
- 2 x 14 bottle labels (controls)
- 6 empty labeled snap-cap bottles

Materials required (but not provided)

- [REF] 11776576322, CalSet Vials, 2 x 56 empty snap-cap bottles
- [REF] 03142949122, ControlSet Vials, 2 x 56 empty snap-cap bottles
- General laboratory equipment

- cobas e** analyzer

Additional materials for **cobas e** 402 and **cobas e** 801 analyzers:

- [REF] 06908799190, ProCell II M, 2 x 2 L system solution
- [REF] 04880293190, CleanCell M, 2 x 2 L measuring cell cleaning solution
- [REF] 07485409001, Reservoir Cup, 8 cups to supply ProCell II M and CleanCell M
- [REF] 05694302001, Assay Tip/Assay Cup tray, 6 magazines x 6 magazine stacks x 105 assay tips and 105 assay cups, 3 wasteliners
- [REF] 07485425001, Liquid Flow Cleaning Cup, 2 adaptor cups to supply ISE Cleaning Solution/Elecsys SysClean for Liquid Flow Cleaning Detection Unit
- [REF] 07485433001, PreWash Liquid Flow Cleaning Cup, 1 adaptor cup to supply ISE Cleaning Solution/Elecsys SysClean for Liquid Flow Cleaning PreWash Unit
- [REF] 11298500316, ISE Cleaning Solution/Elecsys SysClean, 5 x 100 mL system cleaning solution

Assay

For optimum performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator's manual for analyzer-specific assay instructions.

Resuspension of the microparticles takes place automatically prior to use.

Place the cooled (stored at 2-8 °C) **cobas e** pack on the reagent manager. Avoid foam formation. The system automatically regulates the temperature of the reagents and the opening/closing of the **cobas e** pack.

Calibrators:

Place the reconstituted calibrators (in the system-compatible bottles with barcoded labels) in the sample zone.

Read in all the information necessary for calibrating the assay.

After calibration has been performed, discard the calibrators.

Controls:

Place the reconstituted controls in the sample zone.

After the control procedure has been performed, discard the controls.

Calibration

Traceability: This method has been standardized against the BRAHMS PCT LIA assay.

The predefined master curve is adapted to the analyzer using PCT Cal1 and PCT Cal2.

Calibration frequency: Calibration must be performed once per reagent lot using fresh reagent (i.e. not more than 24 hours since the **cobas e** pack was registered on the analyzer).

Calibration interval may be extended based on acceptable verification of calibration by the laboratory.

Renewed calibration is recommended as follows:

- after 12 weeks when using the same reagent lot
- after 28 days when using the same **cobas e** pack on the analyzer
- as required: e.g. quality control findings outside the defined limits

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Quality control

Use PC PCT 1 and PC PCT 2 or other suitable controls for routine quality control procedures.

Controls for the various concentration ranges should be run individually at least once every 24 hours when the test is in use, once per **cobas e** pack, and following each calibration.

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

If necessary, repeat the measurement of the samples concerned.

Follow the applicable government regulations and local guidelines for quality control.

Note: When using 2 reagent kits with different lots in the same run, the controls will be measured with both reagent lots. Use only control values measured with the corresponding lots.

Calculation

The analyzer automatically calculates the analyte concentration of each sample in ng/mL.

Limitations - interference

The effect of the following endogenous substances and pharmaceutical compounds on assay performance was tested. Interferences were tested up to the listed concentrations and no impact on results was observed.

Endogenous substances

Compound	Concentration tested
Bilirubin	≤ 685 μmol/L or ≤ 40 mg/dL
Hemoglobin	≤ 0.559 mmol/L or ≤ 900 mg/dL
Intralipid	≤ 1500 mg/dL
Biotin	≤ 4912 nmol/L or ≤ 1200 ng/mL
Rheumatoid factors	≤ 1200 IU/mL

Criterion: For concentrations ≤ 0.1 ng/mL the deviation is ≤ 0.015 ng/mL. For concentrations > 0.1 ng/mL the deviation is ≤ 15 %.

There is no high-dose hook effect at PCT concentrations up to 1000 ng/mL.

Pharmaceutical substances

In vitro tests were performed on 16 commonly used pharmaceuticals. No interference with the assay was found.

In addition, the following special therapeutic substances were tested. No interference with the assay was found.

Special therapeutic substances

Drug	Concentration tested mg/L
Cefotaxime	≤ 900
Dobutamine	≤ 11.2
Dopamine	≤ 130
Furosemide	≤ 20
Imipenem	≤ 1180
Noradrenaline	≤ 2.0
Vancomycin	≤ 3500

In rare cases, interference due to extremely high titers of antibodies to analyte-specific antibodies, streptavidin or ruthenium can occur. These effects are minimized by suitable test design.

PCT levels can be increased in certain situations without infectious origin. These include, but are not limited to:²⁰

- prolonged or severe cardiogenic shock
- prolonged severe organ perfusion anomalies
- small cell lung cancer or medullary C-cell carcinoma of the thyroid
- early after major trauma, major surgical intervention, severe burns
- treatments which stimulate the release of pro-inflammatory cytokines

- neonates (< 48 hours after birth)²¹

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Limits and ranges

Measuring range

0.02-100 ng/mL (defined by the Limit of Detection and the maximum of the master curve). Values below the Limit of Detection are reported as < 0.02 ng/mL. Values above the measuring range are reported as > 100 ng/mL.

