

# APO A-1 ver.2

Catalog No.

3032612

## Intended Use

Tina quant® @ Apolipoprotein A-1 ver.2 is an immunoturbidimetric assay for the in vitro quantitative determination of apolipoprotein A-1 in human serum and plasma on automated clinical chemistry analyzers.

## Summary<sup>1,2</sup>

Apolipoproteins are the protein constituents of the lipoproteins. The lipoproteins are classified according to their ultracentrifugal flotation density. Apolipoprotein A-1 is the major protein constituent of high-density lipoproteins (HDL). HDL are synthesized by the intestines and the liver. They transport excess cellular cholesterol from extrahepatic tissue and peripheral cells to the liver. Additionally, apolipoprotein A-1 activates the enzyme lecithin-cholesterol-acyltransferase (LCAT), which catalyzes the esterification of cholesterol, thereby enhancing the lipid-carrying capacity of the lipoproteins. Apolipoprotein A-1 levels increase in liver disease, pregnancy and as a result of estrogen administration (e.g. oral contraceptives). Apolipoprotein A-1 levels decrease in inherited hypo- $\alpha$ -lipoproteinemia (e.g. Tangier disease), cholestasis, sepsis and atherosclerosis. The liver synthesizes very low density lipoproteins (VLDL), which mainly contain triglycerides and cholesterol. In the presence of lipoprotein lipase the triglycerides are hydrolyzed and LDL-particles with a high proportion of cholesterol are formed. Apolipoprotein B is the main constituent of LDL.

The combined determination of apolipoprotein A-1/apolipoprotein B and the calculation of the apolipoprotein B: apolipoprotein A-1 ratio can reflect a lipid metabolism disorder and the risk of developing atherosclerosis or coronary heart disease particularly well, thus providing an excellent addition to the classical HDL/LDL-cholesterol determination. A high level of apolipoprotein A-1 (HDL) and a low level of apolipoprotein B (LDL) correlate best with a low risk for these diseases.

## Method Principle<sup>3-6</sup>

Anti-apolipoprotein A-1 antibodies react with the antigen in the sample to form antigen/antibody complexes which, following agglutination, are measured turbidimetrically.

## Working Reagents

### R1 Buffer

*Reactive Ingredients:*

50 mmol/L, TRIS buffer\*, pH 8.0

3.8% Polyethylene Glycol (PEG)

*Nonreactive Ingredients:*

Detergent, preservative

### R2 Anti-Apolipoprotein A-1 Antibody

*Reactive Ingredients:*

Anti-human apolipoprotein A-1 antibodies (sheep), dependent on titer

100 mmol/L TRIS buffer\*, pH 8.0

*Nonreactive Ingredient:*

Preservative

\*TRIS= Tris(hydroxymethyl)-aminomethane

## Precautions and Warnings

For In Vitro Diagnostic Use. Exercise the normal precautions required for handling all laboratory reagents.

## Reagent Preparation

1. R1 Working Solution: Use one Bottle 1 (Buffer) as supplied.



Ready for use.

2. R2 Working Solution: Use one Bottle 2 (Anti-Apolipoprotein A-1 Antibody) as supplied.



Ready for use.

APO A-1 ver.2 R1 and R2 must be used in combination to perform APO A-1 ver.2 assays.

## Storage and Stability

Unopened kit components: Up to the stated expiration date at 2-8 °C.

R1 and R2 Working Solution: 42 days opened and refrigerated on the analyzer.

## Specimen Collection and Preparation

**Serum/Plasma:** Use serum/plasma collected by standard venipuncture technique. Use Li-heparin, Na-heparin, NH<sub>4</sub>-heparin, Na<sub>2</sub>-EDTA, K<sub>2</sub>-EDTA or K<sub>3</sub>-EDTA plasma. Centrifuge samples containing precipitate before performing the assay.

