05402255001V11.0

CREJ2

Creatinine Jaffé Gen.2 (compensated)

cobas®

CÔNG TY TRÁCH NHIỆM HỮU HẠN ROCHE VIỆT NAM
Trương Thị Tố Hoa
Trưởng phòng Đăng ký, Đối ngoại và Quản lý Chất lượng

Order information

REF	CONTENT		Analyzer(s) on which kit(s) can be used
05401755 190	Creatinine Jaffé Gen.2 (compensated) (4 × 100 tests)		**cobas c** 111

Materials required (but not provided):

10759350 190	Calibrator f.a.s. (12 × 3 mL)	Code 401	
10759350 360	Calibrator f.a.s. (12 × 3 mL, for USA)	Code 401	
12149435 122	Precinorm U plus (10 × 3 mL)	Code 300	
12149435 160	Precinorm U plus (10 × 3 mL, for USA)	Code 300	
12149443 122	Precipath U plus (10 × 3 mL)	Code 301	
12149443 160	Precipath U plus (10 × 3 mL, for USA)	Code 301	
05117003 190	PreciControl ClinChem Multi 1 (20 × 5 mL)	Code 391	
05947626 190	PreciControl ClinChem Multi 1 (4 × 5 mL)	Code 391	
05947626 160	PreciControl ClinChem Multi 1 (4 × 5 mL, for USA)	Code 391	
05117216 190	PreciControl ClinChem Multi 2 (20 × 5 mL)	Code 392	
05947774 190	PreciControl ClinChem Multi 2 (4 × 5 mL)	Code 392	
05947774 160	PreciControl ClinChem Multi 2 (4 × 5 mL, for USA)	Code 392	
03121313 122	Precinorm PUC (4 × 3 mL)	Code 240	
03121291 122	Precipath PUC (4 × 3 mL)	Code 241	

English

System information

CREJ2: ACN 690

CRJ2U: ACN 691

Intended use

In vitro test for the quantitative determination of creatinine in human serum, plasma and urine on the **cobas c** 111 system.

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[10,11,12]

This kinetic colorimetric assay is based on the Jaffé method. In alkaline solution, creatinine forms a yellow-red 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 -18 µmol/L (-0.2 mg/dL).

Creatinine + picric acid $\xrightarrow{\text{Alkaline pH}}$ yellow-red complex

Reagents - working solutions

R1 Potassium hydroxide: 900 mmol/L; phosphate: 135 mmol/L; pH ≥ 13.5; preservative; stabilizer

SR Picric acid: 38 mmol/L; pH 6.5; non reactive buffer

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.

EUH 001 Explosive when dry.

Prevention:

VV-206449

CREJ2

Creatinine Jaffé Gen.2 (compensated)

cobas®

P280	Wear protective gloves/ protective clothing/ eye protection/ face 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	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	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: all countries: +49-621-7590, USA: 1-800-428-2336

Reagent handling

Ready for use

Reagent bottle 1 contains excess reagent to reduce the effect of CO_2 uptake. Any remaining reagent should be discarded after the recommended period of on-board use (see below).

Storage and stability

Shelf life at 15-25 °C:	See expiration date on reagent
On-board in use and refrigerated on the analyzer:	4 weeks

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_3-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 (14-47 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.

Urine samples are automatically prediluted 1:25 (1+24) with water by the instrument.

Centrifuge samples containing precipitates before performing the assay.

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

Stability in serum/plasma:[14]	7 days at 15-25 °C 7 days at 2-8 °C 3 months at (–15)-(–25) °C
Stability in urine (without preservative):[14]	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

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, plasma and urine

cobas c 111 **test definition**

Measuring mode	Absorbance
Abs. calculation mode	Kinetic
Reaction direction	Increase
Wavelength A/B	512/583 nm
Calc. first/last	21/26
Serum/plasma	
Compensation	-18 µmol/L (-0.2 mg/dL)
Unit	µmol/L
Reaction mode	R1-S-SR
Urine	
Unit	mmol/L
Reaction mode	R1-S-SR
Predilution	25

Pipetting parameters

Serum/plasma		Diluent (H_2O)
R1	13 µL	71 µL
Sample	10 µL	20 µL
SR	17 µL	16 µL
Total volume	147 µL	

Urine		Diluent (H_2O)
R1	13 µL	71 µL
Sample	10 µL	20 µL
SR	17 µL	16 µL
Total volume	147 µL	

Calibration

Calibrator	Calibrator f.a.s. Deionized water is used automatically by the instrument as the zero calibrator.
Calibration mode	Linear regression

Calibration replicate	Duplicate recommended
Calibration interval	Each lot, every 7 days, and as required following quality control procedures

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

Traceability: This method has been standardized against ID/MS.[a)]

For the USA, this method has been standardized against a primary reference material (SRM[b)] 914 and SRM 967 (ID/MS)).

a) Isotope Dilution Mass Spectrometry

b) Standard Reference Material

Quality control

For quality control, use control materials 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

The **cobas c** 111 analyzer automatically calculates the analyte concentration of each sample.

Conversion factors:	µmol/L × 0.0113 = mg/dL
	mmol/L × 11.336 = mg/dL

Limitations - interference

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

Serum/plasma

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

Hemolysis:[15] No significant interference up to an H index of 400 (approximate hemoglobin concentration: 248 µmol/L or 400 mg/dL).

