LAMB2

cobas®

Tina-quant Lambda Gen.2

Order information

REF		CONTENT		Analyzer(s) on which kit(s) can be used
06749992190	06749992500	Tina-quant Lambda Gen.2 (100 tests)	System ID 07 6813 8	**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
11355279216	C.f.a.s. Proteins (5 x 1 mL)	Code 656	System-ID 07 6557 0
10557897122	Precinorm Protein (3 x 1 mL)	Code 302	System-ID 07 9105 9
11333127122	Precipath Protein (3 x 1 mL)	Code 303	System-ID 07 9106 7
05117003190	PreciControl ClinChem Multi 1 (20 x 5 mL)	Code 391	n. a.
05947626190	PreciControl ClinChem Multi 1 (4 x 5 mL)	Code 391	n. a.
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
20756350322	Diluent NaCl 9 % (6 x 22 mL)	n. a.	System-ID 07 5635 0
04489357190	Diluent NaCl 9 % (50 mL)	System ID 07 6869 3	n. a.

English

Intended use

Immunoturbidimetric in vitro assay for the quantitative determination of bound and free immunoglobulins of the lambda light chain type in human serum and plasma on **cobas c** and COBAS INTEGRA systems.

Summary

Measurement of lambda light chain type with this assay in human serum and plasma, along with measurement of kappa light chain type and other diagnostic tests, aids in the assessment of monoclonal gammopathies associated with benign or malignant proliferative conditions of plasma cells and in the assessment of autoimmune diseases, in suspected patients.

Immunoglobulins are generated against foreign immunogens to initiate elimination of the corresponding molecule or organism. They consist of one or more basic units built from two identical heavy chains (H) and two identical light chains (L). The light and heavy chains are made of variable and constant domains.[1] Somatic recombination and mutations in immunoglobulin genes generate the variable regions that are involved in recognition and binding of the antigens. Every plasma cell clone normally produces a single variable domain sequence for heavy and light chains. Light chains can be categorized into two types, kappa or lambda, which can be present in serum or plasma as bound or free forms.[1] Pathological increases of a cell clone lead to elevated formation of monoclonal immunoglobulins or immunoglobulin fragments (free light chains), which bring about a change in the kappa:lambda ratio. A kappa:lambda ratio outside the normal range is indicative of monoclonal gammopathy, which is usually associated with pre-malignant conditions such as monoclonal gammopathy of undetermined significance (MGUS) or with more advanced malignancies such as multiple myeloma (MM), solitary plasmacytoma, lymphomas, chronic lymphocytic leukemia and Waldenström's macroglobulinemia.[1,2,3,4,5,6,7,8,9]

Overproduction of light chains may occur following an excess of antibody production by B cells, usually as a result of chronic immune stimulation, and for this reason the measurement of light chains has been proposed as a biomarker of B cell activity in a number of autoimmune and chronic inflammatory conditions, such as rheumatoid arthritis or systemic lupus erythematosus.[10]

This test encompasses both bound and free immunoglobulins of the light chain type. It is known that the so-called paraproteins secreted in monoclonal gammopathies (monoclonal immunoglobulinemia) may differ from the respective immunoglobulins of polyclonal origin in amino acid composition and size.[1] This may impair the binding to antibody and hence impair accurate quantitation. On the contrary, great excess of immunoglobulin of polyclonal origin could cause antigen excess (hook effect) and yield results below the detection limit, which may be detected after appropriate dilution of such samples.[11] Furthermore, the occurrence of two monoclonal gammopathies producing differing light chain types could theoretically lead to kappa:lambda ratios in the normal range. Accordingly, quantitative determination of the kappa and lambda light chains cannot completely replace high-resolution electrophoresis, immunoelectrophoresis or immunofixation electrophoresis in the diagnosis of monoclonal gammopathy.[12,13,14]

Test principle

Immunoturbidimetric assay

Anti-lambda antibodies react with the antigen in the sample to form antigen/antibody complexes that, following agglutination, are measured turbidimetrically.

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

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 or K_2-EDTA 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.

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

Stability:[15] 7 days at 15-25 °C
4 weeks at 4-8 °C
2 months at -20 °C (± 5 °C)

Freeze only once.

Materials provided

See "Reagents – working solutions" section for reagents.

