Abbott
CLINICAL CHEMISTRY

ARCHITECT® / AEROSET®

APOLIPOPROTEIN B

This package insert contains information to run the Apolipoprotein B assay on the ARCHITECT *c* Systems™ and the AEROSET System.

NOTE: Changes Highlighted

NOTE: This package insert must be read carefully prior to product use. Package insert instructions must be followed accordingly. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Customer Support

United States:	**1-877-4ABBOTT**
Canada:	**1-800-387-8378 (English speaking customers)**
	1-800-465-2675 (French speaking customers)
International:	**Call your local Abbott representative**

Symbols in Product Labeling

CAL	Calibrator	REF	Catalog number/List number
CAL DILUENT	Calibrator diluent	SN	Serial number
CONC	Concentration		Consult instructions for use
EC REP	Authorized Representative in the European Community		Manufacturer
INGRED	Ingredients		Temperature limitation
IVD	In vitro diagnostic medical device		Use by/Expiration date
LOT	Batch code/Lot number		
R1	Reagent 1		
R2	Reagent 2		

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NAME

APOLIPOPROTEIN B

INTENDED USE

The Apolipoprotein B (ApoB) assay is used for the quantitation of ApoB in human serum or plasma.

SUMMARY AND EXPLANATION OF TEST

Lipids that are synthesized in the intestine or liver need to be transported to tissues and organs for their varied metabolic functions. Given the hydrophobic nature of the neutral fats, triglycerides, and cholesterol esters, lipid transport and delivery via plasma would not be possible without some form of hydrophilic adaptation. Lipids are transported by means of a series of micellar structures known as lipoproteins that consist of an outer monolayer of protein (apolipoprotein) and polar lipids, and an inner core of neutral lipids.

ApoB is the major protein moiety of all lipoproteins other than HDL, and exists in two major forms; ApoB48 and ApoB100. ApoB48 is synthesized in the intestine and is present on chylomicrons and their remnants. ApoB100 is synthesized in the liver and is present on VLDL, IDL, and LDL. The structure of ApoB48 is the same as the N-terminal 48% of ApoB100. The basic biochemistry and clinical importance of ApoB have both been active areas of research. Therefore, a large body of information has been established regarding its synthesis, assembly into lipoproteins, and the atherogenic actions of ApoB-containing lipoproteins such as VLDL and LDL.[1] LDL, which contains a single copy of the ApoB100 molecule, transports lipids into cells by binding to LDL-receptors present on the surface of most cells. Accumulation of excess intracellular lipids can result in atherosclerotic vascular disease. Also, genetic defects in the LDL-receptor itself causes familial hypercholesterolemia, which results in atherosclerosis early in life.[2]

Numerous studies have demonstrated the diagnostic value of Apolipoprotein analysis. An international group of collaborators has stated, "ApoB has been shown to be superior to LDL cholesterol in predicting the risk of vascular events and the progression of vascular disease in a series of prospective epidemiological studies". In relation to use of the ApoB/ApoA-I ratio, they state that the ApoB/ApoA-I ratio was more informative of cardiovascular risk than the conventional indices: total cholesterol/HDL-C, LDL-C/HDL-C or non-HDL-C/LDL/C.[3]

ApoB measurements are useful in the diagnosis of premature coronary artery disease, hyper-β-lipoproteinemia, and hypo-β-lipoproteinemia.[4]

PRINCIPLES OF PROCEDURE

The ApoB assay is an immunoturbidimetric procedure that measures increasing sample turbidity caused by the formation of insoluble immune complexes when antibody to ApoB is added to the sample. Sample containing ApoB is incubated with a buffer, R1, and a sample blank determination is performed prior to the addition of ApoB antibody, R2. In the presence of an appropriate antibody in excess, the ApoB concentration is measured as a function of turbidity.

Methodology: Immunoturbidimetric

REAGENTS

Reagent Kit

REF 9D93 Apolipoprotein B is supplied as a liquid, ready-to-use, two-reagent kit which contains:

R1 3 x 21 mL
R2 3 x 9 mL

Estimated tests per kit: 243
Calculation is based on the minimum reagent fill volume per kit.

