

Detection of Creatinine in Human Urine with Roche c502

Test Name: In vitro test for the quantitative determination of creatinine in human urine on Roche/Hitachi cobas c systems.

Method Name: The Roche Diagnostics creatinine assay is based on the immunoturbidimetric method. In the assay, anti-albumin antibodies react with the antigen in the sample to form antigen/antibody complexes which, following agglutination, are measured turbidimetrically.

Results: Technical Range: 0.06-30.5 mg/L
Reportable Range: 0.08-26.99 mg/L

Reference Ranges:

1st Morning Urine	Range (mg/dL)
Females	28-217
Males	39-259
24-hour Urine	Range (mg/dL)
Females	740-1570 mg/24 h
Males	1040-2350 mg/24 h

Creatinine clearance: 71-151 mL/min

Clinical Significance:

Albumin is a non-glycosylated protein with a molecular weight of 66000 daltons. It is synthesized in liver parenchymal cells at a rate of 14 g/day. Quantitatively, albumin is normally the most important protein component (> 50 %) in plasma, CSF and urine. A small, but abnormal albumin excretion in urine is known as microalbuminuria. Causes of microalbuminuria can be glomerular (e.g., due to diabetic microangiopathy, hypertension, minor glomerular lesion), tubular (inhibition of reabsorption) or postrenal. Albumin is also a marker protein for various forms of proteinuria.

In selective glomerular proteinuria, 100-3000 mg albumin/g creatinine are excreted in the urine. Non-selective glomerular proteinuria is characterized by elevated excretion of high-molecular weight proteins (IgG more than 10 % of the albumin value). Prerenal proteinuria is recognized by a discrepancy between albumin and total protein (albumin accounting for less than 30 %, with concurrent elevation of total protein). Simultaneous elevation of albumin and microproteins is found in glomerulotubular proteinuria occurring due to overloading of tubular reabsorption in glomerulopathy (e.g., nephrotic syndrome), combined glomerular tubulointerstitial nephropathy or in renal failure following diabetic nephropathy or other causes (overflow proteinuria). Albumin has two main functions in plasma: maintaining the oncotic pressure (80 % due to albumin in plasma) and transport. It is the most important transport protein for substances having low water solubility (such as free fatty acids, bilirubin, metal ions, hormones and pharmaceuticals).

Depressed albumin levels are caused by hyperhydration, hepatocellular synthesis insufficiency, secretion disorders in the intravascular space, abnormal distribution between the intravascular and extravascular space,

catabolism and loss of albumin, acute phase reactions and congenital analbuminemia.

Blood brain barrier disorders can be reliably quantified with the aid of the albumin CSF/serum ratio. Elevated albumin ratios are indicative of a blood brain barrier disorder.

By simultaneously determining IgG in CSF and serum while considering the individual albumin ratios, it is possible to differentiate between IgG originating from the blood and CNS-synthesized immunoglobulin. IgG predominates in multiple sclerosis, chronic HIV encephalitis, neurosyphilis and herpes simplex encephalitis.

Submission Criteria:

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 Urine (without preservative)
2 days at 15-25 °C
6 days at 2-8°C
180 days at (-15) - (-25) °C

Stability in Urine (with preservative)
3 days at 15-25 °C
8 days at 2-8 °C
21 days at (-15) - (-25) °C

Rejection Criteria:

Rejection criteria include but are not limited to:

1. Mismatched requisitions
2. Specimens without patient identifiers
3. Specimens stored or shipped incorrectly
4. Specimens collected using expired tubes/cups
5. Specimens with inappropriate preservatives such as formalin or formaldehyde, disinfectant, or detergent added
6. Specimens not analyzed within the appropriate time frame
7. Specimens with quantity not sufficient
8. Hematuria
9. Specimens contaminated with fecal matter
10. Specimens submitted without approval

Authorization:

Diagnostic testing can only be performed with approval from an authorized provider/agency.

Turn Around Time:

1 day.

Instructions for Urine Specimen Submission

General Information

The detection of creatinine in human urine is performed using a Roche cobas i58 analyzer.

