TRUEchemie Ferritin Test Kit

(Immunoturbidimetric assay)

for the quantitative turbidimetric determination of Ferritin in human serum or plasma

INTENDED USE

The TRUEchemie Ferritin Test kit is a quantitative turbidimetric test for the measurement of Ferritin in human serum or plasma.

INTRODUCTION

Ferritin is an iron storage protein consisting of 24 subunits forming a hollow sphere in which up to 4000 iron atoms can be enclosed. Iron-loaded ferritin represents the primary source of reserve iron of each cell and the entire organism readily available for hemoglobin synthesis. Variations in serum ferritin generally are closely related to changes in tissue ferritin. Measurement of serum ferritin concentration gives a quantitative determination of the mobilizable storage iron. Thus, a decreased ferritin level indicates tissue iron depletion and is particularly useful in the early detection of iron deficiency anemia which is the most common deficiency disorder in the industrialized world. Increased serum ferritin concentrations can be suggestive of iron overload in conjunction with iron storage disorders like hereditary or acquired hemochromatosis. They can also be used to evaluate clinical conditions not related to iron storage including chronic liver disease, infections, inflammation and malignancy.

TEST PRINCIPLE

Latex particles coated with specific anti-human ferritin are agglutinated when mixed with samples containing ferritin. The agglutination causes an absorbance change, dependent upon the ferritin contents of the sample that can be quantified by comparison from a calibrator of known ferritin concentration

PACK SIZE

Kit Size	**20 mL**
Cat No.	**ADX970**
Kit contents	
Ferritin Reagent R1	1 X 15 mL
Ferritin Reagent R2	1 X 5 mL
Ferritin Calibrator	1 x 0.5 mL

MATERIALS REQUIRED BUT NOT PROVIDED

1. Pipettes to accurately measure required volumes.
2. Test tubes/rack
3. Timer
4. 37 °C heating block or water bath
5. Photometer capable of accurately measuring absorbance at 578 nm

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
2. Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and HIV. However, handle cautiously as potentially infectious.
3. Avoid ingestion. DO NOT PIPETTE BY MOUTH.
4. An exposure to larger quantities of sodium azide may cause certain health issues like convulsions, low blood pressure and heart rate, loss of consciousness, lung injury and respiratory failure.
5. Follow instructions and procedures described in this 'instruction for use'.
6. Use only fresh samples and avoid direct sunlight.
7. Lot numbers of all the test components R1, R2 and Calibrator, must match each other

REAGENT PREPARATION

Ready to use reagents.

TRUEchemie Ferritin calibrator – Ready to use

REAGENTS COMPOSITION

Ferritin Reagent R1 : Tris buffer 20mmol/L, pH 8.2. Preservative

Ferritin Reagent R2: Latex particles coated with specific anti human Ferritin antibody, pH 8.2. Preservative

Calibrator: Calibrator stored at 2-8 °C and are stable till the expiry date mentioned on the label.

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8 ºC and contaminations are prevented during their use. Do not use reagents over the expiration date

Reagent deterioration: Do not freeze the reagents, frozen Latex or Diluent could change the functionality of the test.

SAMPLE/ SPECIMEN STORAGE

Use fresh Serum (Do not use lipemic or hemolyzed sample).

If the test cannot be carried out on the same day, the serum may be stored at 2-8°C for 48 hours. If stored for a longer period, the sample should be frozen.

Samples with presence of fibrin should be centrifuged before testing.

TEST PROCEDURE

Wavelength: 578 (560 - 580) nm

Temperature: 37ºC

Cuvette light path: 1 cm

Prewarm the reagents to reaction temperature

	Calibrator (µL)	**Sample (µL)**
Ferritin Dilluent (R1)	600	600
Distilled Water	-	-
Calibrator	30	-
Sample	-	30
Incubate for 5 mins at 37ºC		
Ferritin Reagent R2	200	200
Mix & Read immediately against distilled water after 10s and 300s at 578nm.		

Mix well and read absorbance of calibrator and sample against distilled water at 578 nm as follows:

Initial absorbance A0 – Exactly after 10 sec.

Final absorbance A1 – Exactly after 300 sec. after A0 Determine Δ A for Calibrator(C) and Sample(S)

Δ AC = Δ AC1 - Δ AC0

Δ AS = Δ AS1 - Δ AS0

Calculations:

Ferritin concentration in the sample is calculated by interpolation of its (A2-A1) in the calibration curve such as spline, logit log or multipoint non linear graph.