Samples are prediluted automatically on the Roche/Hitachi 911, 912, 917, and MODULAR® P analyzers.

**Storage:** 1 day at 20-25 °C<sup>7</sup>, 3 days at 4-8 °C<sup>7</sup>, or 2 months at -20 °C<sup>8</sup> (only freeze once).

Each laboratory should establish guidelines for determining acceptability of specimens and the corrective action to be taken if a specimen is considered unacceptable. Insert laboratory-specific information on the Quick Reference page of this application sheet.

## Procedure

### Materials Provided

R1 and R2 Working Solutions

### Additional Materials Required

Automated clinical chemistry analyzer

0.9% NaCl

C.f.a.s. Lipids Catalog No. 2172623

Quality control material as recommended below

### Assay

Refer to the appropriate operator's manual and/or the Instrument Settings pages of this application sheet for analyzer-specific assay instructions. For assistance, contact the Roche Technical Support Center.

### Calibrators

STD 1/Blank: Use 0.9% NaCl  
Calibrator Code: 501

STD 2-6: Use C.f.a.s. Lipids  
Calibrator Code: 424

### Standardization

The Apolipoprotein A-1 ver.2 method was standardized against the IFCC SP1-01 reference preparation (WHO-IRP October 1992).<sup>9-12</sup>

### Calibration Frequency

Refer to the individual Instrument Settings pages of this application sheet for analyzer-specific calibration instructions.

### Calibration Verification

None required. If required for troubleshooting purposes, use of a commercially available product is recommended.

Refer to the appropriate operator's manual for detailed calibration instructions. Each laboratory should establish guidelines for corrective action to be taken if calibration is unacceptable. Insert laboratory-specific information on the Quick Reference page of this application sheet.

### Quality Control

Precinorm® L Catalog No. 781827

Precipath® L Catalog No. 1285874

Two levels (normal and abnormal) of other commercially available control material or laboratory-prepared control material may also be used. Refer to the appropriate value sheets/package inserts for additional information.

Roche/Hitachi 911, 912, and 917 analyzer assay-specific control intervals are operator-selectable for 10-1000 samples in increments of 10.

Each laboratory should establish its own control interval using a protocol such as NCCLS Document C24-A: Internal Quality Control Testing Principles and Definitions. Quality control should be performed a minimum of once daily and after every calibration. Each laboratory should establish guidelines for corrective action to be taken if controls do not recover within the specified limits.

Insert laboratory-specific information on the Quick Reference page of this application sheet.

## Calculation

The analyzer computer constructs a calibration curve from absorbance measurements of the standards using a four parameter logit-log fitting function.

The logit-log function fits a smooth line through the data points. The analyzer computer uses absorbance measurements of samples to calculate the concentration by interpolation of the logit-log function. Refer to the appropriate operator's manual for further details.

To convert from conventional units to SI units<sup>13</sup>, multiply the conventional units by 0.01.

$$\begin{aligned} \text{mg/dL} \times 0.01 &= \text{g/L} \\ \text{g/L} \times 100 &= \text{mg/dL} \end{aligned}$$

## Limitations

### Interference<sup>14</sup>

Icterus:<sup>15</sup> No significant interference from unconjugated and conjugated bilirubin up to an I index of 60.

Hemolysis:<sup>15</sup> No significant interference from hemoglobin up to an H index of 1000.

Lipemia (Intralipid®):<sup>15</sup> No significant interference from lipemia up to an L index of 1000.

No high-dose hook effect has been observed up to an apolipoprotein A-1 concentration of 600 mg/dL.

No interference from pharmaceuticals has been observed.

Under assay conditions, anti-human apolipoprotein A-1 antibodies from sheep show no cross-reactivity with apolipoprotein A-II or B.

A list of substances and conditions known to affect apolipoprotein A-1 concentration in vivo is given by both Young<sup>16</sup> and Friedman et al.<sup>17</sup> No representation is made by Roche Diagnostics regarding the completeness of these lists or the accuracy of the information contained therein.