	Reactive Ingredients	Concentration
R1	TRIS	100 mmol/L
	Polyethylene Glycol	30 g/L
	Sodium Azide	0.1%
R2	Anti-human apolipoprotein B goat serum	50%
	TRIS	100 mmol/L
	Sodium Azide	0.1%

REAGENT HANDLING AND STORAGE

Reagent Handling

Remove air bubbles, if present in the reagent cartridge, with a new applicator stick. Alternatively, allow the reagent to sit at the appropriate storage temperature to allow the bubbles to dissipate. To minimize volume depletion, do not use a transfer pipette to remove the bubbles.

CAUTION: Reagent bubbles may interfere with proper detection of reagent level in the cartridge, causing insufficient reagent aspiration which could impact results.

Reagent Storage

Unopened reagents are stable until the expiration date when stored at 2 to 8°C.

Reagent onboard stability is approximately 57 days if quality control results meet acceptance criteria. If quality control results do not meet acceptance criteria, refer to the QUALITY CONTROL section of this package insert.

WARNINGS AND PRECAUTIONS

Precautions for Users

1. For in vitro diagnostic use.
2. Do not use components beyond the expiration date.
3. Do not mix materials from different kit lot numbers.
4. Do not mix fresh reagent with in-use reagents.
5. **CAUTION:** This product requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and be handled in accordance with the OSHA Standard on Bloodborne Pathogens.[5] Biosafety Level 2[6] or other appropriate biosafety practices[7,8] should be used for materials that contain or are suspected of containing infectious agents.
6. This product contains sodium azide. For a specific listing, refer to the REAGENTS section. Contact with acids liberates very toxic gas. This material and its container must be disposed of in a safe way.
   NOTE: Refer to *Section 8* of the instrument-specific operations manual for proper handling and disposal of reagents containing sodium azide.

For product not classified as dangerous per European Directive 1999/45/EC as amended, safety data sheet available for professional user on request.

SPECIMEN COLLECTION AND HANDLING

Suitable Specimens

Serum and plasma are acceptable specimens. Fasting sample (≥ 12 hours) is recommended.[4,9]

- **Serum:** Use serum collected by standard venipuncture techniques into glass or plastic tubes with or without gel barriers. Ensure complete clot formation has taken place prior to centrifugation. Separate serum from red blood cells or gel as soon after collection as possible.

  Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy, may take longer to complete their clotting processes. Fibrin clots may subsequently form in these sera and the clots could cause erroneous test results.
- **Plasma:** Use plasma collected by standard venipuncture techniques into glass or plastic tubes. Acceptable anticoagulants are lithium heparin (with or without gel barrier), sodium heparin, and EDTA. Ensure centrifugation is adequate to remove platelets. Separate plasma from red blood cells or gel as soon after collection as possible.

Refer to the specimen collection tube manufacturer's instructions for processing and handling requirements.

For total sample volume requirements, refer to the instrument-specific ASSAY PARAMETERS section of this package insert and *Section 5* of the instrument-specific operations manual.

SPECIMEN COLLECTION AND HANDLING (Continued)

Specimen Storage

Serum and plasma: Analyze fresh specimens if possible. Repeated freeze/thaw cycles should be avoided to minimize potential protein degradation.

Temperature	Maximum Storage	Bibliographic Reference
2 to 8°C	3 days	10, 11
-20°C	2 months	10
-70 C	1 year*	12

* Thaw overnight at 2 to 8°C.

Guder et al.[10] suggest storage of frozen specimens at -20°C for no longer than the time interval cited above. However, limitations of laboratory equipment make it necessary in practice for clinical laboratories to establish a range around -20°C for specimen storage. This temperature range may be established from either the freezer manufacturer's specifications or your laboratory standard operating procedure(s) for specimen storage.

NOTE: Stored specimens must be inspected for particulates. If present, mix and centrifuge the specimen to remove particulates prior to testing.

PROCEDURE

Materials Provided

REF 9D93 Apolipoprotein B Reagent Kit

Materials Required but not Provided

- REF 6E54 Apo A1/Apo B Calibrator
  CAL 1 x 1 mL
  CAL DILUENT 2 x 2 mL
- Control Material
- Saline (0.85% to 0.90% NaCl) for specimens that require dilution

Assay Procedure

For a detailed description of how to run an assay, refer to *Section 5* of the instrument-specific operations manual.

