# CREP2

cobas®

**Creatinine plus ver.2**

**Order information**

| REF | CONTENT | | Analyzer(s) on which **cobas c** pack(s) can be used |
|---|---|---|---|
| 08057524190 | Creatinine plus ver.2 (600 tests) | System-ID 2046 001 | **cobas c** 303, **cobas c** 503 |

Materials required (but not provided):

| | | | |
|---|---|---|---|
| 10759350190 | Calibrator f.a.s. (12 x 3 mL) | Code 20401 | |
| 03121313122 | Precinorm PUC (4 x 3 mL) | Code 20240 | |
| 03121291122 | Precipath PUC (4 x 3 mL) | Code 20241 | |
| 05117003190 | PreciControl ClinChem Multi 1 (20 x 5 mL) | Code 20391 | |
| 05947626190 | PreciControl ClinChem Multi 1 (4 x 5 mL) | Code 20391 | |
| 05117216190 | PreciControl ClinChem Multi 2 (20 x 5 mL) | Code 20392 | |
| 05947774190 | PreciControl ClinChem Multi 2 (4 x 5 mL) | Code 20392 | |
| 08063494190 | Diluent NaCl 9 % (123 mL) | System-ID 2906 001 | |

**English**

**System information**

**CREP2:** ACN 20460 (Serum/plasma)

**CREP2U:** ACN 20461 (Urine)

**Intended use**

In vitro test for the quantitative determination of creatinine concentration in human serum, plasma and urine on Roche/Hitachi **cobas c** systems.

**Summary**[1,2,3,4,5]

Chronic kidney disease is a worldwide problem that carries a substantial risk for cardiovascular morbidity and death. Current guidelines define chronic kidney disease as kidney damage or glomerular filtration rate (GFR) less than 60 mL/min per 1.73 $m^2$ for three months or more, regardless of cause. The assay of creatinine in serum or plasma is the most commonly used test to assess renal function. Creatinine is a break-down product of creatine phosphate in muscle, and is usually produced at a fairly constant rate by the body (depending on muscle mass). It is freely filtered by the glomeruli and, under normal conditions, is not re-absorbed by the tubules to any appreciable extent. A small but significant amount is also actively secreted.

Since a rise in blood creatinine is observed only with marked damage of the nephrons, it is not suited to detect early stage kidney disease. A considerably more sensitive test and better estimation of glomerular filtration rate (GFR) is given by the creatinine clearance test based on creatinine's concentration in urine and serum or plasma, and urine flow rate. For this test a precisely timed urine collection (usually 24 hours) and a blood sample are needed. However, since this test is prone to error due to the inconvenient collection of timed urine, mathematical attempts to estimate GFR based only on the creatinine concentration in serum or plasma have been made. Among the various approaches suggested, two have found wide recognition: that of Cockroft and Gault and that based on the results of the MDRD trial. While the first equation was derived from data obtained with the conventional Jaffé method, a newer version of the second is usable for IDMS-traceable creatinine methods. Both are applicable for adults. In children, the Bedside Schwartz formula should be used.[6,7,8,9]

In addition to the diagnosis and treatment of renal disease, the monitoring of renal dialysis, creatinine measurements are used for the calculation of the fractional excretion of other urine analytes (e. g., albumin, α-amylase). Numerous methods were described for determining creatinine. Automated assays established in the routine laboratory include the Jaffé alkaline picrate method in various modifications, as well as enzymatic tests.

**Test principle**

This enzymatic method is based on the conversion of creatinine with the aid of creatininase, creatinase, and sarcosine oxidase to glycine, formaldehyde and hydrogen peroxide. Catalyzed by peroxidase the liberated hydrogen peroxide reacts with 4-aminophenazone and HTIB[a)] to form a quinone imine chromogen. The color intensity of the quinone imine chromogen formed is directly proportional to the creatinine concentration in the reaction mixture.

$$\text{creatinine} + H_2O \xrightarrow{\text{creatininase}} \text{creatine}$$

$$\text{creatine} + H_2O \xrightarrow{\text{creatinase}} \text{sarcosine} + \text{urea}$$

$$\text{sarcosine} + O_2 + H_2O \xrightarrow{\text{SOD}} \text{glycine} + HCHO + H_2O_2$$

$$H_2O_2 + \text{4-aminophenazone} + \text{HTIB} \xrightarrow{\text{POD}} \text{quinone imine chromogen} + H_2O + HI$$

Creatine of the sample is destroyed by creatinase, SOD and catalase during incubation in R1.

