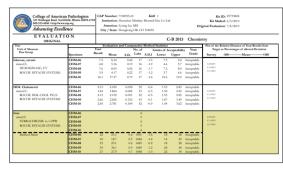
## External quality assurance for reference measurement

 ${\it Mindray\ participates\ RELA}\quad ({\it External\ quality\ control\ for\ reference\ laboratory})\ and\ {\it CAP}\ ({\it College\ of}$ 

American Pathologists external quality control)



College of America 325 Waskgan Road, Nerl 800-323-4940 • Isrpolwaw Advancing Excel	lence	1750 In	Number: 7 stitution: 5 ittention: 1 y / State: 1	henzhen 3 ising Liu i	Mindray MD		Elec Co Li	4	Ori		1D: 257338 illed: 6/3/20 tion: 7/8/20	13	
EVALUATION ORIGINAL			C-B 2013 Chemistry										
Test Link of Measure		Evaluation a Your				nd Comparative Method Statistics No. of Limits of Accentability Your					Plot of the Relative Distance of Your Results from Tarret as Processary of allowed Deviation		
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CO2 mmol/L ENZYMATIC ROGHE HITACH SYSTEMS Method Man Method Man Method Man Man Method Man Man Method Man Man Man Method Man Man Man Method Man Man Method Man Man Method Man Man Method Man Method Method Man Method Method Method Method Method Method Method Method	CHM-66 CHM-07 CHM-08 CHM-09 CHM-09 CHM-07 CHM-67 CHM-67 CHM-66 CHM-67 CHM-66 CHM-68	17 21 25 12 12 12 12 12 12 12 12 12 12 12 12 12	19.2 21.8 19.9 25.3 12.6 87.1 75.9 86.9	22 22 26	5 5 5 4624 4632 4614 4627 4640 31 30 90	-0.1 -0.4 +0.5 +0.3 -0.3 +1.4 +2.5 +2.0	12 15 13 17 6 78 67	29 27 34 19 % 84	Acceptable Acceptable Acceptable Acceptable Acceptable Acceptable Acceptable	CR381 CA383 CC382 CC382			
Gamma Glutamyt Trans U/L	CHM-08 CHM-09 CHM-30 CHM-06 CHM-07	93 194 70 77 40	86.9 193.3 62.7	3.0 9.7 2.5	30 31 30 2 2	+0.1 +2.9	164 55	223	Acceptable Acceptable [20] [20]	CC362			
ROCHE HITACHI SYSTEMS ROCHE GGT-IFOC/37 C	CHM-08 CHM-09 CHM-30	77 74 169			2 2 2 2				[20] [20] [20]				

College of American Pathologists 33 Wunkegm Rood, Northfield, Illinois 60093-2750 800-323-4040 • http://www.cap.org Advancing Excellence			CAP Number: 7198395-01 Ki# 1 Institution: Shenzhen Mindray Biomed Elec Co Ltd Attention: Lixing Lin MD City / State: Hongkong HK CH 518055						Kit ID: 25733824 Kit Mailed: 6/3/2013 Original Evaluation: 7/8/2013		
E V A L U A T I C ORIGINAL		C-B 2013 Chemistry									
Test Unit of Measure		Evaluation and Comparative Method Statistics Your No. of Limits of Acceptability							Plot of the Relative Distance of Your Results fror Target as Percentages of allowed Deviation		
Peer Group	Specimen	Result	Mean		No. of Labs	S.D.I	imits of A Lower	cceptabilit Upper	y Your Grade	Survey	-100Mean+100
ron Bind Unsat	CHM-06	6			2				[20]		
umol/L	CHM-07	9			2				[20]		
	CHM-08	7			2				[20]		
ROCHE HITACHI SYSTEMS	CHM-09	3			2				[20]		
	CHM-10	6			2				[20]		
Transferrin	CHM-06	1.37	1.360	0.040	173	+0.3	1.08	1.64	Acceptable		
g/L	CHM-07	1.23	1.228	0.035	174	+0.1	0.98	1.48	Acceptable	C-8 2013	
ROCHE HITACHI/COBAS c	CHM-08	1.37	1.359	0.041	175	+0.3	1.08	1.64	Acceptable	C-3 2013 C-C 2012	
	CHM-09	1.78	1.747	0.047	174	$\pm 0.7$	1.39	2.10	Acceptable	0.0.2/12	

Packaging Specification									
		Pack	age	Method					
Description	Part.No.	R1	R2						
	105-002198-00	2×40mL	1×16mL						
Fe*(C)	105-002199-00	4×40mL	2×16mL	Colorimetric Assay					
	105-002200-00	4×40mL	2×16mL						
Fe**(CandQ)	105-001583-00	2×40mL	1×16mL						
	105-001584-00	4×40mL	2×16mL	Colorimetric Assay					
	105-001585-00	4×40mL	2×16mL						
FER	105-002244-00	1×12mL	1×7mL	Particle-enhanced Immunoturbidimetric Assav					
	105-002245-00	1×20mL	1×12mL	Particle-enhanced initialiotarbidimetric Assay					
TRF	105-002246-00	1×32mL	1×5mL	Immunoturbidimetric Assay					
	105-002247-00	1×45mL	1×7mL	initianotarbiaintetric Assay					
UIBC	105-002256-00	4×20mL	2×12mL	Colorimetric Method					
UIDC	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

## **Anemia Panel**





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# mindray

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

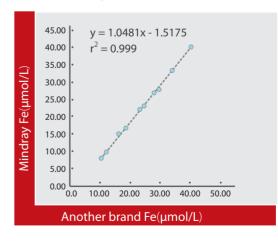
Measurements of iron are used in the diagnosis and treatment of a number of conditions such as iron deficiency anemia, hemochromatosis and chronic liver disease.

#### 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



## 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.

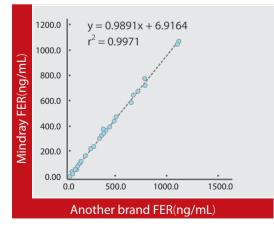
Whereas elevated concentration of Ferritin may occur due to cell destruction, liver disease, tumor cell production and chronic inflammation, low level Ferritin is always indicative of an iron deficiency. This assay can be used to differentiate hypochromic anemia (thalassemia or chronic infection and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



## TRF

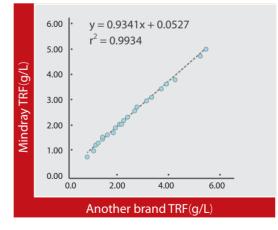
Transferrin is the iron transport protein in serum. It is synthesized in liver and transfers iron through serum to bone marrow to produce blood red cell. The degree of transferrin saturation becomes one of the most sensitive indicators of functional iron depletion if the iron is deficient.

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





### 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

