Detection of Total Protein in Urine with Roche c502

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

Method Name: The Roche Diagnostics Urinary/CSF Protein assay is based on the method described by Iwata and Nishikaze, later modified by Luxton, Patel, Keir, and Thompson. In this method, benzethonium chloride reacts with protein in a basic medium to produce a turbidity that is more stable and evenly distributed than that observed with the SSA or TCA methodologies.

Results: Technical Range: 4-200 mg/dL
Reportable Range: 4.6-198.8 mg/dL

Reference Ranges: 24-hour period: <120 mg/dL

Clinical Significance: Protein measurements in urine are used in the diagnosis and treatment of disease conditions such as renal or heart diseases, or thyroid disorders, which are characterized by proteinuria or albuminuria.

Cerebrospinal fluid (CSF) protein measurements are used in the diagnosis and treatment of conditions such as meningitis, brain tumors and infections of the central nervous system.

Urine is formed by ultrafiltration of plasma across the glomerular capillary wall. Proteins with a relative molecular mass > 40000 are almost completely retained, while smaller substances easily enter the glomerular filtrate. Most CSF protein originates by diffusion from plasma across the blood CSF barrier.

Elevated levels occur as a result of increased permeability of the blood CSF barrier or with increased local synthesis of immunoglobulins.

Turbidimetric methods using trichloroacetic acid (TCA) or sulfosalicylic acid (SSA) precipitate proteins in the sample depending on their size; the resulting turbidity may be unstable and flocculate. Reagents of dye binding methods such as Coomassie blue and pyrogallol red molybdate react with proteins depending on their amino acid composition but may stain glass and plastic ware. Due to their reaction mechanisms all methods, turbidimetric and colorimetric, exhibit different sensitivities to various proteins, especially to protein fragments such as Bence Jones proteins and small proteins such as α1 microglobulin.

Submission Criteria: For specimen collection and preparation, only use suitable tubes or collection containers.
Only the specimens listed below were tested and found acceptable.
Urine:

Use 24-hour urine specimens. Use no preservatives. Refrigerate specimen during collection.

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, therefore 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.

Storage and Stability: 30 days at -20°C
7 days at 2-8°C
1 day at 20-25 °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 total protein in urine is performed using a Roche cobas i58 analyzer.

Specimens must be collected and stored at 20-25 °C if to be analyzed within 1 day, at 2-8°C if to be analyzed within 7 days and stored at -20°C if to be analyzed within 30 days. Please be aware that storing specimens at ≤ -70°C (≤ -94°F) is not permissible.

Specimens MUST be *received* at Reditus Laboratories within 1 day of collection.

Collection Instructions for Urine Specimens

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 24 hours.
5. The specimen(s) *must* be received at the laboratory **no later than** 24 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** 24 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/