a) 2,4,6-triiodo-3-hydroxybenzoic acid

**Reagents - working solutions**

**R1** TAPS buffer (N-Tris(hydroxymethyl)methyl-3-aminopropanesulfonic acid): 30 mmol/L, pH 8.1; creatinase (microorganisms): ≥ 332 µkat/L; sarcosine oxidase (microorganisms): ≥ 132 µkat/L; ascorbate oxidase (microorganisms): ≥ 33 µkat/L; catalase (microorganisms): ≥ 1.67 µkat/L; HTIB: 1.2 g/L; detergents; preservative

**R3** TAPS buffer: 50 mmol/L, pH 8.0; creatininase (microorganisms): ≥ 498 µkat/L; peroxidase (horseradish): ≥ 16.6 µkat/L; 4-aminophenazone: 0.5 g/L; potassium hexacyanoferrate (II): 60 mg/L; detergent; preservative

R1 is in position B and R3 is in position C.

**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.

**Reagent handling**

Ready for use

**Storage and stability**

| | |
|---|---|
| Shelf life at 2-8 °C: | See expiration date on **cobas c** pack label. |
| On-board in use and refrigerated on the analyzer: | 18 weeks |

**Specimen collection and preparation**

For specimen collection and preparation only use suitable tubes or collection containers.

Only the specimens listed below were tested and found acceptable.
Serum.
Plasma: Li-heparin and $K_2$-EDTA plasma

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.

Urine: Collect urine without using additives. If urine must be collected with a preservative for other analytes, only hydrochloric acid (14 to 47 mmol/L urine, e.g. 5 mL 10 % HCl or 5 mL 30 % HCl per liter urine) or boric acid (81 mmol/L, e.g. 5 g per liter urine) may be used. If stabilizers are added to the sample, the sample index feature must not be used.

| | |
|---|---|
| Stability in *serum/plasma:*[10] | 7 days at 15-25 °C |
| | 7 days at 2-8 °C |
| | 3 months at (-15)-(-25) °C |
| Stability in *urine* (without preservative):[10] | 2 days at 15-25 °C |
| | 6 days at 2-8 °C |
| | 6 months at (-15)-(-25) °C |
| Stability in *urine* (with preservative): | 3 days at 15-25 °C |
| | 8 days at 2-8 °C |
| | 3 weeks at (-15)-(-25) °C |

Centrifuge samples containing precipitates before performing the assay.

See the limitations and interferences section for details about possible sample interferences.

Sample stability claims were established by experimental data by the manufacturer or based on reference literature and only for the temperatures/time frames as stated in the method sheet. It is the responsibility of the individual laboratory to use all available references and/or its own studies to determine specific stability criteria for its laboratory.

**Materials provided**

See "Reagents – working solutions" section for reagents.

**Materials required (but not provided)**

See "Order information" section

General laboratory equipment

**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.

The performance of applications not validated by Roche is not warranted and must be defined by the user.

**Application for serum and plasma**

**Test definition**

| | | | |
|---|---|---|---|
| Reporting time | 10 min | | |
| Wavelength (sub/main) | 700/546 nm | | |
| Reagent pipetting | | Diluent ($H_2O$) | |
| R1 | 64 µL | – | |
| R3 | 32 µL | – | |
| *Sample volumes* | *Sample* | *Sample dilution* | |
| | | *Sample* | *Diluent (NaCl)* |
| Normal | 1.7 µL | – | – |
| Decreased | 1.7 µL | 20 µL | 60 µL |
| Increased | 1.7 µL | – | – |

**Application for urine**

**Test definition**

| | | | |
|---|---|---|---|
| Reporting time | 10 min | | |
| Wavelength (sub/main) | 700/546 nm | | |
| Reagent pipetting | | Diluent ($H_2O$) | |
| R1 | 64 µL | – | |
| R3 | 32 µL | – | |
| *Sample volumes* | *Sample* | *Sample dilution* | |
| | | *Sample* | *Diluent (NaCl)* |
| Normal | 1.7 µL | 5 µL | 95 µL |
| Decreased | 1.7 µL | 2 µL | 98 µL |
| Increased | 1.7 µL | 5 µL | 95 µL |

For further information about the assay test definitions refer to the application parameters setting screen of the corresponding analyzer and assay.

**Calibration**

*Application for serum/plasma (ACN 20460)*

| | |
|---|---|
| Calibrators | S1: $H_2O$ |
| | S2: C.f.a.s. |
| Calibration mode | Linear |
| Calibration frequency | 1-point recalibration using S1<br>- after 4 weeks during shelf life<br>Full calibration<br>- after reagent lot change<br>- as required following quality control procedures |

*Application for urine (ACN 20461)*

Transfer of calibration from serum/plasma application (ACN 20460)

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

Traceability: This method has been standardized against ID/MS.

