UIBC

cobas®

Unsaturated Iron-Binding Capacity

Order information

REF		CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
04536355190	04536355500	Unsaturated Iron-Binding Capacity (100 tests)	System-ID 07 3763 1	**cobas c** 311, **cobas c** 501/502, COBAS INTEGRA 400 plus

Materials required (but not provided):

		cobas c 311, **cobas c** 501/502	COBAS INTEGRA 400 plus
12146401216	Fe Standard (1 x 75 mL)	Code 566	System-ID 07 7560 6
12149435122	Precinorm U plus (10 x 3 mL)	Code 300	System-ID 07 7999 7
12149443122	Precipath U plus (10 x 3 mL)	Code 301	System-ID 07 8000 6
05117003190	PreciControl ClinChem Multi 1 (20 x 5 mL)	Code 391	System-ID 07 7469 3
05947626190	PreciControl ClinChem Multi 1 (4 x 5 mL)	Code 391	System-ID 07 7469 3
05117216190	PreciControl ClinChem Multi 2 (20 x 5 mL)	Code 392	System-ID 07 7470 7
05947774190	PreciControl ClinChem Multi 2 (4 x 5 mL)	Code 392	System-ID 07 7470 7

English

Intended use

In vitro test for the quantitative determination of the unsaturated iron-binding capacity in human serum and plasma on **cobas c** and COBAS INTEGRA systems.

Summary

Unsaturated iron-binding capacity (UIBC) measurements, performed with this assay in human serum and plasma, are used as an aid in diagnosis of iron deficiencies and iron overload. UIBC is used in combination with serum iron to determine the total iron-binding capacity (TIBC) and transferrin saturation (TSAT).

Anemia is the most common blood disorder, with iron deficiency anemia being the most common cause of anemia. Therefore, iron panels are routinely run in patients with anemia. Iron plays an essential role in many biochemical processes, in particular in the production of heme for incorporation in hemoglobin and iron-sulfur clusters. It serves as a cofactor for many proteins and enzymes necessary for oxygen and energy metabolism.[1,2]

The total iron content of the body is about 3 to 3.5 g, where the majority (> 95 %) is contained in hemoglobin of erythrocytes (or their precursors in the bone marrow), and also intracellular storages (e.g., ferritin).[1,3] Only a small amount (~3 mg) of Fe is bound to the circulating serum protein transferrin, a complex of ferric iron Fe(III) bound to the plasma protein apotransferrin.[1,3] Normally, about one third of the iron-binding sites of transferrin are occupied by Fe(III). The additional amount of iron that can be bound is the unsaturated (or latent) iron-binding capacity UIBC. The sum of the serum iron and UIBC represents total iron-binding capacity TIBC. TIBC is a measurement for the maximum iron concentration that transferrin can bind. It is used to calculate the transferrin saturation TSAT, which is the percentage of transferrin occupied by iron, and can be calculated by a ratio of serum iron and TIBC.[4]

The serum TIBC varies in disorders of iron metabolism. In iron-deficiency anemia the TIBC is elevated and the TSAT is lowered to 15 % or less.[1] Low serum iron associated with low TIBC is characteristic of the anemia of chronic disorders, malignant tumors, and infections.[5] UIBC and TIBC are also modified in various physiological and clinical conditions. During pregnancy, UIBC, TIBC and transferrin values increase, which is proposed as a mechanism to ensure adequate iron delivery to the fetus.[6,7] Increased UIBC and TIBC levels are observed in frequent blood donors,[8] after a multiday high-altitude climb,[9] iron chelation therapy,[10] exposure to polychlorinated biphenyls,[11] testosterone therapy,[12] and Fontan surgery (for cardiac malformations).[13] Reduced UIBC and TIBC levels are associated with chronic kidney disease,[14] increased mortality after liver transplantation,[15] increased bacterial infection risk after kidney transplantation,[16] and emetogenic severity in cancer chemotherapy.[17]

Test principle

Direct determination with FerroZine.[18,19]

$$\text{Fe(II) + transferrin} \xrightarrow{\text{Alkaline buffer}} \text{transferrin-Fe(III) + Fe(II) (excess)}$$

$$\text{Fe(II) (excess) + 3 FerroZine} \longrightarrow \text{Fe(II)-(FerroZine)}_3$$

The color intensity is directly proportional to the unbound excess iron concentration and indirectly proportional to the unsaturated iron binding capacity. It is determined by measuring the increase in absorbance photometrically.

