

## Apolipoprotein B FS\*

### Order Information

**Cat. No.**

1 7112 99 10 921

**Kit size**

 400 (4 x 100)

### Intended Use

Diagnostic reagent for quantitative in vitro determination of apolipoprotein B in human serum or heparin plasma on automated respons<sup>®</sup>910.

### Summary

Apolipoprotein B (Apo B) is the principal protein component of low density lipoprotein (LDL) which transports cholesterol to the cells thus contributing to atherosclerotic plaque formation in the arteries. Elevated Apo B levels are strongly associated with coronary heart disease (CHD) because of the close relation between Apo B and degree of atherosclerosis. While determination of total cholesterol and triglycerides is used for screening of coronary risk, measurement of Apo B beside apolipoprotein A1 and lipoprotein (a) provides useful information concerning various disorders of the lipoprotein metabolism and can be an alternative to the determination of LDL-cholesterol. Apo B measurements are as well very useful for monitoring of the lipid-lowering therapy. [1,2]

### Method

Immunoturbidimetric test

Determination of Apo B concentration by photometric measurement of antigen antibody reaction of antibodies to Apo B with Apo B present in the sample.

### Reagents

#### Components and Concentrations

R1: TRIS pH 7.5 100 mmol/L  
R2: TRIS pH 7.5 65 mmol/L  
Anti-human apolipoprotein B antibody (goat) <1 %

### Storage and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze and protect from light.

The open-vial stability of the reagent is 18 months until expiry date.

### Warnings and Precautions

- The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- Reagent 2 contains material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
- In very rare cases, samples of patients with gammopathy might give falsified results [3].
- In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
- Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
- Please refer to the safety data sheets (SDS) and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
- For professional use only.

### Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

### Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent rotor.

### Materials Required

General laboratory equipment

### Specimen

Human serum or heparin plasma

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

#### Stability [4]:

1 day	at	20 – 25°C
8 days	at	4 – 8°C
3 months	at	-20°C

Only freeze once. Discard contaminated specimens.

### Calibrators and Controls

DiaSys TruCal Apo A1/B calibrator is recommended for calibration. Calibrator values have been made traceable to a commercially available measurement procedure, standardized against IFCC reference standards (WHO-IRP October 1992) SP3-07. Use DiaSys TruLab L Level 1 and Level 2 for internal quality control. All target values of the controls are traceable to DiaSys reagent/calibrator system. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal Apo A1/B	1 7170 99 10 045	3 x 2 mL
TruLab L Level 1	5 9020 99 10 065	3 x 3 mL
TruLab L Level 2	5 9030 99 10 065	3 x 3 mL

### Performance Characteristics

Measuring range from 0.98 mg/dL up to 240 mg/dL, depending on the concentration of the highest calibrator. Linearity is given within ± 5%. In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.		
Limit of detection**	0.98 mg/dL	
Limit of quantitation**	0.98 mg/dL	
No prozone effect up to 1200 mg/dL.		
Onboard stability	14 days	
Calibration stability	7 days	
Interference by	Interferences ≤ 10% up to	Analyte concentration [mg/dL]
Bilirubin (conjugated)	40 mg/dL	67.1
	50 mg/dL	104
Bilirubin (unconjugated)	30 mg/dL	69.4
	50 mg/dL	111
Hemolysis	600 mg/dL	82.5
	600 mg/dL	110
Lipemia (triglycerides)	2000 mg/dL	52.8
	2000 mg/dL	98.0
For further information on interfering substances, refer to the literature [5-7].		

Precision			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	32.2	79.4	134
CV [%]	2.08	1.66	1.47
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	36.3	67.5	150
CV [%]	2.86	4.96	4.40

  

Method comparison (n=97)	
Test x	DiaSys Apolipoprotein B FS (Hitachi 917)
Test y	DiaSys Apolipoprotein B FS (respons <sup>®</sup> 910)
Slope	1.00
Intercept	-2.58 mg/dL
Coefficient of correlation	0.994

\*\* according to CLSI document EP17-A, Vol. 24, No. 34

### Conversion Factor

Apo B [mg/dL] x 0.0182 = Apo B [μmol/L]

### Reference Range [8]

Women 75 – 150 mg/dL 1.37 – 2.73 μmol/L  
 Men 80 – 155 mg/dL 1.46 – 2.82 μmol/L

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

### Clinical Interpretation

Several studies indicate that increased concentrations of Apo B (> 150 mg/dL in women and > 155 mg/dL in men) and decreased concentrations of Apo A1 (< 120 mg/dL in women and < 110 mg/dL in men) may be good predictors of risk of CHD [2].

