

Tina-quant Transferrin ver.2

Order information

REF		CONTENT		Analyzer(s) on which cobas c pack(s) can be used
08058733190	08058733500	Tina-quant Transferrin ver.2 (500 tests)	System-ID 2115 001	cobas c 303, cobas c 503, cobas c 703

Materials required (but not provided):

11355279216	Calibrator f.a.s. Proteins (5 x 1 mL)	Code 20656	
05117003190	PreciControl ClinChem Multi 1 (20 x 5 mL)	Code 20391	
05947626190	PreciControl ClinChem Multi 1 (4 x 5 mL)	Code 20391	
05117216190	PreciControl ClinChem Multi 2 (20 x 5 mL)	Code 20392	
05947774190	PreciControl ClinChem Multi 2 (4 x 5 mL)	Code 20392	
08063494190	Diluent NaCl 9 % (123 mL)	System-ID 2906 001	

English

System information

TRSF2: ACN 21150

TRSF2U: ACN 21151

Intended use

In vitro test for the quantitative determination of transferrin in human serum, plasma and urine on **cobas c** systems.

Summary

Transferrin measurements, performed with this assay in human serum, plasma or urine, are used as an aid in the diagnosis of iron deficiency or iron overload. Transferrin measurements performed in urine are also used as an aid in the diagnosis of glomerular diseases.

Transferrin is a protein that plays a crucial role in transporting iron throughout the body. Its primary function is to bind and transport iron, facilitating its delivery to cells that require it for essential processes like oxygen transport and energy production.¹ It is a glycoprotein with a molecular weight of 79570 daltons.² It consists of a polypeptide strand with two N-glycosidically linked oligosaccharide chains and exists in numerous isoforms.^{3,4} Transferrin is synthesized in the liver and released into the bloodstream. The rate of synthesis in the liver can be altered in accordance with the body's iron requirements and iron reserves.^{3,5} Transferrin binds to iron in a reversible manner, allowing it to pick up iron from areas of high concentration such as the intestines (where iron is absorbed from the diet), and deliver it to cells that require iron for their metabolic processes. Excess iron that is not immediately needed for cellular processes is stored in the form of ferritin within cells, particularly in the liver, spleen, and bone marrow.⁶ This iron can be released from ferritin when needed to maintain iron homeostasis. 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).^{1,7} 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.⁸

In cases of iron deficiency (which can be the result of prior blood loss, altered iron uptake, or increased iron demand)⁹, cells produce more transferrin receptors on their surface to increase iron uptake.¹ The degree of transferrin saturation appears to be an extremely sensitive indicator of functional iron depletion.¹⁰ Iron deficiency anemia (when hemoglobin production is decreased because of iron deficiency) can be diagnosed by abnormally low serum ferritin levels, and increased transferrin levels.^{10,11,12} In conditions of iron overload (such as hereditary hemochromatosis), transferrin levels may be decreased as the body tries to limit iron absorption. Determination of TSAT is a central step for the diagnosis of hereditary hemochromatosis, either before or in parallel with the establishment of hyperferritinemia.^{13,14} Very high TSAT values (> 80 %) indicate a significant presence of highly toxic non-transferrin-bound serum iron.¹⁴ Apart from hereditary hemochromatosis, other causes of iron overload include alcoholic liver disease, nonalcoholic fatty liver disease,

and hepatitis C infection.¹⁵ Chronic liver diseases are also associated with iron overload and elevated TSAT, but the degree of TSAT elevation tends to be higher in alcoholic liver disease compared to nonalcoholic fatty liver disease and hepatitis C.^{15,16}

Transferrin excreted in urine indicates increased glomerular permeability to plasma proteins that are normally not freely filtered through the glomerulus. Transferrin has a similar small size as albumin (established protein marker to assess glomerular protein filtration), but because it is less anionic, it can pass through the glomeruli more easily than albumin. Hence, urinary transferrin can be used as a biomarker for detection of glomerular damage and renal abnormalities.^{17,18,19}

A variety of methods are available for determining transferrin including radial immunodiffusion, nephelometry and turbidimetry. The Roche transferrin assay is based on the immunological agglutination principle.²⁰

Test principle

Immunoturbidimetric assay.^{21,22,23}

Human transferrin forms a precipitate with a specific antiserum which is determined turbidimetrically.