CALIBRATION

Use TRUEchemie Ferritin Calibrator, which is ready to use.

Calibration curve: Generate a reference curve by successive 1:2 dilutions of calibrator high in saline. Use saline as zero point. Prepare serial dilution of given calibrator by referring the calibrator preparation table below:

Dilution	**1**	**2**	**3**	**4**	**5**	**6**
Calibrator (µl)	-	50	50	50	50	100
Saline(µl)	100	50	50	50	50	-
Factor	0	0.0625	0.125	0.25	0.50	1.00

Multiply each factor to the highest calibrator concentration to get the corresponding calibrator concentrations of each calibrator.

Re-calibrate when control results are out of specified tolerances, when using different lot of reagents and when the instrument is adjusted.

INTERFERENCES

Bilirubin (40 mg/dL), hemoglobin (5 g/L), y and rheumatoid factor (750 UI/mL), do not interfere. Lipids (≥ 2.5 g/L) do interfere. Other substances may interfere.[5]

SYSTEM PARAMETERS

Mode	:	Fixed kinetic
Calibrator concentration	:	Stated on vial
Wave length	:	578 nm(560-580nm)
Units	:	ng/mL
Flow cell Temp	:	37 °C
Blank	:	Distilled water Blank
Reagent volume	:	600 µL(R1) + 200 µL(R2)
Sample volume	:	30 µL
Delay time	:	10 sec.
Read time	:	300 sec.
Normal range	:	Men : 20 – 250 ng/mL ; Women : 20 – 200 ng/mL
Sensitivity	:	10 ng/mL
Linearity	:	up to 1500 ng/mL
Reaction slope	:	Increasing

QUALITY CONTROLS

Control Sera are recommended to monitor the performance of manual and automated assay procedures. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE RANGE

Male 20-250 ng/mL

Female 20-200 ng/mL

According to the distribution range of 95% of normal people. It is suggested that each laboratory verify this reference range or establish its own reference range.

AUTOMATED PROCEDURE

Appropriate Program sheet is available for different analyzers upon request.

PERFORMANCE CHARACTERISTIC

Linearity limit: Up to 1500 ng/mL, under the described assay conditions. If the concentration is greater than linearity (1500 ng/mL), dilute the sample with normal saline (1:5) and repeat the assay. Multiply the result with dilution factor.

The linearity limit depends on the sample / reagent ratio, as well as the analysers used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.

Prozone limit : No prozone effect was detected up to 9000 ng/mL.

Sensitivity/ Limit of detection (LOD):

The limit of detection is 1.2 ng/mL.

Sensitivity is 10 ng/mL.

Values less than 10 ng/mL may give non-reproducible results.

Precision: (%CV)

Intra-assay precision	**n**	**Mean (ng/mL)**	**SD**	**CV (%)**
Low	20	113.5	1.91	1.68
Medium	20	212.8	1.27	1.27
High	20	222.0	1.58	1.58

Inter-assay precision	**n**	**Mean (ng/mL)**	**SD**	**CV (%)**
Low	20	113.6	4.3	3.8
Medium	20	212.7	5.1	2.4
High	20	228.2	6.5	2.8

The reagent has been tested for 20 days, using three different Ferritin concentrations. The coefficient of variation was <5%

Control	**Assigned**	**Measured**
Randox Level 1	115.0	118.2
Randox Level 2	220.0	224.3
Randox Level 3	234.0	242.4

Results obtained using this reagent (y) were compared to those obtained using a commercial reagent (x) with similar characteristics. The correlation coefficient (r^2) was 0.99 and the regression equation is y=0.9958x + 1.3439

REFERENCES

1. Knovich MA et al., Blood Rev. 2009 23(3):95-104.
2. Mazza J et al. Can Med Assoc J 1978; 119: 884-886
3. Rodriguez Perez J et al. Revista Clinica Española 1980: 156 (1): 39-43
4. Milman N et al. Eur J Haematol 1994: 53: 16-20.
5. Young DS. Effects of drugs on clinical laboratory test, 5th ed. AACC Press, 1999.

Index of Symbols

Consult instructions for use	Catalogue number	Use-by date
For *in vitro* diagnostic use only	Batch code	Do not use if package is damaged
Temperature limit 2-8 °C	Keep away from sunlight	Keep dry
Manufacturer	Date of manufacture	
If device is non-sterile	Warnings / Precautions	

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