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SI2

cobas®

Serum Index Gen.2

Order information

REF	CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
04489365 190	Serum Index Gen. 2, 2750 tests	System-ID 07 6870 7	Roche/Hitachi **cobas c** 311, **cobas c** 501/502

English

System information

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

SI2: ACN 750

S-SI2: ACN 752 (STAT, reaction time: 3)

For **cobas c** 502 analyzer:

SI2: ACN 8750

S-SI2: ACN 8752 (STAT, reaction time: 3)

L: ACN 992 (lipemia index)

H: ACN 993 (hemolysis index)

I: ACN 994 (icterus index)

Intended use

In vitro test for the semi-quantitative determination of the lipemia index, hemolysis index and icterus index in human serum and plasma on **cobas c** systems.

Summary[1]

Medical laboratory tests can be affected by endogenous and exogenous constituents in the sample matrix. Some of these potentially interfering factors can be recognized in the pre-analytical phase by a coloured appearance of the sample, whereas others are detected only by receiving additional information and/or by direct analysis. Interference due to lipemia (turbidity), hemolysis and icterus (bilirubin) is difficult to predict because of their strong method-dependence. The limits at which the analysis can be made are described for each method subject to that interference. The European directive for in vitro diagnostics (IVDD) states that providers of reagents must define the appropriate limitations. Each report on laboratory findings should contain a notation characterising the sample's "appearance". If lipemia or a relevant colour is found, the type of finding is characterised in each case, e.g. "lipemic", "hemolytic" or "icteric". A quantification of these interferants is possible with the Serum Index Gen.2 (SI2) application which can be applied on all Roche/Hitachi **cobas c** systems. All analyzers are capable of semi-quantitative measurement and reporting of the lipemia index (L), hemolysis index (H) and icterus index (I).

Serum indices results are very useful for monitoring the degree of potential interference due to lipemia (turbidity), hemolysis and icterus (bilirubin).

Lipemia

Lipemia is defined as turbidity in serum and plasma samples which is visible to the naked eye. The most frequent cause of lipemia is an elevated triglyceride concentration in plasma and serum. This can be caused by food intake, a disturbance of lipoprotein metabolism or an infusion of lipids.

Hemolysis

Hemolysis is defined as the release of intracellular components of erythrocytes and other blood cells into the extracellular space of blood. It can appear in vivo (e.g. due to a transfusion reaction or during malaria parasite infection) as well as in vitro in all components of the pre-analytical phase (sampling, sample transport and storage). After the separation of blood cells, hemolysis is detected in serum and plasma by its red colour caused by hemoglobin.

Icterus

Icterus is defined as an elevated level of different bilirubin species (conjugated and unconjugated) in serum and plasma. Increased levels of bilirubin can be caused by diseases or conditions which, through hemolytic processes, produce bilirubin faster than the liver can metabolize it. Liver immaturity and several other diseases in which the bilirubin conjugation mechanism is impaired cause similar elevations of circulating unconjugated bilirubin. Bile duct obstruction or damage to hepatocellular structure causes increases in the levels of both conjugated (direct) and unconjugated (indirect) bilirubin in the circulation.

IMPORTANT NOTE

The Serum Index Gen.2 test should not be used for the quantitative determination of triglycerides, hemoglobin or bilirubin.

Test principle

The Serum Index Gen.2 assay is based on calculations of absorbance measurements of diluted samples at different bichromatic wavelength pairs to provide a semi-quantitative representation of levels of lipemia, hemolysis and icterus present in serum and plasma samples.

The analyzers take an aliquot of the patient specimen and dilute it in saline solution (0.9 % sodium chloride) to measure the absorbances for lipemia at 660 nm (primary wavelength) and 700 nm (secondary wavelength), for hemolysis at 570 nm (primary wavelength) and 600 nm (secondary wavelength), and for icterus at 480 nm (primary wavelength) and 505 nm (secondary wavelength). From these absorbance values the instrument calculates serum index values using the following factors:

A = 25 (conventional units) or 40 (international units)

B = 122000 (conventional or international units)

C = 10 (conventional or international units)

D = 1600 (conventional units) or 94 (international units)

E = 19000 (conventional or international units)

F = 180000 (conventional or international units)

C, A, and D are sample dilution-dependent and unit-dependent scaling factors to provide semi-quantitative interference levels. B, E and F are correcting factors which correct overlapping interference spectra. They are independent of sample dilution since they are based on ratios of absorbances. Serum indices can be programmed in either conventional or international units. Make sure that the correct scaling factors are set for the units you chose. Refer to the operator manual for instructions on how to program these factors.

Reagents - working solutions

R1 Sodium chloride 9 %

Precautions and warnings

For in vitro diagnostic use.
Exercise the normal precautions required for handling all laboratory reagents.
Disposal of all waste material should be in accordance with local guidelines.
Safety data sheet available for professional user on request.

