# CREJ2

**Creatinine Jaffé Gen.2**

cobas®

**Order information**

| REF | CONTENT | | Analyzer(s) on which **cobas c** pack(s) can be used |
|---|---|---|---|
| 06407137190 | Creatinine Jaffé Gen.2 (1500 tests) | System ID 03 6928 2 | **cobas c** 701/702 |

Materials required (but not provided):

| | | | |
|---|---|---|---|
| 10759350360 | Calibrator f.a.s. (12 x 3 mL) | Code 401 | |
| 12149435160 | Precinorm U plus (10 x 3 mL) | Code 300 | |
| 12149443160 | Precipath U plus (10 x 3 mL) | Code 301 | |
| 03121313122 | Precinorm PUC (4 x 3 mL) | Code 240 | |
| 03121291122 | Precipath PUC (4 x 3 mL) | Code 241 | |
| 05947626160 | PreciControl ClinChem Multi 1 (4 x 5 mL) | Code 391 | |
| 05947774160 | PreciControl ClinChem Multi 2 (4 x 5 mL) | Code 392 | |
| 05172152190 | Diluent NaCl 9 % (119 mL) | System-ID 08 6869 3 | |

**English**

**For use in the USA only**

**System information**

**CREJ2:** ACN 8690 (Rate blanked, compensated, serum and plasma)

**CRJ2U:** ACN 8691 (Rate blanked, urine)

**SCRE2:** ACN 8773 (STAT, compensated, serum and plasma, reaction time: 5)

**SCR2U:** ACN 8774 (STAT, urine, reaction time: 5)

**Intended use**

In vitro test for the quantitative determination of creatinine in human serum, plasma and urine on **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 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**[10,11,12]

This kinetic colorimetric assay is based on the Jaffé method. In alkaline solution, creatinine forms a yellow-orange complex with picrate. The rate of dye formation is proportional to the creatinine concentration in the specimen. The assay uses "rate-blanking" to minimize interference by bilirubin. To correct for non-specific reaction caused by serum/plasma pseudo-creatinine chromogens, including proteins and ketones, the results for serum or plasma are corrected by -26 µmol/L (-0.3 mg/dL).

Creatinine + picric acid —(*Alkaline pH*)→ yellow-orange complex

**Reagents - working solutions**

| | |
|---|---|
| **R1** | Potassium hydroxide: 900 mmol/L; phosphate: 135 mmol/L; pH ≥ 13.5; preservative; stabilizer |
| **R3** | Picric acid: 38 mmol/L; pH 6.5; non reactive buffer |

**(STAT R2)**

R1 is in position B and R3 (STAT R2) 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.

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:

Danger

| | |
|---|---|
| H314 | Causes severe skin burns and eye damage. |

**Prevention:**

| | |
|---|---|
| P280 | Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection. |

**Response:**

| | |
|---|---|
| P301 + P330 + P331 | IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. |
| P303 + P361 + P353 | IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. |

| | |
|---|---|
| P304 + P340 + P310 | IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/ doctor. |
| P305 + P351 + P338 + P310 | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor. |

**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

**Reagent handling**

Ready for use

**Storage and stability**

| | |
|---|---|
| Shelf life at 15-25 °C: | See expiration date on **cobas c** pack label. |
| On-board in use and refrigerated on the analyzer: | 7 days |
| On-board on the reagent manager: | 24 hours |

**Specimen collection and preparation**[13]

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.

| | |
|---|---|
| Stability in *serum/plasma:*[14] | 7 days at 15-25 °C |
| | 7 days at 2-8 °C |
| | 3 months at (-15)-(-25) °C |

Freeze only once.

| | |
|---|---|
| Stability in *urine* (without preservative):[14] | 2 days at 15-25 °C |
| | 6 days at 2-8 °C |
| | 6 months at (-15)-(-25) °C |

Freeze only once.

| | |
|---|---|
| Stability in *urine* (with preservative): | 3 days at 15-25 °C |
| | 8 days at 2-8 °C |
| | 3 weeks at (-15)-(-25) °C |

Freeze only once.