Precautions and warnings

For in vitro diagnostic use for health care professionals. Exercise the normal precautions required for handling all laboratory reagents.

Infectious or microbial waste:
Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards:
Apply all relevant local disposal regulations to determine the safe disposal.

Safety data sheet available for professional user on request.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:

Warning

H317	May cause an allergic skin reaction.
H351	Suspected of causing cancer.

Prevention:

P201	Obtain special instructions before use.
P261	Avoid breathing mist or vapours.
P280	Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.

Response:

P308 + P313	IF exposed or concerned: Get medical advice/attention.
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.
P362 + P364	Take off contaminated clothing and wash it before reuse.

Product safety labeling follows EU GHS guidance.

Contact phone: all countries: +49-621-7590

Reagent handling

Ready for use

Note for cobas c: Put a new cassette direct from the refrigerator on the analyzer, do not allow cassette to come to room temperature.

UIBC

Unsaturated Iron-Binding Capacity

cobas®

Specimen collection and preparation

For specimen collection and preparation only use suitable tubes or collection containers.

Only the specimens listed below were tested and found acceptable.
Serum.
Plasma: Li-heparin plasma.

Li-heparin plasma values are approximately 6 % lower than serum values.

The binding of iron to transferrin is strongly influenced by anions, specifically bicarbonate.[20] In order to avoid drift of UIBC recovery in samples over time the environmental concentration of CO_2 in the laboratory should be kept as constant as possible.

Specimens should be collected in the morning to avoid low results due to diurnal variation.[21]

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.

Centrifuge samples containing precipitates before performing the assay.

See the limitations and interferences section for details about possible sample interferences.

Stability:[22,23] 4 days at 15-25 °C
7 days at 2-8 °C

Materials provided

See "Reagents – working solutions" section for reagents.

Materials required (but not provided)

- See "Order information" section
- General laboratory equipment

Assay

For optimum performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator's manual for analyzer-specific assay instructions.

The performance of applications not validated by Roche is not warranted and must be defined by the user.

Calculation

The systems automatically calculate the analyte concentration of each sample.

Conversion factors: µmol/L x 5.59 = µg/dL
µmol/L x 0.0559 = mg/L

Expected values[24]

Females: 24.2-70.1 µmol/L (135-392 µg/dL)

Males: 22.3-61.7 µmol/L (125-345 µg/dL)

Serum/plasma iron levels are dependent on diet and subject to circadian variation.

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

cobas c systems

System information

For **cobas c** 311/501 analyzers:

UIBCI: ACN 779

For **cobas c** 502 analyzer:

UIBCI: ACN 8779

Reagents - working solutions

R1 Ferrous chloride: 62 µmol/L; sodium hydrogen carbonate: 75 mmol/L; TRIS buffer: 375 mmol/L, pH 8.4; preservative

R3 FerroZine: 20 mmol/L; hydroxylamine: 160 mmol/L; pH 2.5

R1 is in position C and R3 is in position B.

