External quality assurance for reference measurement

Mindray participates RELA （External quality control for reference laboratory）and CAP （College of American Pathologists external quality control）

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Anemia Panel

Anemia occurs when you have less than the normal number of red blood cells in your blood or when the red blood cells in your blood don't have enough hemoglobin. Hemoglobin is a protein that gives the red color to your blood. Its main job is to carry oxygen from your lungs to all parts of your body. If you have anemia, your blood does not carry enough oxygen to all the parts of your body. Without oxygen, your organs and tissues cannot work as well as they should.

It is estimated that approximately 1.62 billion people in the world suffer from anemia. Anemia can cause fatigue, headaches, shortness of breath, dizziness, rapid heartbeat, and a number of other symptoms. There are hundreds of types of anemia, which is divided into three groups: excessive blood loss anemia， excessive red blood cell destruction (hemolysis) anemia and decreased or deficient red blood cell production anemia.

Mindray's anemia panel includes Iron (Fe), Ferritin (FER), Transferrin (TRF) and Unsaturated Iron Binding Capacity (UIBC). These parameters work together to indicate if you have a status of anemia.

Fe

Measurements of iron are used in the diagnosis and treatment of a number of conditions such as iron deficiency anemia, hemochromatosis and chronic liver disease.

Performance characters

Method: Colorimetric Assay

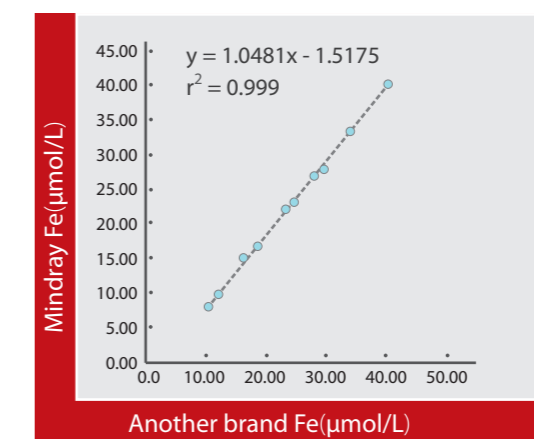Linearity range: 0.9~200 μmol/L

Sensitivity： minimal detectable level as 0.9 μmol/L

Anti-interfering ability： Bilirubin(up to 40 mg/dL),

Lipemia(up to 500 mg/dL), Hemoglobin(up to 50 mg/dL)

Traceability to manufacturer's selected measurement procedure

Method comparison

$$y = 1.0481x - 1.5175$$
$$r^2 = 0.999$$

Mindray Fe(μmol/L) vs Another brand Fe(μmol/L)

Packaging Specification

Description	Part.No.	Package R1	Package R2	Method
Fe*(C)	105-002198-00	2×40mL	1×16mL	Colorimetric Assay
	105-002199-00	4×40mL	2×16mL	
	105-002200-00	4×40mL	2×16mL	
Fe**(C and Q)	105-001583-00	2×40mL	1×16mL	Colorimetric Assay
	105-001584-00	4×40mL	2×16mL	
	105-001585-00	4×40mL	2×16mL	
FER	105-002244-00	1×12mL	1×7mL	Particle-enhanced Immunoturbidimetric Assay
	105-002245-00	1×20mL	1×12mL	
TRF	105-002246-00	1×32mL	1×5mL	Immunoturbidimetric Assay
	105-002247-00	1×45mL	1×7mL	
UIBC	105-002256-00	4×20mL	2×12mL	Colorimetric Method
	105-002257-00	4×54mL	4×16mL	

Anemia panel	Part.No.	Package Size	Intended items
FER Calibrator	105-002311-00	1×4 levels×2 mL	FER
Multimmun Control	105-002303-00	1×2 levels×3 mL	FER, MYO, IgE
TRF Calibrator	105-002317-00	1×5 levels×1 mL	TRF
TRF Control	105-002318-00	1×2 levels×1 mL	TRF
UIBC Calibrator	105-002306-00	1×1 level×1 mL	UIBC
UIBC Control	105-002307-00	1×1 level×5 mL	UIBC

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FER

Ferritin is the iron storage protein with a molecular weight of approximately 450KD.Ferritin is mainly detectable in liver, spleen and bone marrow and is also found in human serum with small amounts. Serum Ferritin concentration usually reflects body iron stores and is considered as one of the most reliable indicators of iron status of patients.