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**

**cobas c** 701/702 **test definition**

| | | | |
|---|---|---|---|
| Assay type | Rate A | | |
| Reaction time / Assay points | 10/23-29 -12-18 (STAT 5 / 11-17) | | |
| Wavelength (sub/main) | 570/505 nm | | |
| Reaction direction | Increase | | |
| Units | µmol/L (mg/dL, mmol/L) | | |
| Reagent pipetting | | Diluent ($H_2O$) | |
| R1 | 13 µL | 77 µL | |
| R3 (STAT R2) | 17 µL | 30 µL | |
| *Sample volumes* | *Sample* | *Sample dilution* | |
| | | *Sample* | *Diluent (NaCl)* |
| Normal | 10 µL | – | – |
| Decreased | 10 µL | 20 µL | 80 µL |
| Increased | 10 µL | – | – |

Enter the correction value for the non-specific protein reaction as the instrument factor **y = ax + b** for mg/dL or for µmol/L, where **a = 1.0** and **b = -0.3** (mg/dL) or **a = 1.0** and **b = -26** (µmol/L).

**Application for urine**

**cobas c** 701/702 **test definition**

| | | | |
|---|---|---|---|
| Assay type | Rate A | | |
| Reaction time / Assay points | 10/23-29 -12-18 (STAT 5 / 11-17) | | |
| Wavelength (sub/main) | 570/505 nm | | |
| Reaction direction | Increase | | |
| Units | µmol/L (mg/dL, mmol/L) | | |
| Reagent pipetting | | Diluent ($H_2O$) | |
| R1 | 13 µL | 77 µL | |
| R3 (STAT R2) | 17 µL | 30 µL | |
| *Sample volumes* | *Sample* | *Sample dilution* | |
| | | *Sample* | *Diluent (NaCl)* |
| Normal | 10 µL | 6 µL | 144 µL |
| Decreased | 10 µL | 2 µL | 180 µL |
| Increased | 10 µL | 10 µL | 115 µL |

**Calibration**

| | |
|---|---|
| Calibrators | S1: $H_2O$ |
| | S2: C.f.a.s. |

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| | |
|---|---|
| Calibration mode | Linear |
| Calibration frequency | 2-point calibration<br>• every 24 hours on board<br>• after reagent lot change<br>• as required following quality control procedures |

Please note: In case of long batches a full recalibration is required every ~150 determinations per rotor.

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

This method has been standardized against a primary reference material (SRM 914 and SRM 967 (ID/MS)).

**Quality control**

*Serum/plasma*

For quality control, use control materials as listed in the "Order information" section.

In addition, other suitable control material can be used.

*Urine*

For quality control, use Precinorm PUC and Precipath PUC as listed in the "Order information" section.

In addition, other suitable control material can be used.

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.

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

**Calculation**

**cobas c** systems automatically calculate the analyte concentration of each sample.

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

**Limitations – interference**

Criterion: Recovery within ± 10 % of initial value at a creatinine concentration of 80 µmol/L (0.90 mg/dL) in serum/plasma and 2500 µmol/L (28.3 mg/dL) in urine.

*Serum/plasma*

Icterus *(CREJ2)*:[15] No significant interference up to an I index of 5 for conjugated bilirubin and 10 for unconjugated bilirubin (approximate conjugated bilirubin concentration: 86 µmol/L or 5 mg/dL; approximate unconjugated bilirubin concentration: 171 µmol/L or 10 mg/dL).

Icterus *(SCRE2)*:[15] No significant interference up to an I index of 2 for conjugated bilirubin and 3 for unconjugated bilirubin (approximate conjugated bilirubin concentration: 34 µmol/L or 2 mg/dL; approximate unconjugated bilirubin concentration: 51 µmol/L or 3 mg/dL).

Hemolysis:[15] No significant interference up to an H index of 1000 (approximate hemoglobin concentration: 621 µmol/L or 1000 mg/dL).

Lipemia (Intralipid):[15] No significant interference up to an L index of 800. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.

Pyruvate: No significant interference from pyruvate up to a concentration of 0.3 mmol/L (2.6 mg/dL).

Glucose: No significant interference from glucose up to a concentration of 25 mmol/L (450 mg/dL).

Ascorbic acid: No significant interference from ascorbic acid up to a concentration of 5 mmol/L (88 mg/dL).

Drugs: No interference was found at therapeutic concentrations using common drug panels.[16,17]

Exception: Antibiotics containing cephalosporin lead to significant false-positive values.[18,19]

Exception: Cefoxitin causes artificially high creatinine results.