Storage and stability

Shelf life at 2-8 °C:	See expiration date on **cobas c** pack label.
On-board in use and refrigerated on the analyzer:	8 weeks

Application for serum and plasma

cobas c 311 **test definition**

Assay type	2-Point End	
Reaction time / Assay points	10 / 23-57	
Wavelength (sub/main)	700 / 546 nm	
Reaction direction	Increase	
Units	µmol/L (µg/dL, mg/L)	
Reagent pipetting		Diluent (H_2O)
R1	55 µL	70 µL
R3	25 µL	20 µL

Sample volumes	*Sample*	*Sample dilution*	
		Sample	Diluent (H_2O)
Normal	20 µL	–	–
Decreased	20 µL	–	–
Increased	10 µL	–	–

cobas c 501/502 **test definition**

Assay type	2-Point End	
Reaction time / Assay points	10 / 34-70	
Wavelength (sub/main)	700 / 546 nm	
Reaction direction	Increase	
Units	µmol/L (µg/dL, mg/L)	
Reagent pipetting		Diluent (H_2O)
R1	55 µL	70 µL
R3	25 µL	20 µL

Sample volumes	*Sample*	*Sample dilution*	
		Sample	Diluent (H_2O)
Normal	20 µL	–	–
Decreased	20 µL	–	–
Increased	10 µL	–	–

Calibration

Calibrators	S1: H_2O S2: Iron Standard
Calibration mode	Linear
Calibration frequency	2-point calibration - after reagent lot change - as required following quality control procedures

Enter the correction value for the calibration with Iron Standard as instrument factor y = ax + b, where a = -1.0 and b = 0.

Calibration interval may be extended based on acceptable verification of calibration by the laboratory.

UIBC

Unsaturated Iron-Binding Capacity

Traceability: This method has been standardized against a primary reference material (weighed in purified material) through iron.

Quality control

For quality control, use control materials as listed in the "Order information" section.

In addition, other suitable control material can be used.

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

Follow the applicable government regulations and local guidelines for quality control.

Limitations - interference

Criterion: Recovery within ± 6 µmol/L of initial values of samples ≤ 60 µmol/L and within ± 10 % for samples > 60 µmol/L.

Icterus:[25] No significant interference up to an I index of 60 for conjugated and unconjugated bilirubin (approximate conjugated and unconjugated bilirubin concentration: 1026 µmol/L or 60 mg/dL).

Hemolysis:[25] No significant interference up to an H index of 40 (approximate hemoglobin concentration: 24.8 µmol/L or 40 mg/dL).

Contamination with erythrocytes will elevate results, because the analyte level in erythrocytes is higher than in normal sera. The level of interference may be variable depending on the content of analyte in the lysed erythrocytes.

Lipemia (Intralipid):[25] No significant interference up to an L index of 300. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.

Anticoagulants: Complexing anticoagulants such as EDTA, oxalate, and citrate must not be used.

Drugs: No interference was found at therapeutic concentrations using common drug panels.[26, 27]

Exception: Oxytetracycline causes artificially high UIBC values at the tested drug level.

Pathologically high levels of albumin (7 g/dL) decrease the apparent UIBC value significantly.

If the patient's serum iron exceeds the binding capacity of the transferrin, a negative UIBC value will result.

In patients treated with iron supplements or metal-binding drugs, the drug-bound iron may not properly react in the test, resulting in falsely low values.

The physiological function of deferoxamine containing drugs is to bind iron to facilitate its elimination from the body. Therefore any deferoxamine concentration interferes with the UIBC assay.

In the presence of high ferritin concentrations > 1200 µg/L the assumption that serum iron is almost completely bound to transferrin is not valid anymore. Therefore, such iron results should not be used to calculate Total Iron Binding Capacity (TIBC) or percent transferrin saturation (% SAT).[28]

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.[29]

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

ACTION REQUIRED

Special Wash Programming: The use of special wash steps is mandatory when certain test combinations are run together on **cobas c** systems. The latest version of the carry-over evasion list can be found with the NaOHD-SMS-SmpCln1+2-SCCS Method Sheets. For further instructions refer to the operator's manual. **cobas c** 502 analyzer: All special wash programming necessary for avoiding carry-over is available via the **cobas** link, manual input is required in certain cases.

Where required, special wash/carry-over evasion programming must be implemented prior to reporting results with this test.

Limits and ranges

Measuring range

3-125 µmol/L (16.8-700 µg/dL, 0.17-7 mg/L)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:2 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 2.

