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IRON
Ferene

Diagnostic reagent for the quantitative in vitro determination of iron in human serum and plasma on photometric systems

REF	Kit Size	Configuration
D03118B	1 x 1.25 mL	1 x 1 L R1 + 1 x 0.25 L R2
D01103	5 x 100 mL	4 x 100 mL R1 + 1 x 100 mL R2
D01104	5 x 50 mL	4 x 50 mL R1 + 1 x 50 mL R2
D01105	5 x 25 mL	4 x 25 mL R1 + 1 x 25 mL R2
D01106	5 x 10 mL	4 x 10 mL R1 + 1 x 10 mL R2
D91911	10 x 50 mL	10 x 40 mL R1 + 4 x 25 mL R2
D0430917	5 x 62.5 mL	4 x 62.5mL R1 + 1 x 62.5mL R2
DA0833	5 x 50 mL	5 x 40 mL R1 + 5 x 10 mL R2
DT1033	4 x 62.5 mL	4 x 50 mL R1 + 4 x 12.5mL R2
DK0732	5 x 50 mL	4 x 50 mL R1 + 1 x 50 mL R2
DE1833	2 x 62.5 mL	2 x 50 mL R1 + 2 x 12.5mL R2
DB20324	4 x 62.5 mL	4 x 50 mL R1 + 4 x 12.5mL R2

Additionally available:

D95305	1 x 3 mL	Iron Standard	
D98485	5 x 3 mL	Calibrator	Diacal Auto
D98485SV	1 x 3 mL	Calibrator	Diacal Auto
D98481	12 x 5 mL	Control normal	Diacon N
D14481	5 x 5 mL	Control normal	Diacon N
D98481SV	1 x 5 mL	Control normal	Diacon N
D98482	12 x 5 mL	Control abnormal	Diacon P
D14482	5 x 5 mL	Control abnormal	Diacon P
D98482SV	1 x 5 mL	Control abnormal	Diacon P

For professional in vitro diagnostic use only.

GENERAL INFORMATION

Method Colorimetric, endpoint, increasing reaction, Ferene
Shelf life 24 months
Storage 2 – 8 °C
Wavelength 595 nm, 600 nm, Hg 623 nm
Temperature 20 – 25 °C, 37 °C
Sample Serum, heparin plasma

INTENDED USE

Diagnostic reagent for the quantitative in vitro determination of iron in human serum and plasma on photometric systems.

DIAGNOSTIC SIGNIFICANCE [1, 2]

Iron exists in the body as a component of haemoglobin and myoglobin as well as bound to transferrin for the transport in plasma and stored in ferritin. Increased iron concentrations occur in hemochromatosis and liver damage. Malabsorption due to gastrointestinal diseases can cause decreased iron levels, and may thus lead to anemia. Blood loss after gastrointestinal lesions or heavy menstrual bleeding can generate anemia, too.

TEST PRINCIPLE

Iron bound to transferrin is released in an acidic medium as ferric iron and is then reduced to ferrous iron in the presence of ascorbic acid. Ferrous iron forms a blue complex with Ferene. The absorbance at 595 nm is directly proportional to the iron concentration.

$$\text{Transferrin } (Fe^{3+})_2 \xrightarrow{\text{Asc. Acid, Buffer}} 2\,Fe^{2+} + \text{Transferrin}$$

$$Fe^{2+} + 3\ \text{Ferene} \rightarrow \text{Ferrous Ferene (blue complex)}$$

REAGENT COMPOSITION

COMPONENTS	CONCENTRATION	
Reagent 1		
Acetate Buffer, pH 4.5	1	mol/L
Thiourea	120	mmol/L
Reagent 2		
Ascorbic Acid	240	mmol/L
Ferene	3	mmol/L
Thiourea	120	mmol/L

MATERIAL REQUIRED BUT NOT PROVIDED

- NaCl solution (9 g/L).
- Clinical chemistry analyser.

REAGENT PREPARATION

Reagents are ready to use.

STORAGE AND STABILITY

Conditions: Protect from direct light.
Close immediately after use.
Do not freeze the reagents!
Avoid contamination.
Storage: at 2 – 8 °C
Stability: up to the expiration date

WARNINGS AND PRECAUTIONS

1. Reagent 1: Danger

H315: Causes skin irritation.
H318: Causes serious eye damage.
P264: Wash hands and face thoroughly after handling.
P280: Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310: Immediately call a poison center or doctor/physician.

2. Standard: Warning

H290: May be corrosive to metals.
P234: Keep only in original container.
P280: Wear protective gloves/protective clothing/eye protection/face protection.
P390: Absorb spillage to prevent material damage.

3. Use only disposable material to avoid iron contamination. Rinse glass material with diluted HCl and copious dist. water.
4. In very rare cases, samples of patients with gammopathy might give falsified results [8].
5. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents.
6. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
7. For professional use only!

SPECIMEN COLLECTION AND STORAGE

Separate serum/plasma at the latest 2 h after blood collection to minimize haemolysis.