Lower limits of measurement

Limit of Blank, Limit of Detection and Limit of Quantitation

Limit of Blank = 0.015 ng/mL

Limit of Detection = 0.02 ng/mL

Limit of Quantitation = 0.06 ng/mL

The Limit of Blank, Limit of Detection and Limit of Quantitation were determined in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP17-A2 requirements.

The Limit of Blank is the 95th percentile value from n ≥ 60 measurements of analyte-free samples over several independent series. The Limit of Blank corresponds to the concentration below which analyte-free samples are found with a probability of 95 %.

The Limit of Detection is determined based on the Limit of Blank and the standard deviation of low concentration samples. The Limit of Detection corresponds to the lowest analyte concentration which can be detected (value above the Limit of Blank with a probability of 95 %).

The Limit of Quantitation is the lowest analyte concentration that can be reproducibly measured with an intermediate precision CV of ≤ 20 %.

Dilution

Samples with PCT concentrations above the measuring range can be diluted manually with PCT negative human serum or plasma. The recommended dilution is 1:4. The concentration of the diluted sample must be ≥ 20 ng/mL. After manual dilution, multiply the result by the dilution factor.

Expected values

Reference range

A study performed with the Elecsys BRAHMS PCT assay using 492 samples from apparently healthy males (245) and females (247) revealed the following normal value: 0.046 ng/mL (95th percentile).

Clinical cutoff

Results obtained with the Elecsys BRAHMS PCT assay are in agreement with the literature.²⁰ A study performed on samples from patients admitted to an ICU (intensive care unit) showed that PCT values:

< 0.5 ng/mL represent a low risk of severe sepsis and/or septic shock

> 2.0 ng/mL represent a high risk of severe sepsis and/or septic shock

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

Clinical performance

Clinical studies were conducted on samples from 283 ICU patients. The patients were classified into categories based on the ACCP/SCCM (American College of Chest Physicians/Society of Critical Care Medicine) consensus criteria on their first day of ICU admission: SIRS (systemic inflammatory response syndrome), sepsis, severe sepsis and septic shock.²²

The PCT values of the patients with SIRS (n = 95) or sepsis (n = 71) compared to patients with severe sepsis (n = 60) or septic shock (n = 57) were as follows:

Results with a cutoff at 0.5 ng/mL

	Clinical classification		
Elecsys BRAHMS PCT	SIRS	Severe sepsis/ septic shock	Total
< 0.5 ng/mL	63	5	68
≥ 0.5 ng/mL	32	112	144

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Elecsys BRAHMS PCT	Clinical classification		Total
	SIRS	Severe sepsis/ septic shock	
Total	95	117	212

Based on the above data the sensitivity was 96 %, the specificity 66 %, the positive predictive value 78 % and the negative predictive value 93 %.

Elecsys BRAHMS PCT	Clinical classification		Total
	SIRS	Sepsis	
< 0.5 ng/mL	63	25	88
≥ 0.5 ng/mL	32	46	78
Total	95	71	166

Based on the above data the sensitivity was 65 %, the specificity 66 %, the positive predictive value 59 % and the negative predictive value 72 %.

Results with a cut-off at 2 ng/mL

Elecsys BRAHMS PCT	Clinical classification		Total
	SIRS	Severe sepsis/ septic shock	
< 2 ng/mL	88	18	106
≥ 2 ng/mL	7	99	106
Total	95	117	212

Based on the above data the sensitivity was 85 %, the specificity 93 %, the positive predictive value 93 % and the negative predictive value 82 %.

Elecsys BRAHMS PCT	Clinical classification		Total
	SIRS	Sepsis	
< 2 ng/mL	88	55	143
≥ 2 ng/mL	7	16	23
Total	95	71	166

Based on the above data the sensitivity was 23 %, the specificity 93 %, the positive predictive value 70 % and the negative predictive value 62 %.

Specific performance data

Representative performance data on the analyzers are given below. Results obtained in individual laboratories may differ.

Precision

Precision was determined using Elecsys reagents, pooled human sera and controls in a protocol (EP05-A3) of the CLSI (Clinical and Laboratory Standards Institute): 2 runs per day in duplicate each for 21 days (n = 84). The following results were obtained:

cobas e 402 and cobas e 801 analyzers					
		Repeatability		Intermediate precision	
Sample	Mean ng/mL	SD ng/mL	CV %	SD ng/mL	CV %
Human serum 1	0.088	0.002	2.6	0.004	5.0
Human serum 2	0.121	0.008	6.9	0.010	7.9
Human serum 3	43.3	0.774	1.8	0.856	2.0
Human serum 4	97.8	1.41	1.4	1.51	1.5
PreciControl PCT1	0.464	0.010	2.1	0.011	2.4
PreciControl PCT2	9.43	0.083	0.9	0.099	1.0

