SI2

cobas®

Sample Index Gen.2

Order information

REF	CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
08063516190	Sample Index Gen.2 (14500 tests)	System-ID 2911 001	**cobas c** 303, **cobas c** 503, **cobas c** 703

English

System information

SI2: ACN 29110 (Serum/plasma)

SI2-B: ACN 29111 (Serum/plasma)

SI2C: ACN 29120 (CSF)

SI2C-B: ACN 29121 (CSF)

SI2U: ACN 29130 (Urine)

SI2U-B: ACN 29131 (Urine)

Intended use

In vitro test for the semi-quantitative determination of the lipemia index, hemolysis index and icterus index in human serum, plasma, urine and CSF 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 Sample Index Gen.2 (SI2) application which can be applied on all **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).

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

Test principle

The Sample 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 human 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 sample index values using the following factors:

c 303	**c 503**	**c 703**
A = 0.000265	A = 0.00025	A = 0.000258
B = 1.22	B = 1.22	B = 1.22
C = 0.00009	C = 0.00009	C = 0.000086
D = 0.0155	D = 0.0155	D = 0.0148
E = 0.19	E = 0.19	E = 0.19
F = 1.8	F = 1.8	F = 1.8

C, A, and D are sample dilution-dependent 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. Sample Index calibration factors are provided by download only.

Reagents - working solutions

R1 Sodium chloride 9 %

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, K_2-EDTA, K_3-EDTA, citrated plasma, NaF/Na-heparin plasma and NaF/K-oxalate plasma
Cerebrospinal fluid
Urine

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 Sample Index Gen.2 in parallel to the respective parameters.

SI2

Sample 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, plasma, urine and CSF

Test definition

Reporting time	3 min	
Wavelength (sub/main)	700/660 nm	
Reagent pipetting		Diluent (H_2O)
R1	8 µL	68 µL

Sample volumes	*Sample*	*Sample dilution*	
		Sample	Diluent (H_2O)
Normal	3.0 µL	-	-
Decreased	3.0 µL	-	-
Increased	3.0 µL	-	-

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

Calibration

Application for serum/plasma (ACN 29110)

Calibrator	H_2O
Calibration mode	Linear Slope
Calibration frequency	Full calibration - after reagent lot change

Application for urine (ACN 29130)

Transfer of calibration from serum/plasma application (ACN 29110)

Application for CSF (ACN 29120)

Transfer of calibration from serum/plasma application (ACN 29110)

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

Calculation

cobas c systems automatically calculate the sample index values of each sample.

The displayed and printed sample index values have no unit.

Limits and ranges

Measuring range

Serum/plasma	
L-index	10-2000
H-index	5-1000
I-index	0.5-60
Urine	
H-index	5-750
CSF	
H-index	5-1000
I-index	0.5-60

Lower limits of measurement

Serum/plasma	
L-index	10
H-index	5
I-index	0.5
Urine	
H-index	5
CSF	
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 3 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. 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 in an internal protocol (repeatability n = 21). Results for repeatability and intermediate precision were obtained on the **cobas c** 503 analyzer.

Serum/plasma

L index

	Mean	SD	CV %
Human serum 1	12.9	1.26	9.8
Human serum 2	494	2.28	0.5
Human serum 3	999	3.82	0.4
Human serum 4	1522	6.23	0.4
Human serum 5	1933	9.07	0.5

H index

	Mean	SD	CV %
Human serum 1	6.33	1.06	16.8
Human serum 2	250	3.01	1.2
Human serum 3	494	1.72	0.3
Human serum 4	765	2.77	0.4
Human serum 5	947	2.95	0.3

I index

	Mean	SD	CV %
Human serum 1	1.52	0.512	33.6
Human serum 2	18.9	0.359	1.9
Human serum 3	27.7	0.483	1.7
Human serum 4	35.9	0.359	1.0
Human serum 5	56.1	0.359	0.6

Urine

H index

	Mean	SD	CV %
Human urine 1	6.62	0.921	13.9
Human urine 2	157	1.43	0.9

Human urine 3	323	1.74	0.5
Human urine 4	489	1.80	0.4
Human urine 5	691	1.97	0.3

CSF

H index

	Mean	SD	CV %
Human CSF 1	7.19	0.814	11.3
Human CSF 2	252	3.96	1.6
Human CSF 3	517	2.13	0.4
Human CSF 4	759	2.15	0.3
Human CSF 5	981	2.76	0.3

I index

	Mean	SD	CV %
Human CSF 1	3.00	0	0.0
Human CSF 2	22.5	0.512	2.3
Human CSF 3	32.2	0.402	1.2
Human CSF 4	42.7	0.483	1.1
Human CSF 5	56	0	0.0

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

Sample index 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).