Specimen Dilution Procedures

The ARCHITECT *c* Systems and the AEROSET System have automatic dilution features; refer to *Section 2* of the instrument-specific operations manual for additional information.

Serum and plasma: Specimens with ApoB values exceeding the highest calibrator are flagged and may be diluted using the Automated Dilution Protocol or the Manual Dilution Procedure.

Automated Dilution Protocol

If using the Automated Dilution Protocol, the system performs a 1:4 dilution of the specimen and automatically corrects the concentration by multiplying the result by the appropriate dilution factor.

Manual Dilution Procedure

Manual dilutions should be performed as follows:

- Use saline (0.85% to 0.90% NaCl) to dilute the sample.
- The operator must enter the dilution factor in the patient or control order screen. The system uses this dilution factor to automatically correct the concentration by multiplying the result by the entered factor.
- If the operator does not enter the dilution factor, the result must be multiplied by the appropriate dilution factor before reporting the result.

NOTE: If a diluted sample result is flagged indicating it is less than the linear low limit, do not report the result. Rerun using an appropriate dilution.

For detailed information on ordering dilutions, refer to *Section 5* of the instrument-specific operations manual.

The patient result flag ">" (ARCHITECT *c* Systems) and the EXT and LH result error codes (AEROSET) may indicate antigen excess. Dilute sample and rerun. Samples were tested for antigen excess up to 738.4 mg/dL (7.384 g/L).

CALIBRATION

The linear high field of the assay parameters must be edited to the concentration of the highest calibrator specified in the value sheet.

Calibration is stable for approximately 38 days (912 hours) and is required with each change in reagent lot number. Verify calibration with at least three levels of controls according to the established quality control requirements for your laboratory. If control results fall outside acceptable ranges, recalibration may be necessary.

A multi-point calibration (Linear) curve is generated using Apo A1/Apo B Calibrator.

For a detailed description of how to calibrate an assay, refer to *Section 6* of the instrument-specific operations manual.

For information on calibrator standardization, refer to the Apo A1/Apo B Calibrator package insert.

QUALITY CONTROL

The following is the recommendation of Abbott Laboratories for quality control. As appropriate, refer to your laboratory standard operating procedure(s) and/or quality assurance plan for additional quality control requirements and potential corrective actions.

- Three levels of quality control are to be run every 24 hours.
- If more frequent control monitoring is required, follow the established quality control procedures for your laboratory.
- If quality control results do not meet the acceptance criteria defined by your laboratory, patient values may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary.
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

RESULTS

Refer to the instrument-specific operations manual for information on results calculations.

- **ARCHITECT System Operations Manual**—*Appendix C*
- **AEROSET System Operations Manual**—*Appendix A*

Representative performance data are given in the EXPECTED VALUES and SPECIFIC PERFORMANCE CHARACTERISTICS sections of this package insert. Results obtained in individual laboratories may vary.

LIMITATIONS OF THE PROCEDURE

Refer to the SPECIMEN COLLECTION AND HANDLING and SPECIFIC PERFORMANCE CHARACTERISTICS sections of this package insert.

The performance characteristics of ApoB on an analyzer other than the ARCHITECT *c* Systems or AEROSET System must be validated and verified.

Grossly lipemic specimens may cause nonspecific light scattering. These specimens can be diluted with isotonic saline to reduce the nonspecific light scattering. Refer to the Specimen Dilution Procedures section of this package insert for specimen dilution instructions.

Samples containing paraproteins (abnormal monoclonal antibodies) may interfere with test results. Samples with elevated total protein concentrations or samples from patients with suspected paraproteinemia can be screened using other laboratory methods such as protein electrophoresis.[13]

EXPECTED VALUES

Reference Range

Serum[14]	Range* (mg/dL)	Range* (g/L)
0 to 1 year		
Male	16 to 124	0.16 to 1.24
Female	17 to 120	0.17 to 1.20
> 1 to 12 years		
Male	48 to 125	0.48 to 1.25
Female	51 to 126	0.51 to 1.26
> 12 to 60 years		
Male	49 to 173	0.49 to 1.73
Female	53 to 182	0.53 to 1.82
> 60 years		
Male	54 to 163	0.54 to 1.63
Female	64 to 182	0.64 to 1.82

* Reference ranges are based on a 90% confidence interval.