## Reportable Range

20 - 400 mg/dL

For Roche/Hitachi analyzers capable of automatic dilution, refer to the individual Instrument Settings pages of this application sheet for extended reportable ranges.

If manual dilution is necessary, dilute the specimen with 0.9% NaCl and reassay using routine (normal) sample volume. Multiply the result obtained from the manual dilution by the appropriate manual dilution factor.

Report values less than 20 mg/dL as less than (<) 20 mg/dL (lower detection limit).

## Maximum Imprecision Specification

Replicate analysis (n = 21, within run) using control sera or patient sample at the normal sample volume should yield a CV of ≤ 7.0% up to 50 mg/dL or a CV of ≤ 4.0% at higher concentrations. If this level of precision cannot be achieved, contact the Roche Technical Support Center.

## Expected Values<sup>14</sup>

Men: 104 - 202 mg/dL

Women: 108 - 225 mg/dL

Each laboratory should establish transferability to its own population and determine its own expected values, if necessary. A suitable protocol that may be used for evaluation of expected values is NCCLS Document C28-P: How to Define, Determine and Utilize Reference Intervals in the Clinical Laboratory. Each laboratory should establish an acceptable reporting format and identify procedures for the reporting of abnormal results. Insert laboratory-specific information on the Quick Reference page of this application sheet.

For diagnostic purposes, the apolipoprotein A-1 results should always be assessed in conjunction with the patient's medical history, clinical examinations, and other findings.

### Specific Performance Characteristics<sup>14</sup>

Data contained within this section is representative of typical performance for Roche/Hitachi systems. Data obtained in your laboratory may differ from these values.

#### Imprecision

Measured imprecision studies, conducted according to a modified NCCLS EP5-T2 protocol using packaged reagents, pooled human serum\*, and control sera yielded the following in mg/dL:

Roche/Hitachi 917 analyzer (37 °C)

n	63	63	63
Mean	47.1*	84.7	170.7
Within Run SD	0.47	0.79	1.66
Within Run CV	1.0%	0.9%	1.0%
Total SD	1.1	2.2	2.6
Total CV	2.3%	2.6%	1.5%

Within-run imprecision studies using packaged reagents, pooled human serum\* and control sera yielded the following results in mg/dL.

Roche/Hitachi 917 analyzer (37 °C)

n	21	21	21
Mean	40*	83	157
Within Run SD	0.4	1.0	1.6
Within Run CV	1.0%	1.2%	1.0%

Roche/Hitachi MODULAR P analyzer (37 °C)

n	21	21	21
Mean	184*	86	169
Within Run SD	1.26	0.89	1.33
Within Run CV	0.7%	1.0%	0.8%

#### Method Comparison Bias

A comparison of this method (y) to other methods and/or analyzers (x) resulted in the following regression statistics calculated by the Passing-Bablok<sup>18,19</sup> regression method:

x method	BN II	917	917†
y method	917†	917†	912
slope	1.07	0.987	0.964
Intercept	-2.49	-4.44	-0.45
SD (md 95)	17.0	12.8	2.5
r	0.961	0.985	1.00
n	75	89	105
Bias** at 104 mg/dL	+4.79	-5.79	-4.19
Bias** at 108 mg/dL	+5.07	-5.84	-4.34
Range of x (mg/dL)	21.0 - 205.0	31.1 - 206.3	11.4 - 300

#### Legend

BN II = Behring/Dade analyzer

917† = Roche/Hitachi 917 analyzer using APO A-1 ver.2

917 = Roche/Hitachi 917 analyzer using APO reference

912 = Roche/Hitachi 912 analyzer using APO A-1 ver.2

SD (md 95) = 95% median distance

r = correlation coefficient

n = number of samples

\*\*Bias at the medical decision level (MDL)<sup>20</sup> was calculated as follows:

$$\text{Bias} = \text{intercept} + (\text{slope} \times \text{MDL}) - \text{MDL}$$

A protocol that may be used for the evaluation is NCCLS EP9-P: Comparison of Methods.

