IRON

En

REF 08V6430

Alinity c

Diagnostic reagent for the determination of Iron concentration.
Liquid. Dual reagent (Ratio: R1/R2: 4/1). Store at +2/+8°C. For In Vitro Diagnostic use. **Do not freeze.**
The products with 08V6430 reference numbers provided are compatible for use with Abbott Alinity biochemistry autoanalyzer series.

The instructions must be followed carefully. The reliability of the test results cannot be guaranteed unless these instructions are followed.

NAME

IRON

INTENDED USE

Iron assay is used for the quantitative determination of Iron concentration in human serum and plasma on Alinity c analyzer.

SUMMARY AND EXPLANATION OF THE TEST

Iron (Fe) is involved in the functioning of all cells. Depending on the oxidation status, it is available in ferrose (Fe^{+2}) or ferric (Fe^{+3}) form. It mostly binds to iron-protoporphyrin (heme) acting as an enzyme co-factor and iron-sulfur (Fe-S) clusters.[1] Hemoproteins play parts on many biological functions such as oxygen binding and carrying (hemoglobins), oxygen metabolism (catalases, peroxidases), cellular respiration and electron transport (cytochromes). In addition, non-heme iron-containing proteins are vital for the fundemental cellular processes such as DNA synthesis, cell proliferation and differentiation, gene regulation, drug metabolism and steroid synthesis.[2] Furthermore, ferrose iron (Fe^{+2}) may cause damage by catalyzing the formation of highly reactive hydroxyl radicals (•OH) from hydrogen peroxide, named as “Fenton reaction”.[3] These hydroxyl radicals harm cell membranes, proteins and DNA.[1] Iron has to circulate bound to plasma transferrin in order to provide highly insoluble Fe^{+3} to the cells via transferrin receptor. Iron can be stored in ferritin and hemosiderin form in the cells.[4] Although stored iron can be mobilized for re-use under normal circumstances, only small amounts of iron is available other than this phisiological “storage”.[1]

Many diseases stem from the instability in iron homeostasis. Too much iron accumulates in anemia associated with hereditary hemochromatosis and iron overload. Adequate amount of iron is not available for heme synthesis in iron deficiency anemia (IDA). In chronic disease anemia (CDA), iron is re-distributed to the macrophages in order to increase resistance against infections.[5]

Control of the iron homeostasis acts both at celullar and systematic level, and contains a complex system consisting of different types of cells, carriers and signals.

The connection between cells absorbing iron from diet (duodenal enterocytes), cells consuming iron (mainly erythroid precursors) and cells storing iron (hepatocytes and tissue macrophages) is strictly regulated for maintaining systemic iron homeostasis.[1] Hepsidine, a B-defensin-like antimicrobial peptide, is thought to be a regulator adjusting the iron absorption and macrophage iron emission.[6] Hepsidine is synthesized in the liver as a result of the changes in the body’s iron need such as anemia, hypoxia and inflammation, and is released into the circulation. It induces the internalization and deterioration of ferroportin, a vital cellular iron-carrying protein in the membrane of macrophages and basolateral area of enterocytes.[7,8] The expression of the proteins playing a role in uptaking, storing and releasing of the iron is determined with the cell’s iron need and is regulated at post-transcriptional level by iron regulatory protein and iron responsive element (IRP/IRE) network.[9]

Most of the Fe in the body (3 – 5 g) is present in the heme-containing proteins carrying and storing oxygen, including hemoglobin (2,5 g) and myoglobin (130 mg). Small amounts (150 mg) are incorporated into enzymes with active sites containing heme or Fe-sulfur clusters, including peroxidases, catalases, ribonucleotide reductase and enzymes of the Krebs cycle and electron transport chain. Most of the non-heme Fe (1 g in adult men) is stored as ferritin or hemosiderin in macrophages and heptocytes. Only a small amount of Fe (3 mg) is bound to the transferrin in circulation.[1] Each milliliter of blood contains 0,4 – 0,5 mg Fe included in Hb. For this reason, 2,5 g Fe is present as a part of Hb in an adult man.[10,11]

