

Liquid Reagents – ready to use

IRON

Ferene
2 Reagents

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

REF

Cont.

D01103 5 x 100 mL 4 x 100 mL Reagent 1
1 x 100 mL Reagent 2

Additionally offered:

D95305 1 x 3 mL Iron Standard
D98485 5 x 3 mL Calibrator Diacon Auto
D98481 12 x 5 mL Control normal Diacon N
D98482 12 x 5 mL Control abnormal Diacon P

TEST PARAMETERS

Method: Colorimetric, Endpoint, Increasing
Reaction, Ferene
Wavelength: 595 nm, 600 nm, Hg 623 nm
Temperature: 20 – 25 °C, 37°C
Sample: Serum, heparin plasma
Linearity: up to 1000 µg/dL (179 µmol/L)
Sensitivity: The lower limit of detection is 2 µg/dL (0.4 µmol/L)

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

REAGENT PREPARATION

Substrate Start:

Reagents are ready for use.

Sample Start:

not possible.

REAGENT STABILITY AND STORAGE

Conditions: Protect from light (R2)
Close immediately after use
Do not freeze the reagents!
at 2 – 8 °C
Storage: up to the expiration date
Stability: up to the expiration date

SAMPLE STABILITY AND STORAGE

Separate serum/plasma at the latest 2 h after blood collection to minimize haemolysis.
Stability [3]: at 20 - 25 °C 7 days
at 4 - 8 °C 3 weeks
at -20 °C 1 year
Discard contaminated specimens.

STANDARD (has to be ordered separately)
Concentration: 100 µg/dL (17.9 µmol/L)
Storage: 2 – 25°C
Stability: up to the expiration date
CLOSE IMMEDIATELY AFTER USE!

INTERFERING SUBSTANCES

no interference up to:
bilirubin 60 mg/dL
hemoglobin 100 mg/dL
triglyceride 2000 mg/dL
copper 200 µg/dL
zinc 400 µg/dL

MANUAL TEST PROCEDURE

Bring reagents and samples to room temperature.

Substrate Start

Pipette into test tubes	Blank	Std./ Cal.	Sample
Sample	-	-	100 µL
Std./Cal.	-	100 µL	-
Dist. Water	100 µL	-	-
Reagent 1	1000 µL	1000 µL	1000 µL
Mix, read absorbance A1 after 1 - 5 min against reagent blank. Then add:			
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.

CALCULATION

$$\text{Iron } [\mu\text{g/dL}] = \frac{\Delta A \text{ sample}}{\Delta A \text{ std/cal}} \times \text{Conc. of Std/Cal } [\mu\text{g/dL}]$$

UNIT CONVERSION

$$\mu\text{g/dL} \times 0.1791 = \mu\text{mol/L}$$

REFERENCE RANGE ^[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	12 th 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

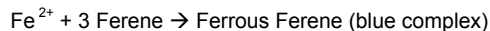
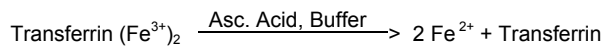
* Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

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.



PERFORMANCE CHARACTERISTICS

LINEARITY

The test has been developed to determine iron conc. 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.

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

METHOD COMPARISON

A comparison between Dialab Iron Ferene (y) and a commercially available test (x) using 70 samples gave following results:

$$y = 0.99 x - 0.33 \text{ µg/dL}; r = 0.999.$$

QUALITY CONTROL

All control sera with iron values determined by this method can be used. We recommend:

REF

Cont.

D98481 12 x 5 mL **DIACON N** Assayed Control Serum Normal

D98482 12 x 5 mL **DIACON P** Assayed Control Serum Abnormal

CALIBRATION

The assay requires the use of an Iron Standard or Calibrator. We recommend:

REF

Cont.

D95305 1 x 3 mL **IRON STANDARD**
D98485 5 x 3 mL **DIACAL AUTO** Assayed Multi Calibration Serum

AUTOMATION

Special adaptations for automated analyzers can be made on request.

WARNINGS AND PRECAUTIONS

- Reagent 1 is irritating: Xi
R36: Irritating to eyes.
S2: Keep out of the reach of children.
S25: Avoid contact with eyes.
S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- Reagent 2:
S25: Avoid contact with eyes.
- Standard:
S24/25: Avoid contact with skin and eyes.
- Use only disposable material to avoid iron contamination. Rinse glass material with diluted HCl and copious dist. water.
- Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents.

WASTE MANAGEMENT

Please refer to local legal requirements.

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2°C 8°C

IVD



DIALAB Produktion und Vertrieb von chemisch – technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
A – 2351 Wiener Neudorf, Austria
IZ-NÖ Süd, Hondastrasse, Objekt M55
Phone: ++43 (0) 2236 660910-0
Fax: ++43 (0) 2236 660910-30 e-mail: office@dialab.at