Lower limits of measurement

Lower detection limit of the test

3 µmol/L (16.8 µg/dL, 0.17 mg/L)

The lower detection limit represents the lowest measurable analyte level that can be distinguished from zero. It is calculated as the value lying 3 standard deviations above that of the lowest standard (standard 1 + 3 SD, repeatability, n = 21).

Note: The technical limits for this assay are defined as -125 µmol/L (-700 µg/dL, -7 mg/L) for the lower limit and -3 µmol/L (-16.8 µg/dL, -0.17 mg/L) for the upper limit. This is due to the instrument factor for UIBC (a = -1; see also above chapter "Calibration"). Results under the lower limit of the measuring range will be flagged with ">TEST". Results above the upper limit of the measuring range will be flagged with "<TEST".

Specific performance data

Representative performance data on the analyzers are given below. Results obtained in individual laboratories may differ.

Precision

Precision was determined using human samples and controls in an internal protocol with repeatability (n = 21) and intermediate precision (3 aliquots per run, 1 run per day, 21 days). The following results were obtained on the **cobas c** 501 analyzer:

Repeatability	*Mean*	*SD*	*CV*
	µmol/L (µg/dL)	*µmol/L (µg/dL)*	*%*
PCCC1	39.9 (223)	0.5 (3)	1.2
PCCC2	56.0 (313)	0.6 (3)	1.1
Human serum A	46.1 (258)	0.6 (3)	1.3
Human serum B	102 (570)	0.5 (3)	0.4
Human serum C	15.5 (86.6)	0.7 (3.9)	4.3

Intermediate precision	*Mean*	*SD*	*CV*
	µmol/L (µg/dL)	*µmol/L (µg/dL)*	*%*
Precinorm U	23.7 (132)	0.8 (5)	3.5
Precipath U	41.7 (233)	0.7 (4)	1.7
Human serum 3	16.5 (92.2)	0.8 (4.5)	4.7
Human serum 4	24.3 (136)	0.8 (5)	3.1

The data obtained on **cobas c** 501 analyzer(s) are representative for **cobas c** 311 analyzer(s).

Method comparison

Serum

UIBC values for human serum and plasma samples obtained on a **cobas c** 501 analyzer (y) were compared with those determined using the corresponding reagent on a Roche/Hitachi MODULAR P analyzer (x).

Sample size (n) = 58

Passing/Bablok[30]	Linear regression
y = 1.01x + 1.86 µmol/L	y = 1.03x + 1.23 µmol/L
τ = 0.956	r = 0.997

The sample concentrations were between 7.50 and 80.1 µmol/L (41.9 and 448 µg/dL).

The data obtained on **cobas c** 501 analyzer(s) are representative for **cobas c** 311 analyzer(s).

COBAS INTEGRA systems

System information

UIBCI: Test ID 0-564 on COBAS INTEGRA 400 plus systems

UIBC

Unsaturated Iron-Binding Capacity

cobas®

Reagents - working solutions

R1 Ferrous chloride: 62 µmol/L; sodium hydrogen carbonate: 75 mmol/L; TRIS buffer: 375 mmol/L, pH 8.4; preservative

SR FerroZine: 20 mmol/L; hydroxylamine: 160 mmol/L, pH 2.5

R1 is in position C and SR is in position B.

Storage and stability

Shelf life at 2-8 °C	See expiration date on **cobas c** pack label
On-board in use at 10-15 °C	2 weeks

Application for serum and plasma

Test definition

Measuring mode	Absorbance
Abs. calculation mode	Endpoint
Reaction mode	R1-S-SR
Reaction direction	Increase
Wavelength A/B	552/629 nm
Calc. first/last	33/64
Unit	µmol/L

Pipetting parameters

		Diluent (H_2O)
R1	80 µL	30 µL
Sample	30 µL	20 µL
SR	25 µL	15 µL
Total volume	200 µL	

Calibration

Calibrator	Standard 1 (high): deionized water (179 µmol/L or 1000 µg/dL)*
	Standard 2 (low): Fe Standard (89.5 µmol/L or 500 µg/dL)
Calibration mode	Linear regression
Calibration replicate	Duplicate recommended
Calibration frequency	- after reagent lot change - as required following quality control procedures

*For technical reasons a virtual concentration of 179 µmol/L (1000 µg/dL) is assigned to the deionized water which is used as standard 1. This concentration is substracted from the results for serum and plasma using a Lab. Correlation Offset of -179 (-1000).