Cellular Fe exceeding immediate needs is stored in a partially deteriorated ferritin form known as Fe oxide and hemosiderin in ferritin nanocavity.[12]

About half of estimated 1 billion people with anemia worldwide have iron deficeincy (ID).[13-15] ID is a disease particularly seen in the children and pre-menopausal women in low- and middle-income countries, however, it can be seen in men, in people of all ages and in developed countries.[16-18] ID stem from phisiologically increasing iron need for dietary iron for growth and developement in children quite often,[17] and almost always from chronic blood loss or pregnancy in adults, particularly in pre-menopausal women.[18] There is a correlation between iron status as well as depression and neurocognitive function in children.[19,20] ID also affects immune function and infection sensitivity.[21,22] Iron supplementation has been reported to reduce the fatigue in non-anemic women with low ferritin levels,[23,24] provide benefit to the exercise performance of women with ID[25] and lessen the restless leg syndrome.[26] Oral iron use in children cures anemia and may improve cognitive performance in older children, but the evidences of its effects on cognitive developement in younger children lack.[17,27,28] Anemia of chronic disease (ACD), also known as inflammation anemia, is a disorder of iron distribution. It is common in the patients with infectious and inflammatory diseases, including chronic kidney disease, inflammatory bowel disease, chronic heart failure, malignancies and liver diseases.[29-33] Iron overload is typically subtle and can cause progressive and sometimes even irreversible tissue damage prior to the formation of clinical symptoms. Iron overload disorders can be categorized according to whether underlying pathophysiological defect is in hepsidine-ferroportin axis, erythroid developement or iron transport.[1,34] Iron overload may occur due to the transfusion of multiple erythrocydes and parenteral iron supplementation.[1]

PRINCIPLES OF THE PROCEDURE

The test has Ferrozin measurement method. At acidic pH, Fe in the serum to be measured is cleaved from transferrin and reduced from ferric (Fe^{+3}) to ferrous (Fe^{+2}) form. It then reacts with the chromogenic ferrozine in reagent 2 to form Fe-chromogen complexes. The absorbance of this complex, which can be measured spectrophotometrically at 560 nm, is proportional to the Fe concentration in the sample.

REAGENTS

Kit Contents

R1 Acetate Buffer. Hydroxylamine hydrochloride (≤ 220 mmol/L).

R2 Ferrzoin (≤ 15 g/L). Buffer. Antibacterial.

Warnings and Precautions

IVD: For in Vitro Diagnostic use only.
Do not use expired reagents.
Reagents with two different lot numbers should not be interchanged.
For professional use.
Follow Good Laboratory Practice (GLP) guidelines.

CAUTION: Human source samples are processed with this product. All human source samples must be treated as potentially infectious materials and must be handled in accordance with OSHA standards.

Danger	
EUH032	: Releases a very toxic gas if contacts with acid.
H317	: May cause allergic skin reaction.
Precaution	
P280	:Use protective gloves / clothes / glasses / mask.
P264	:Wash your hands properly after using.
P272	:Contaminated work clothes should not be allowed to be used outside of the workplace.

Intervention
P302+P352 :Wash with plenty of water and soap if it contacts with skin.
P333+P313 :Seek medical help if it irritates your skin or develops rash.
P362+P364 :Remove contaminated clothes and wash properly before using.

Disposal
P501 :Dispose the vials and contents according to the local regulations.

Reagent Handling

- Reagent cartridges should be kept in an upright position for at least 1 hours after receipt and before use to eliminate any air bubbles that may have formed inside.
- If the cartridge is dropped, it should be kept upright for 1 hours before use to allow the air bubbles to dissipate.
- Foam and air bubbles may form in the reagents; this may prevent accurate detection of the reagent level inside the cartridge, leading to insufficient reagent aspiration and potentially affecting the analysis results.