Reagents - working solutions

R1 Phosphate buffer: 55 mmol/L, pH 7.2; NaCl: 25 mmol/L; polyethylene glycol: 5 %; preservative

R3 Anti-human transferrin antibodies (rabbit): dependent on titer; NaCl: 100 mmol/L; preservative

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

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.

Reagent handling

Ready for use

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: 26 weeks

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. Do not use EDTA or citrate plasma.

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.

Urine

Each urine sample must be centrifuged (10 minutes at approximately 3000 x g) prior to testing.²⁴ Random and timed urine collections are suitable specimens for testing transferrin in urine.

The pH of the urine should be adjusted to pH 7.0.²⁵

Stability in serum and Li-heparin plasma: ²⁶	8 days at 15-25 °C
	8 days at 2-8 °C
	6 months at -20 °C (± 5 °C)

Freeze only once.

Stability in urine:	4 days at 15-25 °C
	7 days at 2-8 °C
	Freezing and thawing is not allowed.

Centrifuge samples containing precipitates before performing the assay.

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

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.

Application for serum and plasma

Test definition

Reporting time	10 min
Wavelength (sub/main)	700/505 nm
Reagent pipetting	Diluent (H ₂ O)
R1	84 µL –
R3	18 µL –
Sample volumes	Sample Sample dilution
	Sample Diluent (NaCl)
Normal	7.5 µL 5.0 µL 100 µL
Decreased	7.5 µL 4.0 µL 122 µL
Increased	7.5 µL 5.0 µL 100 µL

For further information about the assay test definitions refer to the application parameters screen of the corresponding analyzer and assay.

Application for urine

Test definition

Reporting time	10 min
Wavelength (sub/main)	700/340 nm
Reagent pipetting	Diluent (H ₂ O)
R1	84 µL –
R3	18 µL –

Sample volumes	Sample	Sample dilution	
		Sample	Diluent (NaCl)
Normal	9 µL	-	-
Decreased	9 µL	25 µL	50 µL
Increased	9 µL	-	-

For further information about the assay test definitions refer to the application parameters setting screen of the corresponding analyzer and assay.

Calibration

Calibrators	S1: H ₂ O S2-S6: C.f.a.s. Proteins
Calibration mode	Non-linear
Calibration frequency	Automatic full calibration - after reagent lot change Full calibration - as required following quality control procedures

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

Traceability: This method has been standardized against the reference preparation of the IFCC (International Federation of Clinical Chemistry and Laboratory Medicine) ERM-DA470k/IFCC (RPPHS - Reference Preparation for Proteins in Human Serum).²⁷ ERM-DA470k/IFCC is a new batch of the originally certified reference material BCR470/CRM470.

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.

ACTION REQUIRED

Urine: Roche controls must be diluted 1:201 manually with 0.9 % NaCl solution (e.g. mix vigorously 2000 µL of NaCl solution with 10 µL of control material).

Calculation

cobas c systems automatically calculate the analyte concentration of each sample in the unit g/L or mg/L (µmol/L, mg/dL).

Conversion factors:	g/L x 12.6 = µmol/L
	g/L x 100 = mg/dL
	mg/L x 0.1 = mg/dL

Limitations - interference

Serum/plasma

Criterion: Recovery within ± 0.2 g/L of initial values of samples ≤ 2.0 g/L and within ± 10 % for samples > 2.0 g/L.

Icterus:²⁸ 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:²⁸ No significant interference up to an H index of 1000 (approximate hemoglobin concentration: 621 µmol/L or 1000 mg/dL).

Lipemia (Intralipid):²⁸ No significant interference up to an L index of 500. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.