The calibrators must be placed on th CAL/QC rack with standard 1 (high, deionized water) first and standard 2 (low, FE Standard) last.

Calibration interval may be extended based on acceptable verification of calibration by the laboratory.

Traceability: This method has been standardized against a primary reference material (weighed in purified material) through iron.

Quality control

Reference range	Precinorm U plus or PreciControl ClinChem Multi 1
Pathological range	Precipath U plus or PreciControl ClinChem Multi 2
Control interval	24 hours recommended
Control sequence	User defined
Control after calibration	Recommended

For quality control, use control materials as listed in the “Order information” section. In addition, other suitable control material can be used.

The control intervals and limits should be adapted to each laboratory’s individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

Follow the applicable government regulations and local guidelines for quality control.

Limitations - interference

If the patient’s serum iron exceeds the binding capacity of the transferrin, a negative UIBC value results.

Criterion: Recovery within ± 6 µmol/L of initial values of samples ≤ 60 µmol/L and within ± 10 % for samples > 60 µmol/L.

Icterus:[25] No significant interference up to an I index of 60 for conjugated and unconjugated bilirubin (approximate conjugated and unconjugated bilirubin concentration: 1026 µmol/L or 60 mg/dL).

Hemolysis:[25] No significant interference up to an H index of 100 (approximate hemoglobin concentration: 62.1 µmol/L or 100 mg/dL). Avoid hemolyzed specimens. Hemoglobin levels higher than 0.06 mmol/L (1.0 g/L) increase the apparent UIBC value significantly.

Lipemia (Intralipid):[25] No significant interference up to an L index of 200. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration. Lipemic specimens may cause negative values and/or high absorbance flagging.

Anticoagulants: Complexing anticoagulants such as EDTA, oxalate, and citrate must not be used.

Drugs: No interference was found at therapeutic concentrations using common drug panels.[26, 27] *Exceptions:* Methyldopa and oxytetracycline cause artificially high UIBC values at the tested drug level.
The physiological function of deferoxamine containing drugs is to bind iron to facilitate its elimination from the body. Therefore, any deferoxamine concentration interferes with the UIBC assay.

Pathologically high levels of albumin (7 g/dL) decrease the apparent UIBC value significantly.

In the presence of high ferritin concentrations > 1200 µg/L the assumption that serum iron is almost completely bound to transferrin is not valid anymore. Therefore, such iron results should not be used to calculate Total Iron Binding Capacity (TIBC) or percent transferrin saturation (% SAT).[28]

In very rare cases, gammopathy, in particular type IgM (Waldenström’s macroglobulinemia), may cause unreliable results.[29]

For diagnostic purposes, the results should always be assessed in conjunction with the patient’s medical history, clinical examination and other findings.

ACTION REQUIRED
Special Wash Programming: The use of special wash steps is mandatory when certain test combinations are run together on COBAS INTEGRA analyzers. Refer to the CLEAN Method Sheet for further instructions and for the latest version of the Extra wash cycle list.
Where required, special wash/carry-over evasion programming must be implemented prior to reporting results with this test.

Limits and ranges

Measuring range

6.0-125 µmol/L (33.5-700 µg/dL)

Lower limits of measurement

Lower detection limit of the test:
6.0 µmol/L (33.5 µg/dL)

The lower detection limit represents the lowest measurable analyte level that can be distinguished from zero. It is calculated as the value lying 3 standard deviations above that of a zero sample (zero sample + 3 SD, repeatability, n = 30).