Stability [3]:

In serum/plasma	at 20 – 25 °C	7 days
	at 4 – 8 °C	3 weeks
	at - 20 °C	1 year

Discard contaminated specimens. Freeze only once!

STANDARD

(not included in the kit – has to be ordered separately)
Concentration: 100 µg/dL (17.9 µmol/L)
Storage: 2 – 8 °C
Stability: up to the expiration date
Close immediately after use! Avoid contamination.
Protect from light!

TEST PROCEDURE

Bring reagents and samples to room temperature.

Pipette into test tubes	Blank	Std./ Cal.	Sample
Sample	-	-	100 µL
Standard/Calibrator	-	100 µL	-
Distilled Water	100 µL	-	-
Reagent 1	1000 µL	1000 µL	1000 µL
Mix, read absorbance A1 after 1 - 5 min against reagent blank. Then add R2:			
Reagent 2	250 µL	250 µL	250 µL
Mix, read absorbance A2 after 10 min. against reagent blank. ΔA = (A2 – 0.82 A1) Sample or Std./Cal.			

The Factor 0.82 compensates the decrease of the absorbance by addition of reagent 2. The factor is calculated as follows: (sample + R1) / total volume.

Automation

Special adaptations for automated analysers can be made on request.

INTERPRETATION OF RESULTS

Calculation
With Standard or Calibrator:

$$\text{Iron [µg/dL]} = \frac{\Delta A\ \text{Sample}}{\Delta A\ \text{Std/Cal}} \times \text{Conc. Std/Cal [µg/dL]}$$

Unit Conversion
Iron [µg/dL] x 0.1791 = Iron [µmol/L]

QUALITY CONTROL AND CALIBRATION

Control sera with iron values determined by this method can be used.
We recommend the Dialab serum controls **Diacon N** (control serum with values in the normal range) and **Diacon P** (control serum with values in the abnormal range).
Each laboratory should establish corrective action in case of deviations in control recovery.

Calibration
The assay requires the use of an Iron Standard or Calibrator.
We recommend the Dialab **Iron Standard** and the Dialab multi calibration serum **Diacal Auto**.

PERFORMANCE CHARACTERISTICS

LINEARITY, MEASURING RANGE
The test has been developed to determine iron concentrations within a measuring range from 5 – 1000 µg/dL (0.9 – 179 µmol/L). When values exceed this value samples should be diluted 1 + 2 with NaCl solution (9 g/L) and the result multiplied by 3.

SENSITIVITY/LIMIT OF DETECTION

The lower limit of detection is 5 µg/dL (0.9 µmol/L).

PRECISION

Intra-assay n = 20	Mean [µg/dL]	SD [µg/dL]	CV [%]
Sample 1	98.0	1.00	1.02
Sample 2	164	2.01	1.22
Sample 3	216	2.11	0.98

Inter-assay n = 20	Mean [µg/dL]	SD [µg/dL]	CV [%]
Sample 1	85.8	2.13	2.48
Sample 2	144	3.16	2.19
Sample 3	195	3.86	1.98

SPECIFICITY/INTERFERENCES

no interference up to:

Bilirubin	60 mg/dL
Hemoglobin	100 mg/dL
Triglycerides	2000 mg/dL
Copper	200 µg/dL
Zinc	400 µg/dL

For further information on interfering substances refer to Young DS [7].

METHOD COMPARISON

A comparison between Dialab Iron Ferene (y) and a commercially available test (x) using 70 samples gave following results: y = 0.99 x – 0.33 µg/dL; r = 0.999.

TRACEABILITY

The assigned values of the calibrator Diacal Auto have been made traceable to the NIST-SRM® 682 reference material.

EXPECTED VALUES [4]*

		µg/dL	µmol/L
Children	2 weeks	63 – 201	11 – 36
	6 months	28 – 135	5 – 24
	12 months	35 – 155	6 – 28
	2 –12 years	22 – 135	4 – 24
Females	25 years	37 – 165	6.6 – 29.5
	40 years	23 – 134	4.1 – 24.0
	60 years	39 – 149	7.0 – 26.7
Pregnant women	12th gestational week	42 – 177	7.6 – 31.6
	at term	25 – 137	4.5 – 24.5
	6 weeks postpartum	16 – 150	2.9 – 26.9
Males	25 years	40 – 155	7.2 – 27.7
	40 years	35 – 168	6.3 – 30.1
	60 years	40 – 120	7.2 – 21.5

* Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

LIMITATIONS

- Eventual Iron (Ferene) carry-over to reagents Creatinine (Enzymatic, PAP), LDH-L (IFCC), LDH-P (opt. DGKC), Magnesium (Xylidyl blue), Urea UV Auto (Urease/GLDH), Protein Total in Urine/CSF (Pyrogallol red) and Triglycerides (GPO-PAP). The actual carry-over depends on the analyser.

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Wick M. Iron metabolism and its disorders. In: Thomas L, editor. Clinical laboratory diagnostics. 1 st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 268-73.
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