Rheumatoid factors: No significant interference from rheumatoid factors up to a concentration of 1200 IU/mL.

Tina-quant Transferrin ver.2

High-dose hook effect: No false result occurs up to a transferrin concentration of 17 g/L.

Drugs: No interference was found at therapeutic concentrations using common drug panels.^{29,30}

Urine

Criterion: Recovery within ± 0.5 mg/L of initial values of samples ≤ 5.0 mg/L and within $\pm 10\%$ for samples > 5.0 mg/L

Hemolysis: No significant interference up to an H index of 20 (approximate hemoglobin concentration: 20 mg/dL).²⁸ Urine specimen, colored due to presence of erythrocytes or hemoglobin, should not be used.

No significant interference from h-albumin ≤ 5000 mg/L, calcium ≤ 8 mmol/L, citrate ≤ 10 mmol/L, creatinine ≤ 44 mmol/L, glucose ≤ 111 mmol/L, h-immunoglobulin G ≤ 500 mg/L, magnesium ≤ 75 mmol/L, oxalate ≤ 2.2 mmol/L, phosphate ≤ 40 mmol/L, urea ≤ 1000 mmol/L, uric acid ≤ 6 mmol/L and urobilinogen ≤ 15 mg/dL.

High-dose hook effect: No false result occurs up to a transferrin concentration of 650 mg/L (65 mg/dL).

Drugs: No interference was found at therapeutic concentrations using common drug panels. Exception: Ofloxacin causes artificially high transferrin results.³⁰

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.³¹

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. All special wash programming necessary for avoiding carry-over is available via the **cobas** link. The latest version of the carry-over evasion list can be found with the NaOHD/SMS/SCCS Method Sheet. For further instructions, refer to the operator's manual.

Limits and ranges

Measuring range

Serum/plasma

0.1-5.2 g/L (1.26-65.5 $\mu\text{mol/L}$)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:1.5 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 1.5.

Urine

2.2-35.0 mg/L (0.22-3.5 mg/dL)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:3 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 3.

Lower limits of measurement

Serum/plasma

Limit of Blank, Limit of Detection and Limit of Quantitation

Limit of Blank = 0.1 g/L (1.26 $\mu\text{mol/L}$)

Limit of Detection = 0.1 g/L (1.26 $\mu\text{mol/L}$)

Limit of Quantitation = 0.1 g/L (1.26 $\mu\text{mol/L}$)

Urine

Limit of Blank, Limit of Detection and Limit of Quantitation

Limit of Blank = 1.0 mg/L (0.10 mg/dL)

Limit of Detection = 1.5 mg/L (0.15 mg/dL)

Limit of Quantitation = 2.2 mg/L (0.22 mg/dL)

The Limit of Blank, Limit of Detection and Limit of Quantitation were determined in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP17-A2 requirements.

The Limit of Blank is the 95th percentile value from $n \geq 60$ measurements of analyte-free samples over several independent series. The Limit of Blank

corresponds to the concentration below which analyte-free samples are found with a probability of 95 %.

The Limit of Detection is determined based on the Limit of Blank and the standard deviation of low concentration samples.

The Limit of Detection corresponds to the lowest analyte concentration which can be detected (value above the Limit of Blank with a probability of 95 %).

The Limit of Quantitation is the lowest analyte concentration that can be reproducibly measured with a total error of 20 %. It has been determined using low concentration transferrin samples.

Expected values

Serum/plasma³²

2.0-3.6 g/L (25.2-45.4 $\mu\text{mol/L}$)*

* calculated by unit conversion factor

Urine

Normally, transferrin is not freely filtered through the glomerulus.¹⁷

≤ 1.9 mg/L* (0.19 mg/dL)**³³

* The concentration of transferrin in urine of healthy individuals is below the detection limit of this method.

**calculated by unit conversion factor

Because of daily variation in urine secretion, urinary concentrations are generally reported normalized such as mg/day, mg/g creatinine, mg/mmol creatinine, g per creatinine clearance.

