

Detection of Glucose in Human Serum with Roche c502

Test Name: In vitro test for the quantitative determination of glucose in human serum and plasma on Roche/Hitachi cobas c systems.

Method Name: The UV test measures the oxidation of glucose-6-phosphate in the presence of NADP. The rate of NADPH formation during the reaction is directly proportional to the glucose concentration and is measured photometrically.

Results: Technical Range: 2-750 mg/dL
Reportable Range: 2.8-692.3 mg/dL

Reference Ranges: 0-11 months: not established
≥1 year: 70-140 mg/dL

Interpretation

Any of the following results, confirmed on a subsequent day, can be considered diagnostic for diabetes:

-Fasting plasma or serum glucose ≥ 126 mg/dL after an 8-hour fast

-2-Hour plasma or serum glucose ≥ 200 mg/dL during a 75-gram oral glucose tolerance test (OGTT)

-Random glucose > 200 mg/dL, plus typical symptoms

Patients with "impaired" glucose regulation are those whose fasting serum or plasma glucose fall between 101 and 126 mg/dL, or whose 2-hour value on oral glucose tolerance test fall between 140 and 199 mg/dL. These patients have a markedly increased risk of developing type 2 diabetes and should be counseled for lifestyle changes and followed up with more testing. Indications for screening and testing include strong family history, marked obesity, history of babies over 9 pounds, and recurrent skin and genitourinary infections.

Glucose levels of 25 mg/dL or lower in infants younger than 1 week are considered to be potentially life threatening, as are glucose levels of 40 mg/dL or lower in infants older than 1 week.

Clinical Significance: Glucose levels of 400 mg/dL and higher are considered a critical value. Glucose is the major carbohydrate present in the peripheral blood. Oxidation of glucose is the major source of cellular energy in the body. Glucose derived from dietary sources is converted to glycogen for storage in the liver or to fatty acids for storage in adipose tissue. The concentration of glucose in blood is controlled within narrow limits by many hormones, the most important of which are produced by the pancreas. The most frequent cause of hyperglycemia is diabetes mellitus resulting from a deficiency in insulin secretion or action. A number of secondary factors also contribute to elevated blood glucose levels. These include pancreatitis, thyroid dysfunction, renal failure, and liver disease. Hypoglycemia is less frequently observed. A variety of conditions may

cause low blood glucose levels such as insulinoma, hypopituitarism or insulin induced hypoglycemia.

Submission Criteria: 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 K₂-EDTA, NaF/Na₂EDTA, KF/Na₂EDTA NaF/K-Oxalate plasma.

The stability of glucose in specimens is affected by storage temperature, bacterial contamination, and glycolysis. Plasma or serum samples without preservative (NaF) should be separated from the cells or clot within half an hour of being drawn. When blood is drawn and permitted to clot and to stand uncentrifuged at room temperature, the average decrease in serum glucose is ~7 % in 1 hour (5 to 10 mg/dL). This decrease is the result of glycolysis.

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: 3 days at 4°C
8 hours at 25 °C

Rejection Criteria: Rejection criteria include but are not limited to:

1. Specimens containing fibrin or clots.
2. Excessive platelet clumping
3. Leaking specimens
4. Substandard mixing or collection
5. Expired or improperly stored collection tubes.
6. Improperly filled tubes based on collection tube manufacturer's guidelines.
7. Contaminated specimens (IV fluid, foreign particles, etc.)
8. Specimens not analyzed within the appropriate time frame.
9. Samples not shipped at appropriate temperature.
10. Samples without 2 proper identifiers or samples having identifiers that do not match the electronic or paper lab requisition.

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

Turn Around Time: 1 day.

Instructions for Serum Specimen Submission

General Information

The detection of glucose in human serum and plasma is performed using a Roche cobas i58 analyzer.

Specimens must be collected and stored at 4°C if to be analyzed within 3 days, at 25°C if to be analyzed within 8 hours. 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 24 hours of collection.

Collection Instructions for Serum Specimen

1. Do not use expired collection tubes. Store collection tubes as per manufacturers recommendations. Use standard venipuncture practices for collecting samples. Filled gold top serum tubes are preferred.
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 at 4°C (39°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 4°C (39°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 4°C (39°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/>