Lipemia (Intralipid):[15] No significant interference up to an L index of 250. 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 0.4 mmol/L (3.5 mg/dL).

Ascorbic acid: No significant interference from ascorbic acid up to a concentration of 4 mmol/L (70 mg/dL).

Drugs: No interference was found at therapeutic concentrations using common drug panels.[16,17]
Exception: Cefoxitin causes artificially high creatinine results at the therapeutic drug level.[18] Antibiotics containing cephalosporin lead to significant false-positive values.[18,19]

Cyanokit (Hydroxocobalamin) may cause interference with results.

Values < 18 µmol/L (< 0.2 mg/dL) or negative results are reported in rare cases in children < 3 years and 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 ≥ 30 mg/dL.[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 854 µmol/L or 50 mg/dL.

Hemolysis: No significant interference up to a hemoglobin concentration of 683 µmol/L or 1100 mg/dL.

Glucose: No significant interference from glucose up to a concentration of 117 mmol/L (2100 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.[17]

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

Cyanokit (Hydroxocobalamin) may cause interference with results.

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

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 the **cobas c** 111 analyzer. For information about test combinations requiring special wash steps, please refer to the latest version of the carry over evasion list found with the CLEAN Method Sheet and the operator's manual for further instructions.
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

18-1100 µmol/L (0.2-12.4 mg/dL)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:10 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 10.

Urine

0.027-32.5 mmol/L (0.31-368 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.

Lower limits of measurement

Serum/plasma

Lower detection limit of the test:
18 µmol/L (0.2 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).

Urine

Lower detection limit of the test:
0.027 mmol/L (0.31 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	(0.28-1.03 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	(0.38-0.73 mg/dL)
11- < 13 y	46-70 µmol/L	(0.52-0.79 mg/dL)
13- < 15 y	50-77 µmol/L	(0.57-0.87 mg/dL)

Urine

1st morning urine[23]

Females	2.47-19.2 mmol/L	(28-217 mg/dL)
Males	3.45-22.9 mmol/L	(39-259 mg/dL)

24-h urine[25]

Females	7-14 mmol/24 h	(740-1570 mg/24 h)
Males	9-21 mmol/24 h	(1040-2350 mg/24 h)

Creatinine clearance for adults[25,26] 71-151 mL/min

Refer to reference 26 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 **cobas c** 111 analyzer are given below. Results obtained in individual laboratories may differ.

Precision

Precision was determined using human samples and controls in an internal protocol with repeatability (n = 21) and intermediate precision (3 aliquots per run, 1 run per day, 10 days). The following results were obtained:

Serum/plasma

Repeatability	*Mean µmol/L (mg/dL)*	*SD µmol/L (mg/dL)*	*CV %*
Precinorm U	98.2 (1.11)	2.7 (0.03)	2.8
Precipath U	353 (3.99)	3 (0.04)	0.9
Human serum 1	66.5 (0.751)	2.6 (0.030)	4.0
Human serum 2	548 (6.19)	5 (0.05)	0.8

Intermediate precision	*Mean µmol/L (mg/dL)*	*SD µmol/L (mg/dL)*	*CV %*
Precinorm U	94.8 (1.07)	3.5 (0.04)	3.7
Precipath U	335 (3.79)	7 (0.08)	2.1
Human serum 3	56.0 (0.633)	3.1 (0.035)	5.5
Human serum 4	584 (6.60)	8 (0.09)	1.4

Urine

Repeatability	*Mean µmol/L (mg/dL)*	*SD µmol/L (mg/dL)*	*CV %*
Precinorm PUC	8.87 (101)	0.06 (1)	0.7
Precipath PUC	4.43 (50.2)	0.07 (0.8)	1.5
Human urine 1	1.71 (19.4)	0.06 (0.7)	3.4
Human urine 2	13.4 (152)	0.09 (1)	0.7

Intermediate precision	*Mean µmol/L (mg/dL)*	*SD µmol/L (mg/dL)*	*CV %*
Precinorm PUC	8.86 (100)	0.16 (2)	1.8
Precipath PUC	4.48 (50.8)	0.12 (1.4)	2.7
Human urine 3	1.82 (20.6)	0.10 (1.1)	5.4
Human urine 4	13.8 (156)	0.4 (4)	2.7

Method comparison

Creatinine values for human serum, plasma and urine samples obtained on the **cobas c** 111 analyzer (y) were compared with those determined using the corresponding reagent on a COBAS INTEGRA 400 analyzer (x).

Serum/plasma

Sample size (n) = 80

Passing/Bablok[28]	Linear regression
y = 0.996x + 3.276 µmol/L	y = 0.996x + 3.680 µmol/L
τ = 0.973	r = 1.000

The sample concentrations were between 44.9 and 1057 µmol/L (0.507 and 11.9 mg/dL).

Urine

Sample size (n) = 50

Passing/Bablok[28]	Linear regression
y = 1.004x - 0.073 mmol/L	y = 1.008x - 0.118 mmol/L
τ = 0.977	r = 1.000

The sample concentrations were between 1.58 and 31.3 mmol/L (17.9 and 355 mg/dL).

References

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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
REAGENT	Reagent
→	Volume after reconstitution or mixing
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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