L index

Sample size (n) = 107

Passing/Bablok[2]	Linear regression
y = 1.065x - 0.206	y = 1.058x + 0.590
τ = 0.989	r = 1.000

Values ranged from 20 to 1870.

H index

Sample size (n) = 132

Passing/Bablok[2]	Linear regression
y = 1.002x - 1.15	y = 1.003x - 1.79
τ = 0.995	r = 1.000

Values ranged from 16 to 967.

I index

Sample size (n) = 113

Passing/Bablok[2]	Linear regression
y = 1.000x + 0	y = 0.968x + 0.0275
τ = 0.995	r = 1.000

Values ranged from 1 to 57.

Sample index 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** 503 analyzer (x).

L index

Sample size (n) = 80

Passing/Bablok[2]	Linear regression
y = 0.994x + 2.44	y = 0.986x + 2.56
τ = 0.987	r = 1.000

Values ranged from 13 to 1882.

H index

Sample size (n) = 96

Passing/Bablok[2]	Linear regression
y = 1.008x - 1.78	y = 1.008x - 1.92
τ = 0.993	r = 1.000

Values ranged from 6 to 962.

I index

Sample size (n) = 77

Passing/Bablok[2]	Linear regression
y = 1.000x + 0	y = 0.992x + 0.0664
τ = 0.995	r = 1.000

Values ranged from 1 to 60.

Sample index 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).

L index

Sample size (n) = 86

Passing/Bablok[2]	Linear regression
y = 1.016x - 4.79	y = 1.015x - 4.31
τ = 0.988	r = 1.000

Values ranged from 19 to 1897.

H index

Sample size (n) = 64

Passing/Bablok[2]	Linear regression
y = 0.974x + 0.105	y = 0.975x + 0.00833
τ = 0.997	r = 1.000

Values ranged from 14 to 957.

I index

Sample size (n) = 59

Passing/Bablok[2]	Linear regression
y = 1.000x + 0	y = 0.973x + 0.191
τ = 0.995	r = 1.000

Values ranged from 2 to 60.

Sample index 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** 503 analyzer (x).

H index

Sample size (n) = 72

Passing/Bablok[2]	Linear regression
y = 1.006x - 0.382	y = 1.005x - 0.540
τ = 0.996	r = 1.000

Values ranged from 9 to 732.

Sample index 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).

H index

Sample size (n) = 54

Passing/Bablok[2]	Linear regression
y = 0.961x - 0.223	y = 0.966x - 0.668
τ = 0.981	r = 1.000

Values ranged from 5 to 945.

Sample index values for human CSF samples obtained on a **cobas c** 303 analyzer (y) were compared with those determined using the corresponding reagent on a **cobas c** 503 analyzer (x).

H index

Sample size (n) = 73

Passing/Bablok[2]	Linear regression
y = 1.012x - 0.289	y = 1.012x - 0.174
τ = 0.994	r = 1.000

Values ranged from 7 to 987.

I index

Sample size (n) = 75

Passing/Bablok[2]	Linear regression
y = 1.000x + 0	y = 0.986x - 0.0420
τ = 0.995	r = 1.000

Values ranged from 1 to 60.

Sample index values for human CSF 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).

H index

Sample size (n) = 78

Passing/Bablok[2]	Linear regression
y = 0.964x + 1.09	y = 0.963x + 1.21
τ = 0.994	r = 1.000

Values ranged from 6 to 975.

I index

Sample size (n) = 51

Passing/Bablok[2]	Linear regression
y = 1.000x + 0	y = 0.974x + 0.0254
τ = 0.991	r = 1.000

Values ranged from 1 to 57.

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.

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.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see navifyportal.roche.com for definition of symbols used):

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.

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