### Literature

1. Bhatnagar D, Durrington PN. Measurement and clinical significance of apolipoproteins A-I and B. In: Rifai N, Warnick GR, Dominiczak MH, eds. Handbook of lipoprotein testing. Washington: AACC Press, 1997: p. 177-98.
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3. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.
4. Guder WG, da Fonseca-Wollheim F, Heil W, Schmitt Y, Töpfer G, Wisser H, Zawta B. Quality of Diagnostic Samples. 3rd edition; 2010. p. 34-5
5. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
6. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, <https://clinf.wiley.com/aaccweb/aacc/>, accessed in December 2020. Published by AACC Press and John Wiley and Sons, Inc.
7. 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 Jul;38:376-85.
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Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.



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\* Fluid Stable

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### Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	APOB
Shortcut:	
Reagent barcode reference:	703
Host reference:	703

Technic	
Type:	End point
First reagent:[ $\mu$ L]	200
Blank reagent	Yes
Sensitive to light	
Second reagent:[ $\mu$ L]	40
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	340
Secondary wavelength:[nm]	700
Polychromatic factor:	1.0000
1 st reading time [min:sec]	(04:24)
Last reading time [min:sec]	10:00
Reaction way:	Increasing
Linear Kinetics	
Substrate depletion: Absorbance limit	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics	
Substrate depletion: Absorbance limit	
Endpoint	
Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [ $\mu$ L]	0 (no hemolysis)
Cleaner	
Sample [ $\mu$ L]	0
Technical limits	
Concentration technical limits-Lower	1.0000
Concentration technical limits-Upper	240.0000
SERUM	
Normal volume [ $\mu$ L]	3.0
Normal dilution (factor)	1
Below normal volume [ $\mu$ L]	
Below normal dilution (factor)	
Above normal volume [ $\mu$ L]	3.0
Above normal dilution (factor)	6
URINE	
Normal volume [ $\mu$ L]	3.0
Normal dilution (factor)	1
Below normal volume [ $\mu$ L]	
Below normal dilution (factor)	
Above normal volume [ $\mu$ L]	3.0
Above normal dilution (factor)	6
PLASMA	
Normal volume [ $\mu$ L]	3.0
Normal dilution (factor)	1
Below normal volume [ $\mu$ L]	
Below normal dilution (factor)	
Above normal volume [ $\mu$ L]	3.0
Above normal dilution (factor)	6
CSF	
Normal volume [ $\mu$ L]	3.0
Normal dilution (factor)	1
Below normal volume [ $\mu$ L]	
Below normal dilution (factor)	
Above normal volume [ $\mu$ L]	3.0
Above normal dilution (factor)	6
Whole blood	
Normal volume [ $\mu$ L]	3.0
Normal dilution (factor)	1
Below normal volume [ $\mu$ L]	
Below normal dilution (factor)	
Above normal volume [ $\mu$ L]	3.0
Above normal dilution (factor)	6

Results	
Decimals	2
Units	mg/dL
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	Male
Age	
SERUM	>=80.00 <=155.00
URINE	
PLASMA	>=80.00 <=155.00
CSF	
Whole blood	
Gender	Female
Age	
SERUM	>=75.00 <=150.00
URINE	
PLASMA	>=75.00 <=150.00
CSF	
Whole blood	

Contaminants	
Please refer to r910 Carryover Pair Table	

Calibrators details	
Calibrator list	Concentration
Cal. 1/Blank	0
Cal. 2	*
Cal. 3	*
Cal. 4	*
Cal. 5	*
Cal. 6	*
	Max delta abs.
Cal. 1	0.0100
Cal. 2	0.0100
Cal. 3	0.0150
Cal. 4	0.0200
Cal. 5	0.0200
Cal. 6	0.0250
Drift limit [%]	5.00

Calculations	
Model	Logit (X)
Degree	2

\* Enter calibrator value