Specific performance data

Representative performance data on the analyzers are given below. Results obtained in individual laboratories may differ.

Precision

Precision was determined using human samples and controls in an internal protocol with repeatability and intermediate precision (2 aliquots per run,

2 runs per day, 20 days). The following results were obtained on the COBAS INTEGRA 700 analyzer:

	Level 1	Level 2
Mean	25.0 µmol/L	43.4 µmol/L
	(140 µg/dL)	(242 µg/dL)
CV repeatability	1.6 %	0.8 %
CV intermediate precision	1.7 %	1.2 %

The data obtained on COBAS INTEGRA 700 analyzer(s) are representative for COBAS INTEGRA 400 analyzer(s).

Method comparison

UIBC values for human serum and plasma samples obtained on a COBAS INTEGRA 400 analyzer with the COBAS INTEGRA UIBC reagent (y) were compared with those determined using the same reagents on a COBAS INTEGRA 800 analyzer (x) and those determined using the corresponding reagent on a Roche/Hitachi MODULAR P analyzer (x).

COBAS INTEGRA 800 analyzer	n = 73
Passing/Bablok[30]	Linear regression
y = 0.981x - 0.349 µmol/L	y = 0.988x - 0.278 µmol/L
τ = 0.940	r = 0.998

The sample concentrations were between 9.71 and 121 µmol/L (54.3 and 676 µg/dL).

Roche/Hitachi MODULAR P analyzer	n = 69
Passing/Bablok[30]	Linear regression
y = 1.04x + 3.73 µmol/L	y = 1.057x + 2.98 µmol/L
τ = 0.929	r = 0.994

The sample concentrations were between 6.00 and 87.6 µmol/L (33.5 and 490 µg/dL).

References

1 Swinkels DW. Iron Metabolism. In: Rifai N, Chiu RWK, Young I, Burnham CAD, Wittwer CT, editors. Tietz Textbook of Laboratory Medicine, Saunders Elsevier, Philadelphia, 7th edition, 2023, chapter 40, p. 418-418.e40.

2 Pantopoulos K, Porwal SK, Tartakoff A, et al. Mechanisms of mammalian iron homeostasis. Biochemistry 2012 Jul 24;51(29):5705-5724.

3 Finch C. Regulators of iron balance in humans. Blood 1994 Sep 15;84(6):1697-1702.

4 Auerbach M, Adamson JW. How we diagnose and treat iron deficiency anemia. Am J Hematol 2016 Jan;91(1):31-38.

5 Madu AJ, Ughasoro MD. Anaemia of Chronic Disease: An In-Depth Review. Med Princ Pract 2017;26(1):1-9.

6 Amah-Tariah FS, Ojeka SO, Dapper DV. Haematological values in pregnant women in Port Harcourt, Nigeria II: Serum iron and transferrin, total and unsaturated iron binding capacity and some red cell and platelet indices. Niger J Physiol Sci 2011 Dec 20;26(2):173-178.

7 Raza N, Sarwar I, Munazza B, et al. Assessment of iron deficiency in pregnant women by determining iron status. J Ayub Med Coll Abbottabad 2011 Apr-Jun;23(2):36-40.

8 Boinska J, Zekanowska E, Kwapisz J. Pro-hepcidin and iron metabolism parameters in multi-time blood donors. Int J Lab Hematol 2010 Oct;32(5):483-490.

9 Kasprzak Z, Śliwicka E, Hennig K, et al. Vitamin D, Iron Metabolism, and Diet in Alpinists During a 2-Week High-Altitude Climb. High Alt Med Biol 2015 Sep;16(3):230-235.

10 Chen CH, Shu KH, Yang Y. Long-term effects of an oral iron chelator, deferasirox, in hemodialysis patients with iron overload. Hematology 2015;20(5):304-310.

11 Kimáková T, Nevolná Z, Vašková J, et al. Retrospective assessment of specific effects of exposure of workers to PCBs in Slovakia. Ann Agric Environ Med 2018 Sep 25;25(3):421-427.