Exception: Cyanokit (Hydroxocobalamin) may cause interference with results.

Values < 15 µmol/L (< 0.17 mg/dL) or negative results are reported in rare cases in children < 3 years and in elderly patients. In such cases use the Creatinine plus test to assay the sample.

Do not use Creatinine Jaffé for the testing of creatinine in hemolyzed samples from neonates, infants or adults with HbF levels ≥ 60 mg/dL for *CREJ2* applications (≥ 30 mg/dL for *SCRE2* applications).[20] In such cases, use the Creatinine plus test (≤ 600 mg/dL HbF) to assay the sample.

The presence of ketone bodies can cause artificially high results in serum and plasma.

Estimation of the Glomerular Filtration Rate (GFR) on the basis of the Schwartz Formula can lead to an overestimation.[21]

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.[22]

*Urine*

Icterus: No significant interference up to a conjugated bilirubin concentration of 855 µmol/L or 50 mg/dL.

Hemolysis: No significant interference up to a hemoglobin concentration of 621 µmol/L or 1000 mg/dL.

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

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

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

Drugs: No interference was found at therapeutic concentrations using common drug panels.[17]

Exception: Cyanokit (Hydroxocobalamin) may cause interference with results.

The presence of ketone bodies can cause artificially high results in urine.

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

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, manual input is required in certain cases. The latest version of the carry-over evasion list can also be found with the NaOHD/SMS/SmpCln1+2/SCCS Method Sheet and for further instructions refer to the operator's manual.

**Where required, special wash/carry-over evasion programming must be implemented prior to reporting results with this test.**

**Limits and ranges**

**Measuring range**

*Serum/plasma*

15-2200 µmol/L (0.17-24.9 mg/dL)

The technical limit in the instrument setting is defined as 41-2226 µmol/L (0.463-25.2 mg/dL) due to the compensation factor of 26.

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:5 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 5.

*Urine*

375-55000 µmol/L (4.2-622 mg/dL)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:3.6 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 3.6.

**Lower limits of measurement**

*Limit of Blank and Limit of Detection*

*Serum/plasma (CREJ2)*

| | |
|---|---|
| Limit of Blank | 15 µmol/L (0.17 mg/dL) |
| Limit of Detection | 15 µmol/L (0.17 mg/dL) |

The Limit of Blank and Limit of Detection were determined in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP17-A 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 %).

*Lower detection limit of the test*

*Serum/plasma (SCRE2)*

15 µmol/L (0.17 mg/dL)

The lower detection limit represents the lowest measurable analyte level that can be distinguished from zero. It is calculated as the value lying 3 standard deviations above that of the lowest standard (standard 1 + 3 SD, repeatability, n = 21).

*Urine (CRJ2U/SCR2U)*

375 µmol/L (4.2 mg/dL)

The lower detection limit represents the lowest measurable analyte level that can be distinguished from zero. It is calculated as the value lying 3 standard deviations above that of the lowest standard (standard 1 + 3 SD, repeatability, n = 21).

**Expected values**

*Serum/plasma*

| | | |
|---|---|---|
| Adults[23] | | |
| Females | 44-80 µmol/L | (0.50-0.90 mg/dL) |
| Males | 62-106 µmol/L | (0.70-1.20 mg/dL) |
| Children[24] | | |
| Neonates (premature) | 25-91 µmol/L | (0.29-1.04 mg/dL) |
| Neonates (full term) | 21-75 µmol/L | (0.24-0.85 mg/dL) |
| 2-12 m | 15-37 µmol/L | (0.17-0.42 mg/dL) |
| 1-< 3 y | 21-36 µmol/L | (0.24-0.41 mg/dL) |
| 3-< 5 y | 27-42 µmol/L | (0.31-0.47 mg/dL) |
| 5-< 7 y | 28-52 µmol/L | (0.32-0.59 mg/dL) |
| 7-< 9 y | 35-53 µmol/L | (0.40-0.60 mg/dL) |
| 9-< 11 y | 34-65 µmol/L | (0.39-0.73 mg/dL) |
| 11-< 13 y | 46-70 µmol/L | (0.53-0.79 mg/dL) |
| 13-< 15 y | 50-77 µmol/L | (0.57-0.87 mg/dL) |