**Quality control**

For quality control, use control materials as listed in the "Order information" section. In addition, other suitable control material can be used.

| | |
|---|---|
| Serum/plasma: | PreciControl ClinChem Multi 1, PreciControl ClinChem Multi 2 |
| Urine: | Precinorm PUC, Precipath PUC |

The control intervals and limits should be adapted to each laboratory's individual requirements. It is recommended to perform quality control always after lot calibration and subsequently at least every 18 weeks. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

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

**Calculation**

**cobas c** systems automatically calculate the analyte concentration of each sample in the unit µmol/L (mg/dL, mmol/L, mg/L).

| | |
|---|---|
| Conversion factors: | µmol/L x 0.0113 = mg/dL |
| | µmol/L x 0.001 = mmol/L |
| | µmol/L x 0.113 = mg/L |

**Limitations - interference**

Criterion: Recovery within ± 10 % of initial values at creatinine concentrations of 80 µmol/L (0.9 mg/dL) in serum and 2.5 mmol/L (28.3 mg/dL) in urine.

*Serum/plasma*

Icterus:[11] No significant interference up to an I index of 15 for conjugated bilirubin and 20 for unconjugated bilirubin (approximate conjugated bilirubin concentration: 257 µmol/L or 15 mg/dL; approximate unconjugated bilirubin concentration: 342 µmol/L or 20 mg/dL).

Hemolysis:[11] No significant interference up to an H index of 800 (approximate hemoglobin concentration: 497 µmol/L or 800 mg/dL).

Lipemia (Intralipid):[11] No significant interference up to an L index of 2000. There is a poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.

Ascorbic acid: No significant interference from ascorbic acid up to a concentration of 1.70 mmol/L (300 mg/L).

Drugs: No interference was found at therapeutic concentrations using common drug panels.[12,13] Exceptions: Rifampicin, Levodopa and Calcium dobesilate (e.g. Dexium) cause artificially low creatinine results. As tested according to CLSI recommendation Methyldopa causes artificially low creatinine results.[14]

Dicynone (Etamsylate) at therapeutic concentrations may lead to falsely low results.[15]

N-ethylglycine at therapeutic concentrations and DL-proline at concentrations ≥ 1 mmol/L (≥ 115 mg/L) give falsely high results.

Creatine: No significant interference from creatine up to a concentration of 4 mmol/L (524 mg/L).

Hemolyzed samples from neonates, infants or adults with HbF values ≥ 600 mg/dL interfere with the test.[16]

2-Phenyl-1,3-indandione (Phenindione) at therapeutic concentrations interferes with the assay.

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.[17]

Estimation of the glomerular filtration rate (GFR) on the basis of the Schwartz formula can lead to an overestimation.[18]

Acetaminophen intoxications are frequently treated with N-Acetylcysteine. N-Acetylcysteine at a plasma concentration above 333 mg/L and the Acetaminophen metabolite N-acetyl-p-benzoquinone imine (NAPQI) independently may cause falsely low results.

Venipuncture should be performed prior to the administration of Metamizole. Venipuncture immediately after or during the administration of Metamizole may lead to falsely low results. A significant interference may occur at any plasma Metamizole concentration.

*Urine*

Icterus: No significant interference up to a conjugated bilirubin concentration of 1197 µmol/L or 70 mg/dL.

Hemolysis: No significant interference up to an H index of 1000 (approximate hemoglobin concentration of 621 µmol/L or 1000 mg/dL).

Ascorbic acid: No significant interference from ascorbic acid up to a concentration of 22.7 mmol/L (4000 mg/L).

Glucose: No significant interference from glucose up to a concentration of 120 mmol/L (2162 mg/dL).

Urobilinogen: No significant interference from urobilinogen up to a concentration of 676 µmol/L (40 mg/dL).

Urea: No significant interference from urea up to a concentration of 2100 mmol/L (12612 mg/dL).

Drugs: No interference was found at therapeutic concentrations using common drug panels.[13] As tested according to CLSI recommendation α-methyldopa, Levodopa and Calcium dobesilate (e.g. Dexium) cause artificially low creatinine results.

Dicynone (Etamsylate) at therapeutic concentrations may lead to falsely low results.

High homogentisic acid concentrations in urine samples lead to false results.

Acetaminophen, Acetylcysteine and Metamizole are metabolized quickly. Therefore, interference from these substances is unlikely but cannot be excluded.