Whereas elevated concentration of Ferritin may occur due to cell destruction, liver disease, tumor cell production and chronic inflammation, low level Ferritin is always indicative of an iron deficiency. This assay can be used to differentiate hypochromic anemia (thalassemia or chronic infection and tumour anemia)

Performance characters

Method: Particle-enhanced Immunoturbidimetric Assay
Linearity range: 10~1000 ng/mL
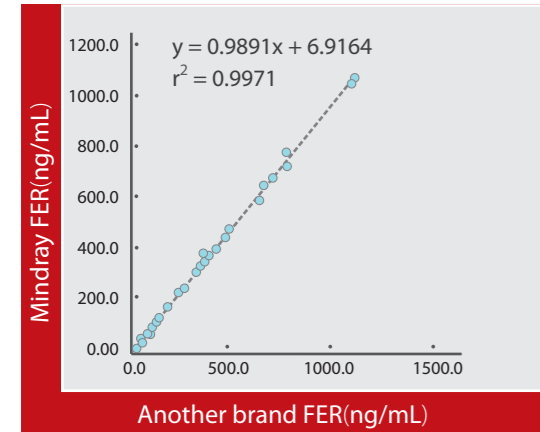Sensitivity： minimal detectable level as 10 ng/mL
Anti-interfering ability： Bilirubin(up to 40 mg/dL),
Lipemia(up to 150 mg/dL), Hemoglobin(up to 500 mg/dL）
Traceability to WHO Standard 94/572 reference material

Method comparison

$y = 0.9891x + 6.9164$
$r^2 = 0.9971$

X-axis: Another brand FER(ng/mL)
Y-axis: Mindray FER(ng/mL)

TRF

Transferrin is the iron transport protein in serum. It is synthesized in liver and transfers iron through serum to bone marrow to produce blood red cell. The degree of transferrin saturation becomes one of the most sensitive indicators of functional iron depletion if the iron is deficient.

TRF level is increased in the case of hypochromic anemia. However, if the anemia is due to a failure to incorporate iron into erythrocytes, the TRF concentration is normal or low but the protein is high saturated with iron. Besides, TRF quantity could also diagnose nephritic syndrome, chronic renal failure, severe burns, severe liver disease, inflammation and protein malnutrition.

Performance characters

Method: Immunoturbidimetric Assay
Linearity range: 0.5~4.5 g/L
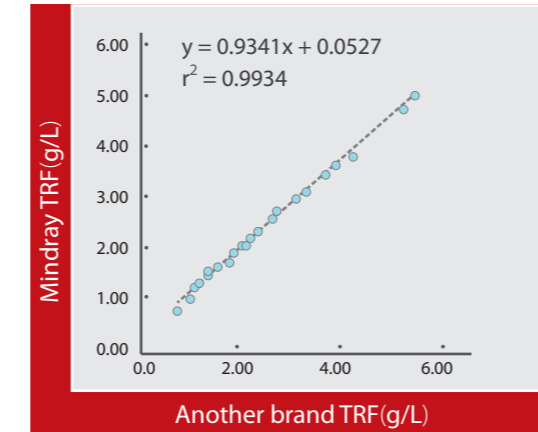Sensitivity： minimal detectable level as 0.5 g/L
Anti-interfering ability： Bilirubin(up to 20 mg/dL),
Lipemia(up to 500 mg/dL), Hemoglobin(up to 500 mg/dL)
Traceability to ERM-DA470k reference material

Method comparison

$y = 0.9341x + 0.0527$
$r^2 = 0.9934$

X-axis: Another brand TRF(g/L)
Y-axis: Mindray TRF(g/L)

UIBC

Transferrin is the plasma iron transport protein binding irons at physiological pH. The additional amount of iron that can be bound is the unsaturated iron binding capacity (UIBC). UIBC is usually determined directly by saturating the transferrin at an alkaline pH with a known but excess amount of iron. Whereas UIBC increases due to hypochromic anemia and erythrocytes over production, low level UIBC could diagnose nephritic syndrome, liver disease and chronic infection.

Performance characters

Method: Colorimetric Method
Linearity range: 3.0~100μmol/L
Sensitivity： minimal detectable level as 3.0 μmol/L
Anti-interfering ability： Bilirubin(up to 40 mg/dL),
Lipemia(up to 500 mg/dL), Hemoglobin(up to 400 mg/dL),
Ascorbic acid(up to 50 mg/dL）
Traceability to SRM937 reference material

Method comparison

$y = 1.0455x - 0.163$
$r^2 = 0.9978$

X-axis: Another brand UIBC(μmol/L)
Y-axis: Mindray UIBC(μmol/L)