Specimens collected without preservative must be collected and stored at 20-25 °C if to be analyzed within 2 days, at 2-8°C if to be analyzed within 6 days and stored at (-15°C) - (-25°C) if to be analyzed within 180 days. Please be aware that storing specimens at $\leq -70^{\circ}\text{C}$ ($\leq -94^{\circ}\text{F}$) is not permissible.

Specimens collected with preservative must be collected and stored at 20-25 °C if to be analyzed within 3 days, at 2-8°C if to be analyzed within 8 days and stored at (-15°C) - (-25°C) if to be analyzed within 21 days. Please be aware that storing specimens at $\leq -70^{\circ}\text{C}$ ($\leq -94^{\circ}\text{F}$) is not permissible.

Specimens MUST be received at Reditus Laboratories within 7 days of collection.

Collection Instructions for Urine Specimen

1. Do not use expired urine collection tubes. Store urine collection tubes as per manufacturers recommendations. Use sterile collection containers for collecting samples.
2. Ensure that the patient's name, date-of-birth, and time/date of collection are recorded on the specimen tube along with the name or initials of the individual collecting the sample.
3. Complete all the demographic information on a sample requisition form through the approved electronic submission process
4. Refrigerate the specimen between 2-8°C (36-46°F) and ship or courier the specimen(s) within 48 hours.
5. The specimen(s) *must* be received at the laboratory **no later than** 48 hours *from the time of collection*.
 - a. **Avoid shipping specimens over weekends or holidays** as they may not be received at the laboratory and cold-packs will not maintain the required 2-8°C (36-46°F) specimen temperature.
 - b. Ensure that specimens shipped by commercial carrier are shipped with **overnight delivery**. If shipping on a Friday for Saturday delivery, ***you must include Saturday Delivery*** during shipment, or the specimens will not be received until the following non-holiday business day. Failure to receive specimens within 24 hours of shipment will result in specimens being rejected from testing.
6. For any questions pertaining to sample collection, storage, or shipping, please contact the Reditus Laboratories using the below contact information.

Instructions for Specimen Transport

7. **Messenger/Courier by ground transport.** Place specimen(s) into a biohazard labeled bag and seal securely. Place the test requisition(s) on the outside of the biohazard labeled bag. Place the sealed biohazard bag and test requisition(s) inside the shipping container. Place cold packs, which have been frozen for at least 24 hours, in the leak-proof outer container. The shipping container must be rigid, such as a Styrofoam cooler, and labeled with the UN 3373 Biological Substance Category B marking. Close securely.
8. **Commercial carrier by ground/air transport.** Place the specimen(s) inside a biohazard labeled bag and seal securely. Place the test requisition(s) on the outside of the biohazard labeled bag. Place the sealed bag and completed test requisitions(s) inside the outer shipping container. Place cold packs, which have been frozen for at least 24 hours, in the leak-proof outer container. Label the outer shipping container with Reditus Laboratories address listed below. Complete the return address section to include the name of the person shipping the package, business name and address, and a business phone number. The shipping container must include the UN3373 Biological Substance Category B marking.
9. *Ship specimens by overnight delivery* to the attention of Clinical Chemistry at Reditus Laboratories. This can be accomplished by use of local courier, shipping corporations or U.S. Postal Service.

- a. **If specimens are shipped on a Friday for Saturday delivery, you must include/indicate *Saturday delivery*** during shipment, or the specimens will not be received until the following non-holiday business day. Failure to receive specimens within 24 hours of shipment will result in specimens being rejected from testing.
10. The specimen(s) must be received at the laboratory **no later than** 48 hours *from the time of collection* and 24 hours from the time of shipment. Do not ship specimens over weekends or holidays as they will not be received, and cold-packs will not maintain the required 2-8°C (36-46°F) specimen temperature.

NOTE: Testing may be delayed, or specimens may be considered UNSATISFACTORY if the above instructions are not followed or the requisition form is not filled out completely. If there are any questions about specimen collection, handling, or shipping please contact the Reditus Laboratories to speak with laboratory personnel.

Ship specimens by a local courier or overnight by commercial carrier to the designated laboratories indicated below.

Send to: Reditus Laboratories
200 Enterprise Drive
Pekin, IL 61554

Phone: (469) 498-0222

Website: <https://www.redituslabs.com/>