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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:	mg/dL x 0.01 = g/L
	g/L x 100 = mg/dL

Expected values

	lambda[14,16]	kappa/lambda ratio[17]
Serum	0.83-2.24 g/L	1.29-2.61

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:

LAMB2: ACN 284

For **cobas c** 502 analyzer:

LAMB2: ACN 8284

Reagents - working solutions

R1	TRIS/HCl buffer: 50 mmol/L, pH 8.0; PEG 7 %; stabilizers and preservative
R2	Polyclonal anti-human lambda antibody (goat): dependent on titer; TRIS/HCl buffer: 20 mmol/L, pH 7.5; stabilizers and preservative

R1 is in position B and R2 is in position C.

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:	12 weeks

Application for serum and plasma

cobas c 311 **test definition**

Assay type	2-Point End		
Reaction time / Assay points	10 / 6-57		
Wavelength (sub/main)	800/340 nm		
Reaction direction	Increase		
Units	g/L (mg/dL)		
Reagent pipetting		Diluent (H_2O)	
R1	125 µL	–	
R2	45 µL	–	
Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	4.5 µL	9 µL	180 µL
Decreased	4.5 µL	3 µL	150 µL
Increased	4.5 µL	9 µL	180 µL

cobas c 501/502 **test definition**

Assay type	2-Point End		
Reaction time / Assay points	10 / 10-70		
Wavelength (sub/main)	800/340 nm		
Reaction direction	Increase		
Units	g/L (mg/dL)		
Reagent pipetting		Diluent (H_2O)	
R1	125 µL	–	
R2	45 µL	–	
Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	4.5 µL	9 µL	180 µL
Decreased	4.5 µL	3 µL	150 µL
Increased	4.5 µL	9 µL	180 µL

Calibration

Calibrators	S1-S6: C.f.a.s. Proteins
Calibration mode	RCM2
Calibration frequency	Full calibration
	- after reagent lot change
	- 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 CRM 470 standard using the Lievens equation.[14]

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 ± 0.09 g/L of initial values of samples ≤ 0.9 g/L and within ± 10 % for samples > 0.9 g/L.

Icterus:[18] 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:[18] No significant interference up to an H index of 1000 (approximate hemoglobin concentration: 621 µmol/L or 1000 mg/dL).

Lipemia (Intralipid):[18] No significant interference up to an L index of 1000. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.

Drugs: No interference was found at therapeutic concentrations using common drug panels.[19, 20]

Rheumatoid factors: No significant interference from rheumatoid factors up to a concentration of 450 IU/mL.

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High dose hook-effect: No false result occurs up to a lambda concentration of 30 g/L.

Samples from patients with unclear clinical diagnosis should be subject to protein electrophoresis to identify a possible antigen excess or monoclonal gammopathy. Antigen excess may be detected by appropriate predilution of the specimen with 0.9 % sodium chloride solution.

In sera with monoclonal lambda components, differing results may be obtained with commercial assays employing antibodies from different sources (rabbit, sheep, goat).

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.[21]

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

0.5-7.5 g/L (50-750 mg/dL)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:2.4 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 2.4.

Lower limits of measurement

Lower detection limit of the test

0.2 g/L (20 mg/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 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.

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*
	g/L (mg/dL)	*g/L (mg/dL)*	*%*
Precinorm Protein	1.08 (108)	0.02 (2)	1.7
Precipath Protein	2.26 (226)	0.02 (2)	1.1
Human serum 1	0.88 (88)	0.01 (1)	1.3
Human serum 2	2.39 (239)	0.03 (3)	1.1
Intermediate precision	*Mean*	*SD*	*CV*
	g/L (mg/dL)	*g/L (mg/dL)*	*%*
Precinorm Protein	1.06 (106)	0.02 (2)	1.9
Precipath Protein	2.30 (230)	0.03 (3)	1.4
Human serum 1	0.88 (88)	0.02 (2)	2.5
Human serum 2	2.41 (241)	0.03 (3)	1.2

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

Method comparison

Lambda light chain values for human serum samples obtained on a **cobas c** 501 analyzer (y) were compared with those determined using the corresponding reagent on a Roche/Hitachi 917 analyzer (x).

Sample size (n) = 267

Passing/Bablok[22]	Linear regression
y = 0.959x + 0.023 g/L	y = 0.939x + 0.077 g/L
τ = 0.943	r = 0.996

The sample concentrations were between 0.558 and 6.37 g/L (55.8 and 637 mg/dL).

