

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.No.	Kit Size	Content
DIA010151	62.5 ml	2x25 ml R1 + 1x12.5 ml R2
DIA010152	5 x 20 ml	4x20 ml R1 + 1x20 ml R2
DIA010153	5 x 25 ml	4x25 ml R1 + 1x25 ml R2

Additionally offered:

DIA060070	1 x 3 mL	Iron Standard
DIA040012	1 x 3 mL	Diacal Auto (Calibrator)
DIA030012	1 x 5 mL	Diacon N (Control Normal)
DIA030022	1 x 5 mL	Diacon P (Control Abnormal)

### TEST PARAMETERS

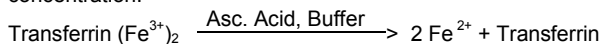
<b>Method:</b>	Colorimetric, endpoint, increasing reaction, Ferene
<b>Wavelength:</b>	595 nm, 600 nm, Hg623nm
<b>Temperature:</b>	20 – 25 °C, 37°C
<b>Sample:</b>	Serum, heparin plasma
<b>Linearity:</b>	up to 1000 µg/dL (179 µmol/L)
<b>Sensitivity:</b>	The lower limit of detection is 5 µg/dL (0.9 µmol/L)

### SUMMARY [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.



### REAGENT COMPOSITION

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

### REAGENT PREPARATION

Reagents are ready to use.

### MATERIALS REQUIRED BUT NOT PROVIDED

NaCl solution (9 g/L)  
General laboratory equipment

### REAGENT STABILITY AND STORAGE

**Conditions:** Protect from light (R2)  
Close immediately after use  
Do not freeze the reagents!  
Avoid contamination.

**Storage:** at 2 – 8 °C

**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. Freeze only once!

### STANDARD

(not included in the kit – has to be ordered separately)

**Concentration:** 100 µg/dL (17.9 µmol/L)

**Storage:** 2 – 25°C

**Stability:** up to the expiration date

### MANUAL 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:			
Reagent 2	250 µL	250 µL	250 µL
Mix, read absorbance A2 after 10 min. against reagent blank. $\Delta A = [(A2 - 0.82 A1) \text{ Sample or Std./Cal.}]$			

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

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

### 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 <sup>th</sup> 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.

### 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:

<b>Bilirubin</b>	60 mg/dL
<b>Hemoglobin</b>	100 mg/dL
<b>Triglyceride</b>	2000 mg/dL
<b>Copper</b>	200 µg/dL
<b>Zinc</b>	400 µg/dL

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

#### METHOD COMPARISON

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

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

#### CALIBRATION

The assay requires the use of an Iron Standard or Calibrator. We recommend the Diagnostica **Iron Standard** and the Diagnostica multi calibration serum **Diacal Auto**. The assigned values of Diagnostica Auto have been made traceable to the NIST-SRM® 682 reference material.

#### QUALITY CONTROL

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

#### AUTOMATION

Special applications for automated analyzers can be made on request.

#### WARNINGS AND PRECAUTIONS

- 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.  
P312: Call a poison center or doctor/physician if you feel unwell.
- 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.
- Use only disposable material to avoid iron contamination. Rinse glass material with diluted HCl and copious dist. water.
- In very rare cases, samples of patients with gammopathy might give falsified results [8].
- Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents.
- For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
- For professional use only!

#### WASTE MANAGEMENT

Please refer to local legal requirements.