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

**ACTION REQUIRED**

**Special Wash Programming:** The use of special wash steps is mandatory when certain test combinations are run together on **cobas c** systems. All special wash programming necessary for avoiding carry-over is available via the **cobas** link. The latest version of the carry-over evasion list can be found with the NaOHD/SMS/SCCS Method Sheet for information. For further instructions refer to the operator's manual.

**Limits and ranges**

**Measuring range**

*Serum/plasma*

5-2700 µmol/L (0.06-30.5 mg/dL)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:4 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 4.

*Urine*

0.1-54 mmol/L (1.1-610 mg/dL)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:2.5 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 2.5.

**Lower limits of measurement**

*Limit of Blank, Limit of Detection and Limit of Quantitation*

*Serum/plasma*

| | |
|---|---|
| Limit of Blank | = 5 µmol/L (0.057 mg/dL) |
| Limit of Detection | = 5 µmol/L (0.057 mg/dL) |
| Limit of Quantitation | = 10 µmol/L (0.113 mg/dL) |

*Urine*

| | |
|---|---|
| Limit of Blank | = 0.1 mmol/L (1.13 mg/dL) |
| Limit of Detection | = 0.1 mmol/L (1.13 mg/dL) |
| Limit of Quantitation | = 0.3 mmol/L (3.39 mg/dL) |

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 95$^{th}$ 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 a total error of 20 %. It has been determined using low concentration creatinine samples.

**Expected values**

**µmol/L**

*Serum/plasma*

| | |
|---|---|
| Adults[19] | |
| Females | 45-84 µmol/L |
| Males | 59-104 µmol/L |
| Children[20] | |
| Neonates (premature) | 29-87 µmol/L |
| Neonates (full term) | 27-77 µmol/L |
| 2-12 months | 14-34 µmol/L |
| 1-< 3 years | 15-31 µmol/L |
| 3-< 5 years | 23-37 µmol/L |
| 5-< 7 years | 25-42 µmol/L |
| 7-< 9 years | 30-47 µmol/L |
| 9-< 11 years | 29-56 µmol/L |
| 11-< 13 years | 39-60 µmol/L |
| 13-< 15 years | 40-68 µmol/L |

**mg/dL**

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**Creatinine plus ver.2**

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| *Serum/plasma* | |
|---|---|
| Adults[19] | |
| Females | 0.51-0.95 mg/dL |
| Males | 0.67-1.17 mg/dL |
| Children[20] | |
| Neonates (premature) | 0.33-0.98 mg/dL |
| Neonates (full term) | 0.31-0.88 mg/dL |
| 2-12 months | 0.16-0.39 mg/dL |
| 1-< 3 years | 0.18-0.35 mg/dL |
| 3-< 5 years | 0.26-0.42 mg/dL |
| 5-< 7 years | 0.29-0.47 mg/dL |
| 7-< 9 years | 0.34-0.53 mg/dL |
| 9-< 11 years | 0.33-0.64 mg/dL |
| 11-< 13 years | 0.44-0.68 mg/dL |
| 13-< 15 years | 0.46-0.77 mg/dL |

**mmol/L**

| *Urine* | |
|---|---|
| 1st morning urine[19] | |
| Females | 2.55-20.0 mmol/L |
| Males | 3.54-24.6 mmol/L |
| 24-hour urine[21] | |
| Females | 6-13 mmol/24 h |
| Males | 9-19 mmol/24 h |
| Creatinine clearance[21] | 66-143 mL/min |

**mg/dL**

| *Urine* | |
|---|---|
| 1st morning urine[19] | |
| Females | 29-226 mg/dL |
| Males | 40-278 mg/dL |
| 24-hour urine[21] | |
| Females | 720-1510 mg/24 h |
| Males | 980-2200 mg/24 h |
| Creatinine clearance[21] | 66-143 mL/min |

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

**Specific performance data**

Representative performance data on the analyzers are given below. These data represent the performance of the analytical procedure itself.

Results obtained in individual laboratories may differ due to heterogenous sample materials, aging of analyzer components and mixture of reagents running on the analyzer.

**Precision**

Precision was determined using human samples and controls in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP05-A3 requirements with repeatability (n = 84) and intermediate precision (2 aliquots per run, 2 runs per day, 21 days). Results for repeatability and intermediate precision were obtained on the **cobas c** 503 analyzer.