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

Specific performance data

Representative performance data on the analyzers are given below. These data represent the performance of the analytical procedure itself.

Results obtained in individual laboratories may differ due to heterogenous sample materials, aging of analyzer components and mixture of reagents running on the analyzer.

Precision

Precision was determined using human samples and controls in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP05-A3 requirements with repeatability ($n = 84$) and intermediate precision (2 aliquots per run, 2 runs per day, 21 days). Results for repeatability and intermediate precision were obtained on the **cobas c** 503 analyzer.

Serum/plasma

Repeatability	Mean g/L	SD g/L	CV %
PCCC ^{1a)}	1.93	0.0118	0.6
PCCC ^{2b)}	3.09	0.0260	0.8
Human serum 1	0.255	0.00553	2.2
Human serum 2	1.84	0.0144	0.8
Human serum 3	2.46	0.0170	0.7
Human serum 4	3.19	0.0280	0.9
Human serum 5	4.10	0.0482	1.2

Intermediate precision	Mean g/L	SD g/L	CV %
PCCC ^{1a)}	1.93	0.0198	1.0
PCCC ^{2b)}	3.09	0.0313	1.0
Human serum 1	0.255	0.00925	3.6
Human serum 2	1.84	0.0210	1.1
Human serum 3	2.46	0.0188	0.8
Human serum 4	3.19	0.0299	0.9
Human serum 5	4.04	0.0546	1.3

Urine

Repeatability	Mean	SD	CV
	mg/L	mg/L	%
PCCC1 ^{a)}	10.5	0.198	1.9
PCCC2 ^{b)}	16.5	0.0945	0.6
Human urine 1	4.45	0.0879	2.0
Human urine 2	9.32	0.103	1.1
Human urine 3	16.7	0.110	0.7
Human urine 4	26.1	0.144	0.5
Human urine 5	31.6	0.221	0.7
Intermediate precision	Mean	SD	CV
	mg/L	mg/L	%
PCCC1 ^{a)}	10.5	0.229	2.2
PCCC2 ^{b)}	16.6	0.180	1.1
Human urine 1	4.41	0.156	3.5
Human urine 2	9.32	0.323	3.5
Human urine 3	16.7	0.185	1.1
Human urine 4	26.1	0.214	0.8
Human urine 5	31.6	0.301	1.0

a) PreciControl ClinChem Multi 1

b) PreciControl ClinChem Multi 2

The data obtained on **cobas c 503** analyzer(s) are representative for **cobas c 303** analyzer(s) and **cobas c 703** analyzer(s).

Method comparison

Serum/plasma

Transferrin values for human serum and plasma samples obtained on a **cobas c 503** analyzer (y) were compared with those determined using the corresponding reagent on a **cobas c 501** analyzer (x).

Sample size (n) = 65

Passing/Bablok ³⁴	Linear regression
$y = 1.000x + 0.0308 \text{ g/L}$	$y = 0.999x + 0.0352 \text{ g/L}$
$\tau = 0.981$	$r = 0.999$

The sample concentrations were between 0.120 and 5.08 g/L.

Transferrin values for human serum and plasma samples obtained on a **cobas c 303** analyzer (y) were compared with those determined using the corresponding reagent on a **cobas c 501** analyzer (x).

Sample size (n) = 73

Passing/Bablok ³⁴	Linear regression
$y = 0.987x + 0.0657 \text{ g/L}$	$y = 0.963x + 0.109 \text{ g/L}$
$\tau = 0.963$	$r = 0.997$

The sample concentrations were between 0.130 and 5.09 g/L.

Transferrin values for human serum and plasma samples obtained on a **cobas c 703** analyzer (y) were compared with those determined using the corresponding reagent on a **cobas c 503** analyzer (x).

Sample size (n) = 74

Passing/Bablok ³⁴	Linear regression
$y = 1.010x - 0.0466 \text{ g/L}$	$y = 1.011x - 0.0418 \text{ g/L}$
$\tau = 0.947$	$r = 0.999$

The sample concentrations were between 0.175 and 4.87 g/L.

