Detection of Alkaline Phosphatase in Human Serum with Roche c502

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

Method Name: Colorimetric assay that measures the increase in absorbance caused by the catalytic activity of alkaline phosphatase on p-nitrophenyl. It is determined by measuring the increase in absorbance.

Results: Technical Range: 5-1200 U/L
Reportable Range: 5-957 U/L

Reference Ranges:

Age Range	Female (U/L)	Male (U/L)
0-14 days	82-249	82-249
15 days-1 year	122-473	122-473
1-9 years	142-336	142-336
10-12 years	128-420	128-420
13-14 years	55-255	115-471
15-16 years	49-116	81-333
17-18 years	43-86	53-149
≥ 19 years	45-117	45-117

Clinical Significance:

Alkaline phosphatase in serum consists of four structural genotypes: the liver bone kidney type, the intestinal type, the placental type and the variant from the germ cells. It occurs in osteoblasts, hepatocytes, leukocytes, the kidneys, spleen, placenta, prostate and the small intestine. The liver bone kidney type is particularly important.

A rise in the alkaline phosphatase occurs with all forms of cholestasis, particularly with obstructive jaundice. It is also elevated in diseases of the skeletal system, such as Paget's disease, hyperparathyroidism, rickets and osteomalacia, as well as with fractures and malignant tumors. A considerable rise in the alkaline phosphatase activity is sometimes seen in children and juveniles. It is caused by increased osteoblast activity following accelerated bone growth.

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 plasma

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. Centrifuge samples containing precipitates before performing the assay.

Storage and Stability: 60 days at -20 °C
7 days at 2-8 °C
7 days at 20-25 °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 alkaline phosphatase in human serum and plasma is performed using a Roche cobas i58 analyzer. Serum specimens are preferred.

Specimens must be collected and stored at 2-25°C if to be analyzed within 7 days and stored at -20°C if to be analyzed within 60 days. Please be aware that storing specimens at ≤ -70°C (≤ -94°F) is not permissible.

Specimens MUST be *received* at Reditus Laboratories within 7 days 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 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/