To convert results from mg/dL to g/L, multiply mg/dL by 0.01.

A study was conducted using 121 serum samples from volunteers. Data were analyzed as described by Clinical and Laboratory Standards Institute (CLSI) protocol NCCLS C28-A.[15] From this study, 95% of all specimens fell within 57.88 to 158.22 mg/dL (0.58 to 1.58 g/L), with samples ranging from 51.23 to 166.81 mg/dL (0.51 to 1.67 g/L).

It is recommended that each laboratory determine its own reference range based upon its particular locale and population characteristics.

SPECIFIC PERFORMANCE CHARACTERISTICS

Reportable Range (Accuracy by Recovery)

The ApoB assay reportable range is from 11 mg/dL (0.11 g/L) to the highest calibrator concentration. Human serum containing a known concentration of ApoB was diluted with saline and the resulting samples were analyzed. Observed mean results across the reportable range were within 3 mg/dL (0.03 g/L) or 10%, whichever is greater, of the target concentrations. Representative data are summarized below.

%Recovery = (Observed Mean / Target Concentration) × 100

Target Concentration (mg/dL)	Observed Mean (mg/dL)	Delta* (mg/dL)	Percent (%) Recovery*
2.0	-0.1	-2.2	-7.3
8.1	5.1	-3.0	62.9
13.5	10.6	-2.8	78.9
27.0	25.6	-1.4	94.8
53.9	50.0	-3.9	92.7
107.9	112.4	4.5	104.2
161.8	163.7	1.9	101.2
215.7	216.0	0.2	100.1
269.7	271.4	1.7	100.7

* Delta and %Recovery were calculated prior to rounding Target Concentration and Observed Mean values.

Limit of Quantitation (LOQ)

The LOQ for ApoB is ≤ 3 mg/dL (0.03 g/L). The LOQ is the analyte concentration at which the CV = 20%. Performance studies produced an LOQ of 2.8 mg/dL (0.028 g/L).

SPECIFIC PERFORMANCE CHARACTERISTICS (Continued)

Interfering Substances

Interference studies were conducted using CLSI protocol NCCLS EP7-P.[16] Interference effects were assessed by Dose Response and Paired Difference methods, at the medical decision level of the analyte.

Interfering Substance	Interferent Concentration	N	Target (mg/dL)	Observed (% of Target)
Bilirubin	30 mg/dL (513 µmol/L)	4	97.7	98.8
	60 mg/dL (1,026 µmol/L)	4	97.7	96.7
Hemoglobin	1,000 mg/dL (10.0 g/L)	4	90.9	101.2
	2,000 mg/dL (20.0 g/L)	4	90.9	102.0
Human triglyceride	750 mg/dL (8.5 mmol/L)	4	102.0	102.8
	1,000 mg/dL (11.3 mmol/L)	4	102.0	104.6
Intralipid	1,000 mg/dL (10.0 g/L)	4	102.1	101.7
	2,000 mg/dL (20.0 g/L)	4	102.1	101.9

Bilirubin solutions at the above concentrations were prepared by addition of a bilirubin stock to human serum pools. Hemoglobin solutions at the above concentrations were prepared by addition of hemolysate to human serum pools. Human triglyceride solutions at the above concentrations were prepared by mixing an elevated triglyceride human serum pool with a normal triglyceride human serum pool. Intralipid solutions at the above concentrations were prepared by addition of Intralipid to human serum pools.

Precision

The imprecision of the ApoB assay is ≤ 6.5% Total CV. Representative data from studies using CLSI protocols NCCLS EP5-T2[17] and EP5-A[18] are summarized below.

Control		Level 1	Level 2	Level 3
N		80	80	80
Mean (mg/dL)		43.4	98.3	140.3
Within Run	SD	1.93	1.26	1.89
	%CV	4.4	1.3	1.3
Between Run	SD	0.59	1.17	2.56
	%CV	1.4	1.2	1.8
Between Day	SD	1.87	0.00	4.53
	%CV	4.3	0.0	3.2
Total	SD	2.75	1.72	5.53
	%CV	6.3	1.8	3.9

Method Comparison

Correlation studies were performed using CLSI protocol NCCLS EP9-A.[19]

Serum results from the ApoB assay on the AEROSET System were compared with those from a commercially available immunoturbidimetric methodology.