#### Interference

Interference studies were performed using the Roche/Hitachi 917 analyzer.

Interferent	Level of Interferent mg/dL	APO A-1 Conc. mg/dL	Effect mg/dL	Significant?*
Bilirubin	67	142	+2.2	No
Hemoglobin	1016	125	+1.2	No
Lipemia (Intralipid)	1207	137	+9.1	No

\*The criterion for determining no significant interference is that the sample containing the interferent recovers within  $\pm 10\%$  of the baseline value.

## References

1. Riesen WF. Apolipoproteine. In: Thomas L, ed. *Labor und Diagnose* 5th edition, Frankfurt 1998;171-190.
2. Brewer HB, Gregg RE, Hoeg JM, Fojo SS. Apolipoproteins and Lipoproteins in Human Plasma: an overview. *Clin Chem* 1988;34:B4-B8.
3. Becker W, Rapp W, Schwick HG, Störiko K. Methoden zur quantitativen Bestimmung von Plasmaproteinen durch Immunpräzipitation. *Z Klin Chem Klin Biochem* 1968;6:113-122.
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## Kit Configurations

	<b>R1</b>	<b>R2</b>
Cat. No. 3032612	6 x 19 mL	6 x 5 mL

Barcoded for the Roche/Hitachi 911/912/917 analyzers and Roche/Hitachi MODULAR P module

# Roche/Hitachi Instrument Settings

## 911

## Application Code 168 Parameter Block 9

1 Chemistry Parameters										
Test	[APOA1][00168]			Test Name	[APOA1]		Unit	[mg/dL]		
Data Mode	[ON BOARD]			Report Name	[Apolipoprotein A1]					
Control Interval	[1000]			Instrument Factor (Y=aX+b) a [ 1.0]						
				b [ 0.0]						
Expected Value	< SERUM >			Expected Value < URINE >						
Age	(M)			(F)						
	[100][Y]	[104]-[202]	[108]-[225]	[-99999]-[999999]						
	[100][Y]	[104]-[202]	[108]-[225]							
		[104]-[202]	[108]-[225]							
Technical Limit	< SERUM >			< URINE >						
	[ 20]-[ 400]	[-99999]-[999999]								
STD	Conc.	Pos.*	Sample	Pre.	Dil.	Calib.	Lot No.*	Qualitative	[SERUM]	
(1)	[ 0]	[18]	[ 6]	[ 0]	[ 0]	[501]	[000000]	(1)	[ 9.9]	[<10.0]
(2)	[ 0]†	[ 0]	[ 5]	[ 3]	[250]	[424]	[000000]	(2)	[ 0]	[ ]
(3)	[ 0]†	[ 0]	[ 5]	[ 3]	[125]	[424]	[000000]	(3)	[ 0]	[ ]
(4)	[ 0]†	[ 0]	[10]	[ 6]	[200]	[424]	[000000]	(4)	[ 0]	[ ]
(5)	[ 0]†	[ 0]	[10]	[ 6]	[150]	[424]	[000000]	(5)	[ 0]	[ ]
(6)	[ 0]†	[ 0]	[20]	[ 6]	[160]	[424]	[000000]	(6)	[ ]	[ ]

\* Operator entry is not allowed. STD Pos. must be entered in the Calibrator ID field on the System Parameters screen.

† Enter the calculated lot-specific calibrator values on the Chemistry Parameters screen in the Parameter Job.