*Serum/plasma*

| *Repeatability* | *Mean* | *SD* | *CV* |
|---|---|---|---|
| | *µmol/L* | *µmol/L* | *%* |
| PCCC1[b)] | 89.6 | 0.578 | 0.6 |
| PCCC2[c)] | 341 | 1.09 | 0.3 |
| Human serum 1 | 14.8 | 0.621 | 4.2 |
| Human serum 2 | 75.6 | 0.550 | 0.7 |
| Human serum 3 | 605 | 2.33 | 0.4 |
| Human serum 4 | 1343 | 4.40 | 0.3 |
| Human serum 5 | 2351 | 7.99 | 0.3 |

| *Intermediate precision* | *Mean* | *SD* | *CV* |
|---|---|---|---|
| | *µmol/L* | *µmol/L* | *%* |
| PCCC1[b)] | 89.6 | 0.811 | 0.9 |
| PCCC2[c)] | 341 | 2.41 | 0.7 |
| Human serum 1 | 14.8 | 0.657 | 4.4 |
| Human serum 2 | 75.7 | 0.652 | 0.9 |
| Human serum 3 | 602 | 2.68 | 0.4 |
| Human serum 4 | 1343 | 5.35 | 0.4 |
| Human serum 5 | 2351 | 9.73 | 0.4 |

b) PreciControl ClinChem Multi 1

c) PreciControl ClinChem Multi 2

*Urine*

| *Repeatability* | *Mean* | *SD* | *CV* |
|---|---|---|---|
| | *mmol/L* | *mmol/L* | *%* |
| PN PUC[d)] | 8.50 | 0.0425 | 0.5 |
| PP PUC[e)] | 4.29 | 0.0281 | 0.7 |
| Human urine 1 | 0.315 | 0.0130 | 4.1 |
| Human urine 2 | 2.22 | 0.0207 | 0.9 |
| Human urine 3 | 13.1 | 0.0681 | 0.5 |
| Human urine 4 | 25.7 | 0.141 | 0.5 |
| Human urine 5 | 46.6 | 0.265 | 0.6 |

| *Intermediate precision* | *Mean* | *SD* | *CV* |
|---|---|---|---|
| | *mmol/L* | *mmol/L* | *%* |
| PN PUC[d)] | 8.53 | 0.0662 | 0.8 |
| PP PUC[e)] | 4.29 | 0.0360 | 0.8 |
| Human urine 1 | 0.315 | 0.0147 | 4.7 |
| Human urine 2 | 2.22 | 0.0342 | 1.5 |
| Human urine 3 | 13.1 | 0.407 | 3.1 |
| Human urine 4 | 25.7 | 0.191 | 0.7 |
| Human urine 5 | 46.8 | 0.359 | 0.8 |

d) Precinorm PUC

e) Precipath PUC

The data obtained on **cobas c** 503 analyzer(s) are representative for **cobas c** 303 analyzer(s).

**Method comparison**

Creatinine values for human serum, plasma and urine samples obtained on a **cobas c** 503 analyzer (y) were compared with those determined using the corresponding reagent on a **cobas c** 501 analyzer (x).

*Serum/plasma*

Sample size (n) = 75

| Passing/Bablok[22] | Linear regression |
|---|---|
| y = 1.012x - 0.820 µmol/L | y = 1.018x - 3.71 µmol/L |
| τ = 0.996 | r = 1.000 |

The sample concentrations were between 22.4 and 2560 µmol/L.

*Urine*

Sample size (n) = 74

| Passing/Bablok[22] | Linear regression |
|---|---|
| y = 0.982x - 0.0149 mmol/L | y = 0.981x - 0.00393 mmol/L |
| τ = 0.990 | r = 1.000 |

The sample concentrations were between 0.159 and 52.9 mmol/L.

Creatinine values for human serum, plasma and urine samples obtained on a **cobas c** 303 analyzer (y) were compared with those determined using the corresponding reagent on a **cobas c** 501 analyzer (x).

*Serum/plasma*

Sample size (n) = 72

| Passing/Bablok[22] | Linear regression |
|---|---|
| y = 1.011x + 1.86 µmol/L | y = 1.006x + 2.81 µmol/L |
| τ = 0.981 | r = 1.000 |

The sample concentrations were between 15.6 and 2595 µmol/L.

*Urine*

Sample size (n) = 73

| Passing/Bablok[22] | Linear regression |
|---|---|
| y = 1.010x + 0.0279 mmol/L | y = 1.010x + 0.0377 mmol/L |
| τ = 0.986 | r = 1.000 |

The sample concentrations were between 0.237 and 53.0 mmol/L.

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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 |
| → | Volume after reconstitution or mixing |
| GTIN | Global Trade Item Number |



CE 0123

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