Reagent Storage [35]

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	+2/+8°C	Until expiration date	Store in upright position.
Onboard	System Temperature	*60 days*	

Indications of Reagent Deterioration

When a calibration error occurs or the control value falls outside the accepted range, the reagents may be considered to have deteriorated. In this case, the test results are not valid and the samples should be reanalyzed. Recalibration may be required.

SAMPLE COLLECTION AND PREPARATION FOR ANALYSIS

Sample Types

The recommended sample types for this test are listed below.

Sample Type	Collection Tube
Serum	Serum tubes
Plasma	Lithium heparined sample collection tubes

Follow the instructions provided with your sample collection tubes for use and handling.

Sample Conditions

- For the analysis, samples that have been left to stand as short as possible should be preferred.
- To obtain reliable results, serum should be free of fibrin, blood cells, or foreign particles. In samples obtained from individuals receiving anticoagulant or thrombolytic therapy, fibrin residues may be observed due to incomplete clotting.
- To reduce the risk of contamination between samples, a new pipette or pipette tip should be used for each procedure.
- Non-hemolytic samples should be used.

Preparation for Analysis

- When preparing sample tubes, the manufacturer's instructions should be followed; separation by standing alone is not sufficient.
- Samples should be free of air bubbles. Before analysis, bubbles should be removed using a stick, and a separate stick should be used for each sample.
- If the samples contain fibrin, red blood cells, or other particulate matter, centrifuge them again before testing to ensure reliable results.
- If samples do not appear homogeneous, they should be mixed by low-speed vortexing or by inverting the tube 10 times.
- The sample should be placed in a centrifuge tube and centrifuged; particularly in samples containing a lipid layer, the lipid-containing portion should not be transferred, and only the supernatant should be transferred to a separate container or secondary tube for testing.

Sample Storage [54,58]

Temperature	Maximum Storage Time
+2/+8°C	21 days
+20/+25°C	7 days
-20°C	1 year

The information provided applies to serum and plasma samples. Repeated freeze–thaw cycles of samples should be avoided.[60]

PROCEDURE

Materials Provided
Iron Reagent Kit
Materials Required but Not Provided

- Multiconstituent Calibrator
- Commercially available controls
- Saline solution (0.85%–0.90% NaCl) for sample dilution

Assay Procedure

- If primary or aliquot tubes are used, ensure that a sufficient amount of sample is available.
- To prevent evaporation of the sample, make sure that the tube volume is adequate before each test.
- Minimum Sample Volume Requirements:
  - Sample volume for a single test: 8 µL
  - This volume does not include dead space or the additional aspiration volume.

Sample Dilution Procedures

This method shows measurement linearity up to 1000 µg/dL. For samples with results above this value, the automatic dilution procedure of the autoanalyzer should be applied or manual dilution may be performed. The system dilutes the sample at a 1:5 ratio and automatically calculates the concentration by multiplying the result by the dilution factor.

Calibration

The use of a Lyophilized Multiconstituent Calibrator is required for this test.

Multiconstituent Calibrator- Lyophilized
Ref.No: 06R56-02

Calibration stability is 30 days. Changes in the reagent lot number require recalibration. Calibration is necessary if quality control results are not within acceptable limits.

Quality Control Procedures

Commercially available control materials with values assigned by this method may be used.

At least two levels of control should be run every 24 hours. Each laboratory should establish its own quality control procedures. If more stringent control monitoring is required, refer to the quality control procedures established for your laboratory.

EXPECTED VALUES

Each laboratory should investigate the transferability of expected values for its own patient population and, if necessary, establish its own reference range.

Reference Range

Adult [53]
Women : 50 - 170 µg/dL
Men : 65 - 175 µg/dL

SPECIFIC PERFORMANCE CHARACTERISTICS

Precision

			Within-Run [48](Repeatability)		Within-Laboratory [48](Total)*	
Sample	**n**	**Mean (µg/dL)**	**SD**	**%CV**	**SD**	**%CV**
Level 1	80	81.79	1.11	1.35	1.21	1.48
Level 2	80	237.06	2.87	1.21	3.19	1.35

*: Includes within-run, between-run, and between-day variability.