1 Chemistry Parameters											
Test	[APOA1]										
Assay Code	[2POINT END][10][ - ]				Wavelength (2nd/Primary)			[700] / [340]			
Assay Point	[15]-[23]-[ 0]-[ 0]				Diluent/Rgt. Stability			[00311] [ 0]			
	< SERUM >				< URINE >						
S. Vol. (Normal)	[10]	[ 6]	[200]	[10]	[ 6]	[200]					
S. Vol. (Decrease)	[10]	[ 6]	[200]	[10]	[ 6]	[200]					
S. Vol. (Increase)	[20]	[ 6]	[200]	[20]	[ 6]	[200]					
ABS. Limit	[ 0]						[ 0]	[INCREASE]			
Prozone Limit	[32000]						[32000]	[UPPER]			
Reagent	T1	[250]	[ 0]	[00168]	[42]						
	T2	[ 0]	[ 0]	[00168]	[ 0]						
	T3	[ 50]	[ 0]	[00168]	[42]						
	T4	[ 0]	[ 0]	[00168]	[ 0]						
Calibration Type	[LOGIT-LOG (4P)]				[6]	[6]	[0]	[ - ]			
Auto Time Out	Blank	[ 0]					SD Limit	[ 150]			
	Span	[ 0]					Duplicate Limit	[ 150]			
	2 Point	[ 0]					Sensitivity Limit	[3000]			
	Full	[ 0]					S1 ABS Limit	[-32000][32000]			
Auto Change	Lot	[ FULL]					Compensated Limit	[ ]			
	Bottle	[CANCEL]									

911 continued on next page

# Roche/Hitachi Instrument Settings

(911 continued)

## Procedure

### **Calibrators**

STD 1: Use 0.9% NaCl

Calibrator Code: 501

STD 2-6: Use C.f.a.s. Lipids

Calibrator Code: 424

(Multi-point calibration is achieved by instrument parameter settings.)

**NOTE:** Multiply the value in the C.f.a.s. Lipids calibrator package insert by the following factors to determine the calibrator values to enter in the Chemistry Parameters screen in the Parameter Job menu.

STD 2: 0.208

STD 3: 0.408

STD 4: 1.000

STD 5: 1.312

STD 6: 2.334

### **Calibration Frequency**

Calibration is automatically performed by the analyzer. A Full calibration occurs with each reagent lot change and should be requested as required following quality control procedures.

## Extended Reportable Range

The extended reportable range using automatic rerun is 10 - 400 mg/dL.

# Roche/Hitachi Instrument Settings

## 912

### Application Code 168

#### Application Screen, Analyze Window

**Select Test:** APOA1      **Analyzer Cycle Time:** 10 sec      **Diluent:** 00311 0  
**Test Name:** APOA1      **Assay/Time/Point:** 2 Point End      10 15 23 0 0  
**App Code:** 168      **Wave (2nd/Primary):** 700 340

<b>Sample Volume</b>	Class 1	Class 2		<b>Reagent</b>
<b>Normal:</b>	10 6 200	10 6 200		R1: 250 0 00168 42
<b>Decrease:</b>	10 6 200	10 6 200		R2: 0 0 00168 0
<b>Increase:</b>	20 6 200	20 6 200		R3: 50 0 00168 42
				R4: 0 0 00168 0

	Class 1	Class 2	Dec/Inc
<b>Abs. Limit:</b>	0	0	Increase
<b>Prozone Limit:</b>	32000	0	Upper

#### Application Screen, Calibration Window

**Select Test:** APOA1  
**Calibration Type:** Logit-Log (4P)  
**Point:** 6      **Span Point:** 6  
**Weight:** 0

##### Auto Calibration

	Time Out	Change Over		
Blank:	0 hr	Lot:	Full	<b>SD Limit:</b> 150
Span:	0 hr	Bottle:	Cancel	<b>Duplicate Limit:</b> 10 % 30 Abs.
2 Point:	0 hr			<b>Sensitivity Range:</b> 6 17
Full:	0 hr			<b>S1 Abs Range:</b> -32000 32000