*Urine*

| | | |
|---|---|---|
| 1st morning urine[23] | | |
| Females | 2470-19200 µmol/L | (28-217 mg/dL) |
| Males | 3450-22900 µmol/L | (39-259 mg/dL) |
| 24-hour urine[25] | | |
| Females | 7000-14000 µmol/24 h | (740-1570 mg/24 h) |
| Males | 9000-21000 µmol/24 h | (1040-2350 mg/24 h) |
| Creatinine clearance[25,26] | | 71-151 mL/min |

Refer to reference for a prospective study on creatinine clearance in children.[27]

Roche has not evaluated reference ranges in a pediatric population.

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. Results obtained in individual laboratories may differ.

**Precision**

Precision was determined using human samples and controls in an internal protocol. *Serum/plasma:* Repeatability (n = 21), intermediate precision (3 aliquots per run, 1 run per day, 21 days);
*Urine:* Repeatability (n = 21), intermediate precision (3 aliquots per run, 1 run per day, 10 days). The following results were obtained:

*Serum/plasma*

**CREJ2:**

| *Repeatability* | *Mean* | *SD* | *CV* |
|---|---|---|---|
| | *µmol/L (mg/dL)* | *µmol/L (mg/dL)* | *%* |
| Precinorm U | 97.0 (1.10) | 2.4 (0.03) | 2.5 |
| Precipath U | 357 (4.03) | 3 (0.03) | 0.9 |
| Human serum A | 72.9 (0.824) | 1.7 (0.019) | 2.3 |
| Human serum B | 198 (2.24) | 2 (0.02) | 1.1 |
| Human serum C | 1812 (20.5) | 18 (0.2) | 1.0 |
| *Intermediate precision* | *Mean* | *SD* | *CV* |
| | *µmol/L (mg/dL)* | *µmol/L (mg/dL)* | *%* |
| Precinorm U | 95.5 (1.08) | 2.1 (0.02) | 2.2 |
| Precipath U | 354 (4.00) | 6 (0.07) | 1.7 |
| Human serum D | 51.3 (0.580) | 1.9 (0.021) | 3.7 |
| Human serum E | 193 (2.18) | 3 (0.03) | 1.7 |
| Human serum F | 2005 (22.7) | 43 (0.5) | 2.1 |

**SCRE2:**

| *Repeatability* | *Mean* | *SD* | *CV* |
|---|---|---|---|
| | *µmol/L (mg/dL)* | *µmol/L (mg/dL)* | *%* |
| Precinorm U | 82.4 (0.931) | 1.4 (0.016) | 1.6 |
| Precipath U | 344 (3.89) | 4 (0.05) | 1.0 |
| Human serum A | 62.4 (0.705) | 1.2 (0.014) | 2.0 |
| Human serum B | 189 (2.14) | 2 (0.02) | 1.1 |
| Human serum C | 1871 (21.1) | 18 (0.2) | 1.0 |
| *Intermediate precision* | *Mean* | *SD* | *CV* |
| | *µmol/L (mg/dL)* | *µmol/L (mg/dL)* | *%* |
| Precinorm U | 100 (1.13) | 4 (0.05) | 4.0 |
| Precipath U | 334 (3.77) | 10 (0.11) | 3.0 |
| Human serum 3 | 522 (5.90) | 12 (0.14) | 2.4 |
| Human serum 4 | 64 (0.72) | 3 (0.03) | 5.0 |

*Urine*

**CRJ2U:**

| *Repeatability* | *Mean* | *SD* | *CV* |
|---|---|---|---|
| | *µmol/L (mg/dL)* | *µmol/L (mg/dL)* | *%* |
| Control Level 1 | 7549 (85.3) | 115 (1.3) | 1.5 |
| Control Level 2 | 3932 (44.4) | 44 (0.5) | 1.1 |
| Human urine A | 2140 (24.2) | 25 (0.3) | 1.2 |
| Human urine B | 18510 (209) | 187 (2) | 1.0 |