Method comparison

a) A comparison of the Elecsys BRAHMS PCT assay (y) with the BRAHMS PCT LIA (x) using human heparin plasma gave the following correlations (ng/mL):

Number of samples measured: 152

Passing/Bablok²³

$$y = 1.065x - 0.090$$

$$\tau = 0.856$$

Linear regression

$$y = 1.143x - 0.194$$

$$r = 0.981$$

The sample concentrations were between 0.3 and 82 ng/mL.

b) A comparison of the Elecsys BRAHMS PCT assay (y) with the BRAHMS PCT sensitive KRYPTOR (x) using human heparin plasma gave the following correlations (ng/mL):

Number of samples measured: 185

Passing/Bablok²³

$$y = 0.850x - 0.035$$

$$\tau = 0.953$$

Linear regression

$$y = 1.090x - 0.709$$

$$r = 0.988$$

The sample concentrations were between 0.04 and 85 ng/mL.

c) A comparison of the Elecsys BRAHMS PCT assay, [REF] 07301715190 (cobas e 801 analyzer; y), with the Elecsys BRAHMS PCT assay, [REF] 05056888200 (cobas e 601 analyzer; x), gave the following correlations (ng/mL):

Number of samples measured: 177

Passing/Bablok²³

$$y = 0.995x - 0.017$$

$$\tau = 0.990$$

Linear regression

$$y = 0.997x - 0.083$$

$$r = 1.00$$

The sample concentrations were between 0.026 and 99.9 ng/mL.

d) A comparison of the Elecsys BRAHMS PCT assay, [REF] 08828679190 (cobas e 402 analyzer; y), with the Elecsys BRAHMS PCT assay, [REF] 08828679190 (cobas e 801 analyzer; x), gave the following correlations (ng/mL):

Number of samples measured: 135

Passing/Bablok²³

$$y = 0.989x - 0.003$$

$$\tau = 0.992$$

Linear regression

$$y = 0.990x - 0.019$$

$$r = 1.00$$

The sample concentrations were between 0.104 and 99.1 ng/mL.

Analytical specificity

The Elecsys BRAHMS PCT assay did not show any significant cross reactions with the following substances, when tested with PCT concentrations of approximately 0.4 ng/mL and 1.5 ng/mL:

Substances	Maximum tested concentration ng/mL
Human katacalcin	30
Human calcitonin	10
Salmon calcitonin	30000
Eel calcitonin	30000
Human alpha-CGRP ^{b)}	10000
Human beta-CGRP	10000

b) Calcitonin Gene-Related Peptide

Concordance with BRAHMS PCT LIA/BRAHMS PCT sensitive KRYPTOR

A comparison study was performed with the Elecsys BRAHMS PCT assay and the BRAHMS PCT LIA. Cutoff values of 0.5 ng/mL and 2 ng/mL have been evaluated.

Elecsys BRAHMS PCT	BRAHMS PCT LIA		Total
	< 0.5 ng/mL	≥ 0.5 ng/mL	
< 0.5 ng/mL	104	49	153
≥ 0.5 ng/mL	6	370	376
Total	110	419	529

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	BRAHMS PCT LIA		
Elecsys BRAHMS PCT	< 2 ng/mL	≥ 2 ng/mL	Total
< 2 ng/mL	266	10	276
≥ 2 ng/mL	11	242	253
Total	277	252	529

The concordance between both assays was 90 % at the cutoff value of 0.5 ng/mL and 96 % at the cutoff-value of 2 ng/mL.

The Elecsys BRAHMS PCT assay was also compared to the BRAHMS PCT sensitive KRYPTOR. Cutoff values of 0.5 ng/mL and 2 ng/mL have been evaluated.

	BRAHMS PCT sensitive KRYPTOR		
Elecsys BRAHMS PCT	< 0.5 ng/mL	≥ 0.5 ng/mL	Total
< 0.5 ng/mL	183	20	203
≥ 0.5 ng/mL	2	392	394
Total	185	412	597

	BRAHMS PCT sensitive KRYPTOR		
Elecsys BRAHMS PCT	< 2 ng/mL	≥ 2 ng/mL	Total
< 2 ng/mL	312	24	336
≥ 2 ng/mL	1	260	261
Total	313	284	597

The concordance between both assays was 96 % at the cutoff value of 0.5 ng/mL and 96 % at the cutoff-value of 2 ng/mL.

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This product may not be used by purchaser to conduct any Point-of-Care testing including but not limited to any near patient testing on hospital wards and/or emergency departments and/or in doctor's offices and/or in any other locations outside private or public clinical laboratories. No general patent or other license of any kind other than this specific right of use from purchase is granted hereby.

For further information, please refer to the appropriate user guide or operator's manual for the analyzer concerned, the respective application sheets 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.

Reagent developed in collaboration with B-R-A-H-M-S GmbH.

B-R-A-H-M-S PCT is a registered trademark of Thermo Fisher Scientific Inc.

B · R · A · H · M · S



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.

The Summary of Safety & Performance Report can be found here: <https://ec.europa.eu/tools/eudamed>

Symbols

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

CONTENT

Contents of kit

Elecsys BRAHMS PCT



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

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

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