#### Application Screen, Range Window

**Select Test:** APOA1      **Report Name:** Apolipoprotein A1      **Data Mode:** On Board  
**Test Name:** APOA1       **Control Interval:** 1000      **Unit:** mg/dL      **Instrument Factor:**  
**App Code:** 168      a = 1.0      b = 0.0

**Select Sample Type:** Ser/Pl

##### Expected Ranges:

	Age	Male	Female		<input checked="" type="checkbox"/> <b>Use Qualitative Table</b>
100 Years	104 - 202		108 - 225		(1) 9.9 <10.0
100 Years	104 - 202		108 - 225		(2) 0
	104 - 202		108 - 225		(3) 0
					(4) 0
					(5) 0
					(6) 0

**Default Age:** Over 100 Years

**Default Sex:** Male

**Repeat Range:** \_\_\_\_\_ - \_\_\_\_\_

**Class 1 Technical Range:** 20 - 400

**Class 2 Technical Range:** -99999 - 999999

\_\_\_\_ User-definable.

912 continued on next page

**Application Screen, Others Window**

<Standard>	(1)	(2)	(3)	(4)	(5)	(6)
Calib. Code:*	501	424	424	424	424	424
Concentration:**	0	—	—	—	—	—
Position:*	—	—	—	—	—	—
Sample Volume:	6	5	5	10	10	20
Diluted S. Vol:	0	3	3	6	6	6
Diluent Volume:	0	250	125	200	150	160

— User-definable.

\* Enter the calibrator codes and calibrator positions in the Calibration menu, Installation screen, Edit Calibrator window.

\*\* Enter the calculated lot-specific calibrator values in the Calibration menu, Installation screen, Edit Concentrations window.

**Procedure**

**Calibrators**

STD 1: Use 0.9% NaCl  
Calibrator Code: 501

STD 2-6: Use C.f.a.s. Lipids  
Calibrator Code: 424  
(Multi-point calibration is achieved by instrument parameter settings.)

**NOTE:** Multiply the value in the C.f.a.s. Lipids calibrator package insert by the following factors to determine the calibrator values to enter in the Calibration menu, Installation screen, Edit Concentrations window.

- STD 2: 0.208
- STD 3: 0.408
- STD 4: 1.000
- STD 5: 1.312
- STD 6: 2.334

**Calibration Frequency**

Calibration is automatically performed by the analyzer. A Full calibration occurs with each reagent lot change and should be requested as required following quality control procedures.

**Extended Reportable Range**

The extended reportable range using automatic rerun is 10 - 400 mg/dL.

# Roche/Hitachi Instrument Settings

## 917

**Application Code 168**

MAINT/UTILITY, Application Window

No.	Test	Type				
			<b>Analyze</b>	Calib	Range	Others
x*	APOA1	Ser/Pl	Assay/Time/Point	2 Point End	<input type="text" value="10"/>	<input type="text" value="16"/>
x	xxxxx	xxxxx	Wave (2nd/Primary)	<input type="text" value="700"/>	<input type="text" value="340"/>	<input type="text" value="25"/>
x	xxxxx	xxxxx	S.Vol (Normal)	<input type="text" value="10.0"/>	<input type="text" value="6.0"/>	<input type="text" value="200"/>
x	xxxxx	xxxxx	S.Vol (Decrease)	<input type="text" value="10.0"/>	<input type="text" value="6.0"/>	<input type="text" value="200"/>
x	xxxxx	xxxxx	S.Vol (Increase)	<input type="text" value="20.0"/>	<input type="text" value="6.0"/>	<input type="text" value="200"/>
x	xxxxx	xxxxx	Diluent	<input type="text" value="00951"/>	<input type="text" value="0"/>	
x	xxxxx	xxxxx	Reagent (R1) T1	<input type="text" value="250"/>	<input type="text" value="0"/>	<input type="text" value="00168"/>
x	xxxxx	xxxxx	Reagent (R2) T2	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="00168"/>
x	xxxxx	xxxxx	Reagent (R3) T3	<input type="text" value="50"/>	<input type="text" value="0"/>	<input type="text" value="00168"/>
x	xxxxx	xxxxx	Reagent (R4) T4	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="00168"/>
x	xxxxx	xxxxx	Abs. Limit	<input type="text" value="0"/>	<input type="text" value="Increase"/>	<input type="text" value=""/>
x	xxxxx	xxxxx	Prozone Limit	<input type="text" value="32000"/>	<input type="text" value="0"/>	<input type="text" value="Upper"/>
x	xxxxx	xxxxx	Cell Detergent	<input type="text" value="Detergent 1"/>	<input type="text" value=""/>	<input type="text" value=""/>