Serum results from the ApoB assay on an ARCHITECT *c* System were compared with the ApoB assay on the AEROSET System.

	AEROSET vs. Comparative Method	ARCHITECT vs. AEROSET
N	80	93
Y - Intercept	-2.92	-5.56
Correlation Coefficient	0.979	0.996
Slope	1.06	1.0
Mean %Bias	3.1	-6.3
Range (mg/dL)	43.3 to 190.3	20.2 to 269.3

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TRADEMARKS

ARCHITECT®

Apolipoprotein B Serum/Plasma—Conventional and SI Units

Configure assay parameters — General

● General O Calibration O SmartWash O Results O Interpretation

Assay: **ApoB** Type: **Photometric** Version: †
Number: **1054**

● Reaction definition O Reagent / Sample O Validity checks

Reaction mode: **End up**

	Primary	Secondary	Read times
Wavelength:	**604** /	**None**	Main: **31 – 33**

Last required read: **33**
Absorbance range: ___ – ___ Color correction: ___ – ___
Sample blank type: **Self** Blank: **14 – 16**

O Reaction definition ● Reagent / Sample O Validity checks

		R1	R2
Reagent:	**APOB0**	Reagent volume:	**200** **67**
Diluent:	**Saline**	Water volume:	___ ___
Diluent dispense mode:	**Type 0**	Dispense mode:	**Type 0** **Type 0**

Dilution name	Sample	Diluted sample	Diluent	Water	Dilution factor	Default dilution
STANDARD :	**2.0**	___	___	___ =	**1:1.00**	●
1:4 :	**25.0**	**2.0**	**75**	___ =	**1:4.00**	O
_____ :	___	___	___	___ =		O

O Reaction definition O Reagent / Sample ● Validity checks

Reaction check: **None**

Maximum absorbance variation: ___

Configure assay parameters — Calibration

O General ● Calibration O SmartWash O Results O Interpretation

Assay: **ApoB** Calibration method: **Linear**

● Calibrators O Volumes O Intervals O Validity checks

Calibrator set: **APO**
Replicates: **3** [Range 1 – 3]

Calibrator level:	Concentration:
Blank: **Water**	**0**††
Cal 1: **APO1**	‡
Cal 2: **APO2**	‡
Cal 3: **APO3**	‡
Cal 4: **APO4**	‡
Cal 5: **APO5**	‡

O Calibrators ● Volumes O Intervals O Validity checks

Calibrator: **APO**

Calibrator level	Sample	Diluted sample	Diluent	Water
Blank: **Water**	**2.0**	___	___	___
Cal 1: **APO1**	**2.0**	___	___	___
Cal 2: **APO2**	**2.0**	___	___	___
Cal 3: **APO3**	**2.0**	___	___	___
Cal 4: **APO4**	**2.0**	___	___	___
Cal 5: **APO5**	**2.0**	___	___	___

O Calibrators O Volumes ● Intervals O Validity checks

Calibration intervals:
Full interval: **912** (hours)
Calibration type:
Adjust type: **None**

O Calibrators O Volumes O Intervals ● Validity checks

Blank absorbance range: _____ – _____
Span: **Blank** – **Blank**
Span absorbance range: _____ – _____
Expected cal factor: **0.00**
Expected cal factor tolerance %: **0**

Configure assay parameters — SmartWash

O General O Calibration ● SmartWash O Results O Interpretation

Assay: **ApoB**

COMPONENT	REAGENT / ASSAY	WASH	Volume	Replicates
R1	**FER0B**	**Detergent A**	**345**	**1**
R1	**AMIK9**	**Detergent A**	**345**	**1**
R1	**VANCO**	**Detergent A**	**345**	**1**
R1	**GENT9**	**Detergent A**	**345**	**1**
R2	**FER0B**	**Detergent A**	**345**	**1**
R2	**AMIK9**	**Detergent A**	**345**	**1**
R2	**VANCO**	**Detergent A**	**345**	**1**
R2	**GENT9**	**Detergent A**	**345**	**1**
Cuvette	**Trig**	**10% Detergent B*** **	**345**	