Lower Measurement Limits

The lower measurement limits refer to the range between the lower limit of quantitation (LLoQ) and the upper limit of quantitation (ULoQ), within which

the analyte concentration can be measured with the required medical and laboratory accuracy without dilution, concentration, or any pre-treatment.[44] The LoD and LoQ values have been verified using the CLSI EP17-A2:2012 protocol.[45]

	µg/dL
LoD**	2.2
LoQ***	4

**** :** The LoD represents the lowest concentration at which the analyte can be detected with 95% probability, based on ≥ 60 replicates of samples with low analyte levels.

*****:**When determining the LoQ value, a coefficient of variation (%CV) of ≤20% is used as the basis.

Measuring Interval

This method shows measurement linearity up to 4- 1000 µg/dL. For samples with results above this value, the automatic dilution procedure should be applied. For additional information, please refer to the instrument's user manual. Linearity studies data have been verified by using CLSI EP06-A:2003 protocol.[46]

Interference

Endogenous interferant and analyte concentrations that have been used in the Iron scanning tests has been determined according to "CLSI EP37-ED1:2018" and "CLSI EP07-ED3:2018" manuals.[50,51]

The total acceptable error rate, which is going to be used to detect whether the observed differential value obtained from Iron interference scanning test is appropriate, is determined as ±10%.[52]

In Iron test results, no significant interaction has been observed in the determined endogenous interferant and analyte concentrations or between interferants and analyte.

Interferant-Concentration	Iron Target (µg/dL)	n	Observed Recovery %
Bilirubin 48 mg/dL	78.8	3*	102
Lipemia 1336 mg/dL	69.8	3*	104
Copper 1425 µg/dL	46	3*	96

*In calculating how many times the control and test samples (containing interferent), prepared as a serum pool, would be run repetitively, the within-run SD values previously determined for the relevant method and the total allowable error rate defined as the interference limit were used. In the calculations, a type 1 error (α error) rate of 5% and a type 2 error (β error) rate of 10% (90% power) were accepted.[51]

Because intravenous iron preparations and iron chelators bind iron much more loosely than iron-binding dyes, chromogenic iron-binding tests often measure iron from circulating iron preparations and chelators as well, leading to falsely elevated iron concentrations.[55-57]

It should be noted that, in addition to endogenous interferents, various drugs and metabolites; anticoagulants (e.g., heparin, EDTA, citrate, oxalate) and preservatives (e.g., sodium fluoride, iodoacetate, hydrochloric acid); substances that may come into contact with samples during collection and handling (such as serum separation devices, sample collection containers and their contents, catheters, catheter flushing solutions, skin disinfectants, hand sanitizers and lotions, glassware detergents, powdered gloves, etc.); dietary substances known to affect certain tests (e.g., caffeine, beta-carotene, poppy seeds); or certain substances present in a sample that may cause interference due to foreign proteins (e.g., heterophilic antibodies), autoimmune responses (e.g., autoantibodies), or malignancy (e.g., paraproteins causing interference in phosphate tests and indirect ion-selective electrode methods) may lead to various interferences and erroneous evaluations for many different reasons.[51]

These performance characteristics were obtained using an autoanalyzer. Results may vary when different equipment or manual procedures are used.

Method Comparison

As a result of the statistical evaluation of method comparison data, the table was constructed according to the Passing–Bablok regression method as follows [49]:

Archem Iron – Roche Cobas Integra 400 Plus

	Units	n	Correlation Coefficient	Intercept	Slpoe	Concentration Range
Serum	µg/dL	100	0.9997	0.18	1.02	16-954

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SYMBOLS

IVD	In Vitro Diagnostic Medical Device
LOT	Lot Number
R1	Reagent 1
R2	Reagent 2
GTIN	Global Trade Item Number
REF	Reference Number
GLP	Good Laboratory Practices
FOR USE WITH	Identifies Products to Be Used Together
PRODUCT OF TURKEY	Product of Turkey
	Manufacturer
	Expiration Date
	Temperature Limits
	Consult Instructions for Use
	Caution
	Number of Tests

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