12 Dhindsa S, Ghanim H, Batra M, et al. Effect of testosterone on hepcidin, ferroportin, ferritin and iron binding capacity in patients with hypogonadotropic hypogonadism and type 2 diabetes. Clin Endocrinol (Oxf) 2016 Nov;85(5):772-780.

13 Tomkiewicz-Pajak L, Plazak W, Kolcz J, et al. Iron deficiency and hematological changes in adult patients after Fontan operation. J Cardiol 2014 Nov;64(5):384-389.

14 Avci Çiçek E, Rota S, Dursun B, et al. Evaluation of serum NGAL and hepcidin levels in chronic kidney disease patients. Ren Fail 2016;38(1):35-39.

15 Chow JK, Werner BG, Ruthazer R, et al. Increased serum iron levels and infectious complications after liver transplantation. Clin Infect Dis 2010 Aug 1;51(3):e16-23.

16 Fernández-Ruiz M, López-Medrano F, Andrés A, et al. Serum iron parameters in the early post-transplant period and infection risk in kidney transplant recipients. Transpl Infect Dis 2013 Dec;15(6):600-611.

17 Miya T, Kondo H, Gemma A. Serum iron levels increased by cancer chemotherapy correlate the chemotherapy-induced nausea and vomiting. Int J Clin Oncol 2018 Dec;23(6):1196-1200.

18 Stookey LL. FerroZine - a new spectrophotometric reagent for iron. Anal Chem 1970;42:779-781.

19 Persijn JP, Van der Slik W, Riethorst A. Determination of serum iron and latent iron-binding capacity (LIBC). Clin Chim Acta 1971;35:91-98.

20 Harris WR. Thermodynamics of Anion Binding to Human Serum Transferrin. Biochemistry 1985;24:7412-7418.

21 Fairbanks VF, Klee GG. Biochemical aspects of hematology. In: Tietz NW, ed. Fundamentals of Clinical Chemistry. 3rd ed. Philadelphia: WB Saunders 1987:789-824.

22 Weissman N, Pileggi VJ. Inorganic ions. In: Henry RJ, Cannon DC, Winkelman W, eds. Clinical Chemistry, Principles and Techniques. 2nd ed. Hagerstown: Harper & Row 1974;4:639-754.

23 WHO Publication: Use of anticoagulants in diagnostic laboratory investigations, WHO/DIL/LAB/99.1 Rev.2:Jan 2002.

24 Löhr B, El-Samalouti V, Junge W, et al. Reference Range Study for Various Parameters on Roche Clinical Chemistry Analyzers. Clin Lab 2009;55:465-471.

25 Glick MR, Ryder KW, Jackson SA. Graphical Comparisons of Interferences in Clinical Chemistry Instrumentation. Clin Chem 1986;32:470-475.

26 Breuer J. Report on the Symposium “Drug effects in Clinical Chemistry Methods”. Eur J Clin Chem Clin Biochem 1996;34:385-386.

27 Sonntag O, Scholer A. Drug interference in clinical chemistry: recommendation of drugs and their concentrations to be used in drug interference studies. Ann Clin Biochem 2001;38:376-385.

28 Tietz NW, Rinker AD, Morrison SR. When Is a Serum Iron Really a Serum Iron? A Follow-up Study on the Status of Iron Measurements in Serum. Clin Chem 1996;42(1):109-111.

29 Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. Clin Chem Lab Med 2007;45(9):1240-1243.

30 Bablok W, Passing H, Bender R, et al. A general regression procedure for method transformation. Application of linear regression procedures for method comparison studies in clinical chemistry, Part III. J Clin Chem Clin Biochem 1988 Nov;26(11):783-790.

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

UIBC

Unsaturated Iron-Binding Capacity

cobas®

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard:

CONTENT	Contents of kit
	Volume for reconstitution
GTIN	Global Trade Item Number
Rx only	For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

CE 0123

Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim
www.roche.com
+800 5505 6606

Roche