*** Select "**Detergent B**" for software prior to Version 2.2.

Apolipoprotein B Serum/Plasma—Conventional Units

Configure assay parameters — Results

O General O Calibration O SmartWash ● Results O Interpretation

Assay: **ApoB** Result units: **mg/dL**
Assay defaults:
Low-Linearity: **11**
High-Linearity: **240**‡‡
Gender and age specific ranges:*

GENDER	AGE (UNITS)	NORMAL**	EXTREME
Male	**0 – 130 (Y)**	**49 – 173**	
Female	**0 – 130 (Y)**	**53 – 182**	
Either	**0 – 130 (Y)**	**49 – 182**	

Configure result units

Assay: **ApoB**
Version: †
Result units: **mg/dL**
Decimal places: **0** [Range 0 – 4]
Correlation factor: **1.0000**
Intercept: **0.0000**

Apolipoprotein B Serum/Plasma—SI Units

Configure assay parameters — Results

O General O Calibration O SmartWash ● Results O Interpretation

Assay: **ApoB** Result units: **g/L**
Assay defaults:
Low-Linearity: **0.11**
High-Linearity: **2.40**‡‡
Gender and age specific ranges:*

GENDER	AGE (UNITS)	NORMAL**	EXTREME
Male	**0 – 130 (Y)**	**0.49 – 1.73**	
Female	**0 – 130 (Y)**	**0.53 – 1.82**	
Either	**0 – 130 (Y)**	**0.49 – 1.82**	

Configure result units

Assay: **ApoB**
Version: †
Result units: **g/L**
Decimal places: **2** [Range 0 – 4]
Correlation factor: **1.0000**
Intercept: **0.0000**

* User defined.
** Reference range is from >12 years to 60 years of age.
† Due to differences in instrument systems and unit configurations, version numbers may vary.
†† Displays the number of decimal places defined in the decimal places parameter field.
‡ Refer to concentration specified on calibrator labeling or value sheet.
‡‡ Edit to highest calibrator concentration specified in the calibrator value sheet.

AEROSET SYSTEM ASSAY PARAMETERS

AEROSET®

Apolipoprotein B Serum/Plasma—Conventional Units

Assay Configuration: Outline Page

Assay Name	Assay #	Line
ApoB	54	B-Line

Quantitative Ranges

Min Text	Min	Panic-L	L-Reference-H**	Panic-H	Max	Max Text
*	0.0*	0.0	49	182	0.0	0.0*	*
		11	L-Linear Range-H		240‡‡	

Reference Ranges*

Age	Male	Female
0 Year	49 – 173	53 – 182
0 Year	0.0 – 0.0	0.0 – 0.0
0 Year	0.0 – 0.0	0.0 – 0.0
0 Year	0.0 – 0.0	0.0 – 0.0

Qualitative Ranges N/A

Assay Configuration: Base Page

Reaction Mode	Wavelength-Prim/Sec	Read time-Main/Flex	AbsMaxVar
END UP	604 / ___	31 – 33 / 0 – 0	0.0
Sample Blank Test	**Blank Read Time**	**Abs Window**	**Abs Limits**
ApoB (54)	14 – 16	0 – 0	0.0 – 0.0

	S.Vol	DS.Vol	D.Vol	W.Vol		
Standard	2.0	0.0	0	0		Rgt Name/Pos
Dil 1	25.0	2.0	75	0	Diluent:	DILUENT D–18*
Dil 2	2.0	0.0	0	0	Type#	0

	Rgt Name/Pos	R.Vol	W.Vol	Type#
Reagent 1	APOB011 – ___*	200	0	0
Reagent 2	APOB012 – ___*	67	0	0

Reaction Check	Read Time – A/B	Range	Minimum
————	1 – 1 / 1 – 1	0.0 – 0.0	0.0

Factor/Intercept	Decimal Places	Units
1.0 / 0.0	0	mg/dL

Assay Configuration: Calibration Page

Calib Mode					Interval (H)	
Linear					912	
Blank/Calib Replicates			**Extrapolation %**		**Span**	**Span Abs Range**
3 / 3			1		**BLK** – 1	0.0 – 0.0