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

COBAS INTEGRA systems

System information

LAMB2: Test ID 0-303

Reagents - working solutions

R1	TRIS/HCl buffer: 50 mmol/L, pH 8.0; PEG: 7 %; stabilizers and preservative
SR	Polyclonal anti-human lambda antibody (goat): dependent on titer; TRIS/HCl buffer: 20 mmol/L, pH 7.5; stabilizers and preservative

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

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	12 weeks

Application for serum/plasma

Test definition

Measuring mode	Absorbance
Abs. calculation mode	Endpoint
Reaction mode	D-R1-S-SR
Reaction direction	Increase
Wavelength A/B	340/659 nm
Calc. first/last	33/63
Typical prozone effect	> 49 g/L
Antigen excess check	No
Predilution factor	21
Unit	g/L

Pipetting parameters

		Diluent (H_2O)
R1	125 µL	
Sample	4.5 µL	5 µL
SR	45 µL	
Total volume	179.5 µL	

Calibration

Calibrator	C.f.a.s. Proteins
Calibration dilution ratio	1:7, 1:12, 1:24, 1:35, 1:42, 1:57 performed automatically by the instrument
Calibration mode	Logit/log 4
Calibration replicate	Duplicate recommended

Calibration interval	Each lot and as required following quality control procedures

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

Enter the assigned lot-specific lambda value of the undiluted calibrator indicated in the package insert for the calibrator C.f.a.s. Proteins.

Traceability: This method has been standardized against the CRM 470 standard using the Lievens equation.[14]

Quality control

Reference range	Precinorm Protein
Pathological range	PreciControl ClinChem Multi 2, Precipath Protein
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

Criterion: Recovery within ± 10 % of initial value at a lambda concentration of 0.9 g/L.

Icterus:[18] 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).[a)]

Hemolysis:[18] No significant interference up to an H index of 1000 (approximate hemoglobin concentration: 621 µmol/L or 1000 mg/dL).[b)]

Lipemia (Intralipid):[18] No significant interference up to an L index of 2000. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.

High dose hook-effect: No false result occurs up to a lambda concentration of 49 g/L.

Rheumatoid factors: No significant interference from rheumatoid factors up to a concentration of 250 IU/mL.

Criterion: Recovery within ± 10 % of initial value.

Drugs: No interference was found at therapeutic concentrations using common drug panels.[19, 20]

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.[21]

Samples from patients with unclear clinical diagnosis should be subject to protein electrophoresis to identify a possible antigen excess or monoclonalgammopathy. Antigen excess may be detected by appropriate predilution of the specimen with 0.9 % sodium chloride solution. In sera with monoclonal lambda components, differing results may be obtained with commercial assays employing antibodies from different sources (rabbit, sheep, goat).

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.

a) Measured at analyte concentrations up to approximately 1.1 g/L

b) Measured at analyte concentrations up to approximately 1.19 g/L

Limits and ranges

Measuring range

0.9-7.5 g/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.

Determine samples having lower concentrations via the rerun function. For samples with lower concentrations, the rerun function reduces the sample predilution factor to 3.5. The results are automatically multiplied by the reduced predilution factor.

Lower limits of measurement

Lower detection limit of the test:

0.3 g/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 a zero sample (zero sample + 3 SD, repeatability, n = 21).

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 (1 aliquot per run, 1 run per day, 21 days). The following results were obtained on the COBAS INTEGRA 700 analyzer:

Repeatability	*Mean* *g/L*	*SD* *g/L*	*CV* *%*
Precinorm Protein	1.23	0.01	1.1
Precipath Protein	2.20	0.02	0.7
Human serum	1.42	0.01	0.9

Intermediate precision	*Mean* *g/L*	*SD* *g/L*	*CV* *%*
Precinorm Protein	1.35	0.04	2.6
Precipath Protein	2.30	0.03	1.3
Human serum	1.50	0.03	1.9

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

Method comparison

Lambda light chain values for human serum and plasma samples obtained on a COBAS INTEGRA 700 analyzer (y) were compared with those determined using the same reagent on a Roche/Hitachi 917 analyzer (x).

Roche/Hitachi 917 analyzer	Sample size (n) = 114
Passing/Bablok[22]	Linear regression
y = 0.994x - 0.030 g/L	y = 0.998x - 0.067 g/L
τ = 0.934	r = 0.990

The sample concentrations were between 0.31 and 12.5 g/L.

References

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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:

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

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