Urine

Transferrin values for human urine samples obtained on a **cobas c 503** analyzer (y) were compared with those determined using the corresponding reagent on a **cobas c 501** analyzer (x).

Sample size (n) = 74

Passing/Bablok ³⁴	Linear regression
$y = 1.028x - 0.170 \text{ mg/L}$	$y = 1.020x - 0.144 \text{ mg/L}$
$\tau = 0.965$	$r = 0.998$

The sample concentrations were between 2.20 and 33.1 mg/L.

Transferrin values for human urine samples obtained on a **cobas c 303** analyzer (y) were compared with those determined using the corresponding reagent on a **cobas c 501** analyzer (x).

Sample size (n) = 60

Passing/Bablok ³⁴	Linear regression
$y = 1.065x - 0.0249 \text{ mg/L}$	$y = 1.054x + 0.190 \text{ mg/L}$
$\tau = 0.942$	$r = 0.996$

The sample concentrations were between 2.73 and 32.8 mg/L.

Transferrin values for human urine samples obtained on a **cobas c 703** analyzer (y) were compared with those determined using the corresponding reagent on a **cobas c 503** analyzer (x).

Sample size (n) = 62

Passing/Bablok ³⁴	Linear regression
$y = 0.987x - 0.0967 \text{ mg/L}$	$y = 0.992x - 0.167 \text{ mg/L}$
$\tau = 0.976$	$r = 0.999$

The sample concentrations were between 2.30 and 34.1 mg/L.

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.

References

- 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.
- de Jong G, van Dijk JP, van Eijk HG. The biology of transferrin. Clin Chim Acta 1990 Sep;190(1-2):1-46.
- Wick M, Pinggera W, Lehmann P, eds. Clinical Aspects and Laboratory. Iron Metabolism, Anemias: Concepts in the anemias of malignancies and renal and rheumatoid diseases. 6th ed. Vienna/New York: Springer-Verlag 2011;4-34,140.
- Prinsen BH, de Sain-van der Velden MG, Kaysen GA, et al. Transferrin synthesis is increased in nephrotic patients insufficiently to replace urinary losses. J Am Soc Nephrol 2001 May;12(5):1017-1025.
- Gkouvatsos K, Papanikolaou G, Pantopoulos K. Regulation of iron transport and the role of transferrin. Biochim Biophys Acta 2012 Mar;1820(3):188-202.
- Torti FM, Torti SV. Regulation of ferritin genes and protein. Blood 2002 May 15;99(10):3505-3516.
- Finch C. Regulators of iron balance in humans. Blood 1994 Sep 15;84(6):1697-1702.
- Auerbach M, Adamson JW. How we diagnose and treat iron deficiency anemia. Am J Hematol 2016 Jan;91(1):31-38.
- Muñoz M, García-Erce JA, Remacha ÁF. Disorders of iron metabolism. Part II: iron deficiency and iron overload. J Clin Pathol 2011 Apr;64(4):287-296.
- Camaschella C. Iron deficiency: new insights into diagnosis and treatment. Hematology Am Soc Hematol Educ Program 2015;2015:8-13.
- Nielsen OH, Soendergaard C, Vikner ME, et al. Rational Management of Iron-Deficiency Anaemia in Inflammatory Bowel Disease. Nutrients 2018 Jan 13;10(1):82.