	Sample	S.Vol	DS.Vol	D.Vol	W.Vol	Blk Abs Range
BLK	Water	2.0	0.0	0	0	0.0 – 0.0
C1	APO 1	2.0	0.0	0	0	Cal Deviation
C2	APO 2	2.0	0.0	0	0	0.0
C3	APO 3	2.0	0.0	0	0	FAC Limit (%)
C4	APO 4	2.0	0.0	0	0	10
C5	APO 5	2.0	0.0	0	0	

Assay Configuration: SmartWash Page

Rgt Probe

Reagent	Wash	Vol
FER0B31	AlkW	345
AMIK941	AlkW	345
VANCO51	AlkW	345
FER0B12	AlkW	345
AMIK942	AlkW	345
VANCO52	AlkW	345

Cuvette

Assay Name	Wash	Vol
—	—	—

Sample Probe

Wash
—

Apolipoprotein B Serum/Plasma—SI Units

Assay Configuration: Outline Page

Assay Name	Assay #	Line
ApoB	54	B-Line

Quantitative Ranges

Min Text	Min	Panic-L	L-Reference-H**	Panic-H	Max	Max Text
*	0.0*	0.0	0.49	1.82	0.0	0.0*	*
		0.11	L-Linear Range-H		2.40‡‡	

Reference Ranges*

Age	Male	Female
0 Year	0.49 – 1.73	0.53 – 1.82
0 Year	0.0 – 0.0	0.0 – 0.0
0 Year	0.0 – 0.0	0.0 – 0.0
0 Year	0.0 – 0.0	0.0 – 0.0

Qualitative Ranges N/A

Assay Configuration: Base Page

Reaction Mode	Wavelength-Prim/Sec	Read time-Main/Flex	AbsMaxVar
END UP	604 / ___	31 – 33 / 0 – 0	0.0
Sample Blank Test	**Blank Read Time**	**Abs Window**	**Abs Limits**
ApoB (54)	14 – 16	0 – 0	0.0 – 0.0

	S.Vol	DS.Vol	D.Vol	W.Vol		
Standard	2.0	0.0	0	0		Rgt Name/Pos
Dil 1	25.0	2.0	75	0	Diluent:	DILUENT D–18*
Dil 2	2.0	0.0	0	0	Type#	0

	Rgt Name/Pos	R.Vol	W.Vol	Type#
Reagent 1	APOB011 – ___*	200	0	0
Reagent 2	APOB012 – ___*	67	0	0

Reaction Check	Read Time – A/B	Range	Minimum
————	1 – 1 / 1 – 1	0.0 – 0.0	0.0

Factor/Intercept	Decimal Places	Units
1.0 / 0.0	2	g/L

Assay Configuration: Calibration Page

Calib Mode					Interval (H)	
Linear					912	
Blank/Calib Replicates			**Extrapolation %**		**Span**	**Span Abs Range**
3 / 3			1		**BLK** – 1	0.0 – 0.0

	Sample	S.Vol	DS.Vol	D.Vol	W.Vol	Blk Abs Range
BLK	Water	2.0	0.0	0	0	0.0 – 0.0
C1	APO 1	2.0	0.0	0	0	Cal Deviation
C2	APO 2	2.0	0.0	0	0	0.0
C3	APO 3	2.0	0.0	0	0	FAC Limit (%)
C4	APO 4	2.0	0.0	0	0	10
C5	APO 5	2.0	0.0	0	0	

Assay Configuration: SmartWash Page

Rgt Probe

Reagent	Wash	Vol
FER0B31	AlkW	345
AMIK941	AlkW	345
VANCO51	AlkW	345
FER0B12	AlkW	345
AMIK942	AlkW	345
VANCO52	AlkW	345

Cuvette

Assay Name	Wash	Vol
—	—	—

Sample Probe

Wash
—

Refer to **Assay Configuration** in *Section 2* of the **AEROSET System Operations Manual** for information regarding assay parameters.

* User defined or instrument defined.

** Reference range is from >12 years to 60 years of age.

‡‡ Edit to highest calibrator concentration specified in the calibrator value sheet.