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| | | | |
|---|---|---|---|
| Human urine C | 45264 (511) | 442 (5) | 1.0 |
| *Intermediate precision* | *Mean* | *SD* | *CV* |
| | *µmol/L (mg/dL)* | *µmol/L (mg/dL)* | *%* |
| Control Level 1 | 8130 (91.9) | 164 (1.9) | 2.0 |
| Control Level 2 | 15533 (176) | 251 (3) | 1.6 |
| Human urine 3 | 19353 (219) | 385 (4) | 2.0 |
| Human urine 4 | 7932 (89.6) | 166 (1.9) | 2.1 |

**SCR2U:**

| | | | |
|---|---|---|---|
| *Repeatability* | *Mean* | *SD* | *CV* |
| | *µmol/L (mg/dL)* | *µmol/L (mg/dL)* | *%* |
| Control Level 1 | 7849 (88.7) | 108 (1.2) | 1.4 |
| Control Level 2 | 4083 (46.1) | 61 (0.7) | 1.5 |
| Human urine A | 2217 (25.1) | 20 (0.2) | 0.9 |
| Human urine B | 19248 (218) | 150 (2) | 0.8 |
| Human urine C | 47049 (532) | 582 (7) | 1.2 |
| *Intermediate precision* | *Mean* | *SD* | *CV* |
| | *µmol/L (mg/dL)* | *µmol/L (mg/dL)* | *%* |
| Control Level 1 | 6943 (78.5) | 114 (1.3) | 1.6 |
| Control Level 2 | 15394 (174) | 228 (3) | 1.5 |
| Human urine 3 | 24230 (274) | 354 (4) | 1.5 |
| Human urine 4 | 2184 (24.7) | 54 (0.6) | 2.5 |

Results for intermediate precision in urine and for STAT applications were obtained on the **cobas c** 501 analyzer.

**Method comparison**

Creatinine values for human serum, plasma and urine samples obtained on a **cobas c** 701 analyzer (y) were compared with those determined using the corresponding reagent on a **cobas c** 501 analyzer (x).

*Serum/plasma*

**CREJ2:**

Sample size (n) = 83

| Passing/Bablok[28] | Linear regression |
|---|---|
| y = 0.990x + 0.592 µmol/L | y = 0.991x - 0.281 µmol/L |
| τ = 0.975 | r = 1.000 |

The sample concentrations were between 44 and 2194 µmol/L (0.50 and 24.8 mg/dL).

**SCRE2:**

Sample size (n) = 82

| Passing/Bablok[28] | Linear regression |
|---|---|
| y = 0.999x + 1.31 µmol/L | y = 0.999x + 1.17 µmol/L |
| τ = 0.985 | r = 1.000 |

The sample concentrations were between 40.4 and 2040 µmol/L (0.457 and 23.1 mg/dL).

*Urine*

**CRJ2U:**

Sample size (n) = 205

| Passing/Bablok[28] | Linear regression |
|---|---|
| y = 0.999x - 53.67 µmol/L | y = 1.005x - 70.76 µmol/L |
| τ = 0.977 | r = 0.999 |

The sample concentrations were between 402 and 51344 µmol/L (4.54 and 580 mg/dL).

**SCR2U:**

Sample size (n) = 207

| Passing/Bablok[28] | Linear regression |
|---|---|
| y = 0.998x - 42.4 µmol/L | y = 1.005x - 74.7 µmol/L |
| τ = 0.976 | r = 0.999 |

The sample concentrations were between 398 and 52296 µmol/L (4.50 and 591 mg/dL).

**References**


1 Thomas C, Thomas L. Labordiagnostik von Erkrankungen der Nieren und ableitenden Harnwege. In: Thomas L, ed. Labor und Diagnose, 6th ed. Frankfurt/Main: TH-Books 2005;520-585.

2 Lamb E, Newman DJ, Price CP. Kidney function tests. In: Burtis CA, Ashwood ER, Bruns DE. Tietz textbook of clinical chemistry and molecular diagnostics. 4th ed. St.Louis, MO: Elsevier Saunders 2006;797-835.

3 http://www.kidney.org/

4 http://www.nkdep.nih.gov/

5 Lamb EJ, Tomson CRV, Roderick PJ. Estimating kidney function in adults using formulae. Ann Clin Biochem 2005;42:321-345.

6 Miller WG. Editorial on Estimating glomerular filtration rate. Clin Chem Lab Med 2009;47(9):1017-1019.

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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 for reconstitution |
| GTIN | Global Trade Item Number |

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