Reagent handling

Ready for use

Storage and stability

SI2

Shelf life at 2-8 °C:	See expiration date on **cobas c** pack label.
On-board in use and refrigerated on the analyzer:	12 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, K_2-EDTA, K_3-EDTA, citrated plasma, NaF/Na-heparin plasma and NaF/K-oxalate 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.

Centrifuge samples containing precipitates before performing the assay.

Note: Measure the Serum Index Gen.2 in parallel to the respective parameters.

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Serum Index Gen.2

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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.

Applications for serum and plasma

cobas c 311 **test definition**

Assay type	1 Point		
Reaction time/Assay points	10 / 5 (STAT: 3 / 5)		
Wavelength (sub/main)	700/340 nm		
Reaction direction	Increase		
Units	mAbs		
Reagent pipetting		Diluent (H_2O)	
R1	15 µL	135 µL	
Sample volumes	*Sample*	*Sample dilution*	
		Sample	Diluent (H_2O)
Normal	6.0 µL	-	-
Decreased	6.0 µL	-	-
Increased	6.0 µL	-	-

cobas c 501/502 **test definition**

Assay type	1 Point		
Reaction time/Assay points	10 / 5 (STAT: 3 / 5)		
Wavelength (sub/main)	700/340 nm		
Reaction direction	Increase		
Units	mAbs		
Reagent pipetting		Diluent (H_2O)	
R1	15 µL	135 µL	
Sample volumes	*Sample*	*Sample dilution*	
		Sample	Diluent (H_2O)
Normal	6.0 µL	-	-
Decreased	6.0 µL	-	-
Increased	6.0 µL	-	-

Calibration

Calibrator	H_2O
Calibration mode	Linear
Calibration frequency	Blank calibration • after reagent lot change

Calculation

Roche/Hitachi **cobas c** systems automatically calculate the serum index values of each sample.

The displayed and printed serum index values have no unit.

With the use of the scaling factors for conventional units, the displayed and printed out values for H and I correspond to an approximate concentration of hemoglobin and bilirubin in mg/dL.

There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.

With the use of the scaling factors for international units, the displayed and printed out values for H and I correspond to an approximate concentration of hemoglobin and bilirubin in µmol/L.

IMPORTANT NOTE

Limits for H, I and L index implemented are based on scaling factors for conventional units in all application settings for **cobas c** systems. When using scaling factors in international units for H and I index the respective serum index limits have to be changed in all applications.

Please refer to the operator manual for information on how to change application parameters.

Use the following factor to recalculate limits for H and I, no recalculation for L limit is required.

H: Limit H (international units) = Limit H (conventional units) x 0.621

I: Limit I (international units) = Limit I (conventional units) x 17.1

Measuring range

(based on scaling factors for conventional units)

Serum/Plasma	
L-index	10-2000
H-index	5-1200
I-index	0.5-60

Lower detection limit	
L-index	10
H-index	5
I-index	0.5

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

Specific performance data

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

All results were obtained by using scaling factors for conventional units.

Precision

Precision was determined using human samples and controls in an internal protocol (repeatability n = 21). The following results were obtained:

L index

	Mean	SD	CV %
Human serum 1	708	5	0.6
Human serum 2	1478	16	1.1

H index

	Mean	SD	CV %
Human serum 1	118	1	0.8
Human serum 2	680	2	0.3

I index

	Mean	SD	CV %
Human serum 1	8.0	0.0	0.0
Human serum 2	37.0	0.0	0.0

Method comparison

Serum index values for human serum/plasma samples obtained on a Roche/Hitachi **cobas c** 501 analyzer (y) were compared with those determined using the serum index on a Roche/Hitachi 917 analyzer (x).

L index	Sample size (n) = 165
Passing/Bablok[2]	Linear regression
y = 0.971x – 2.16	y = 0.980x – 5.59

τ = 0.835	r = 0.999

Values ranged from 10.0 to 1936.

H index	Sample size (n) = 153
Passing/Bablok[2]	Linear regression
y = 1.048x – 0.399	y = 1.040x + 3.21
τ = 0.580	r = 0.999

Values ranged from 5.00 to 857.

I index	Sample size (n) = 101
Passing/Bablok[2]	Linear regression
y = 1.043x – 0.043	y = 1.046x – 0.052
τ = 0.994	r = 1.000

Values ranged from 1.00 to 55.0.

References

1 Guder WG, da Fonseca-Wolheim F, Heil W, et al. The Haemolytic, Icteric and Lipemic Sample Recommendations Regarding their Recognition and Prevention of Clinically Relevant Interferences. J Lab Med 2000;24:357-364.

2 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.

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 after reconstitution or mixing
GTIN	Global Trade Item Number

CE

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