- 12 Cohen-Solal A, Leclercq C, Deray G, et al. Iron deficiency: an emerging therapeutic target in heart failure. *Heart* 2014 Sep 15;100(18):1414-1420.
- 13 Adams PC. Epidemiology and diagnostic testing for hemochromatosis and iron overload. *Int J Lab Hematol* 2015 May;37 Suppl 1:25-30.
- 14 Kawabata H. The mechanisms of systemic iron homeostasis and etiology, diagnosis, and treatment of hereditary hemochromatosis. *Int J Hematol* 2018 Jan;107(1):31-43.
- 15 Milic S, Mikolasevic I, Orlic L, et al. The Role of Iron and Iron Overload in Chronic Liver Disease. *Med Sci Monit* 2016 Jun 22;22:2144-2151.
- 16 Hino K, Nishina S, Hara Y. Iron metabolic disorder in chronic hepatitis C: mechanisms and relevance to hepatocarcinogenesis. *J Gastroenterol Hepatol* 2013 Dec;28 Suppl 4:93-98.
- 17 Matheson A, Wilcox MD, Flanagan J, et al. Urinary biomarkers involved in type 2 diabetes: a review. *Diabetes Metab Res Rev* 2010 Mar;26(3):150-171.
- 18 Greenan-Barrett J, Doolan G, Shah D, et al. Biomarkers Associated with Organ-Specific Involvement in Juvenile Systemic Lupus Erythematosus. *Int J Mol Sci* 2021 Jul 16;22(14):7619.
- 19 Bastard JP, Fellahi S, Regeniter A, et al. Aside from acute renal failure cases, are urinary markers of glomerular and tubular function useful in clinical practice? *Clin Biochem* 2019 Mar;65:1-6.
- 20 Gottschalk R, Wigand R, Dietrich CF, et al. Total iron-binding capacity and serum transferrin determination under the influence of several clinical conditions. *Clin Chim Acta* 2000 Mar;293(1-2):127-138.
- 21 Lizana J, Hellsing K. Manual immunonephelometric assay of proteins, with use of polymer enhancement. *Clin Chem* 1974;20:1181-1186.
- 22 Tietz NW. *Fundamentals of Clinical Chemistry*, 2nd ed. Philadelphia, PA:WB Saunders Co 1976;278-280.
- 23 Burtis CA, Ashwood ER, Bruns DE, eds. *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics*, 4th ed. Philadelphia, PA: WB Saunders 2006;219-243.
- 24 European Confederation of Laboratory Medicine (ECLM). *European Urinalysis Guidelines*. *Scand J Clin Lab Invest* 2000;60:1-96.
- 25 Tietz NW, ed. *Clinical Guide to Laboratory Tests*, 4th ed. Philadelphia: WB Saunders Co 2006;1062.
- 26 Guder WG, Narayanan S, Wisser H, et al. List of Analytes; Preanalytical Variables. Brochure in: *Samples: From the Patient to the Laboratory*. Darmstadt: GIT-Verlag 1996.
- 27 Zegers I, Keller T, Schreiber W, et al. Characterization of a New Serum Protein Reference Material ERM-DA470k/IFCC: Value Assignment by Immunoassay. *Clin Chem* 2010;56(12):1880-1888.
- 28 Glick MR, Ryder KW, Jackson SA. Graphical Comparisons of Interferences in Clinical Chemistry Instrumentation. *Clin Chem* 1986;32:470-475.
- 29 Breuer J. Report on the Symposium "Drug effects in Clinical Chemistry Methods". *Eur J Clin Chem Clin Biochem* 1996;34:385-386.
- 30 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.
- 31 Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. *Clin Chem Lab Med* 2007;45(9):1240-1243.
- 32 Dati F, Schumann G, Thomas L, et al. Consensus of a group of professional societies and diagnostic companies on guidelines for interim reference ranges for 14 proteins in serum based on the standardization against the IFCC/BCR/CAP reference material (CRM 470). *Eur J Clin Chem Clin Biochem* 1996;34:517-520.
- 33 Rifai N, Gubar K, Silverman LM. Immunoturbidimetry: An Attractive Technique for the Determination of Urinary Albumin and Transferrin. *Clin Biochem* 1987;20:179-181.
- 34 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.

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.

COBAS, NAVIFY, PRECICONTROL and TINA-QUANT are trademarks of Roche. All other product names and trademarks are the property of their respective owners. Additions, deletions or changes are indicated by a change bar in the margin.

© 2024, Roche Diagnostics

CE 0123



Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim
www.roche.com

+800 5505 6606