Timing

R1

R2

R3

2Tests

Delete

Read

MAINT/UTILITY, Application Window

No.	Test	Type				
			<b>Analyze</b>	Calib	Range	Others
x*	APOA1	Ser/Pl	Calibration Type	Logit-Log (4P)	<input type="text" value=""/>	<input type="text" value=""/>
x	xxxxx	xxxxx	Point	<input type="text" value="6"/>	Span Point	<input type="text" value="6"/>
x	xxxxx	xxxxx	Weight	<input type="text" value="0"/>		
x	xxxxx	xxxxx	Auto Calibration			
x	xxxxx	xxxxx	Blank	<input type="text" value="0"/>	Change Over	
x	xxxxx	xxxxx	Span	<input type="text" value="0"/>	Full	<input type="text" value=""/>
x	xxxxx	xxxxx	2Point	<input type="text" value="0"/>	Cancel	<input type="text" value=""/>
x	xxxxx	xxxxx	Full	<input type="text" value="0"/>		
x	xxxxx	xxxxx	SD Limit	<input type="text" value="150"/>		
x	xxxxx	xxxxx	Duplicate Limit	<input type="text" value="10"/>	%	<input type="text" value="30"/>
x	xxxxx	xxxxx	Sensitivity Limit	<input type="text" value="6"/>		<input type="text" value="17"/>
x	xxxxx	xxxxx	S1Abs Limit	<input type="text" value="-32000"/>		<input type="text" value="32000"/>

Delete

Read

\* User-definable.

917 continued on next page

# Roche/Hitachi Instrument Settings

## 917

MAINT/UTILITY, Application Window

No.	Test	Type					
x*	APOA1	Ser/Pl	Application Code	168	Unit	mg/dL	[A]
x	XXXXX	XXXXX	Report Name	Apolipoprotein A-1			
x	XXXXX	XXXXX	Data Mode	On Board [A]			
x	XXXXX	XXXXX	Control Interval	1000			
x	XXXXX	XXXXX	Instrument Factor (Y=aX+b)	a=	1.0	b=	0.0
x	XXXXX	XXXXX	Technical Limit	20		400	
x	XXXXX	XXXXX	Repeat Limit	*		*	
x	XXXXX	XXXXX	Expected Value				
x	XXXXX	XXXXX					
x	XXXXX	XXXXX	(Male)	100	Y	[A]	104 202
x	XXXXX	XXXXX		100	Y	[A]	104 202
x	XXXXX	XXXXX					104 202
x	XXXXX	XXXXX	(Female)	100	Y	[A]	108 225
x	XXXXX	XXXXX		100	Y	[A]	108 225
x	XXXXX	XXXXX					108 225
x	XXXXX	XXXXX	(Default) Male	[A]	Range1	[A]	

Yes	[A]
(1) 9.9	<10.0
(2) 0	
(3) 0	
(4) 0	
(5) 0	
(6)	

Delete	Read
--------	------

MAINT/UTILITY, Application Window

No.	Test	Type							
x*	APOA1	Ser/Pl	<Standard>	(1)	(2)	(3)	(4)	(5)	(6)
x	XXXXX	XXXXX	Calib. Code**	501	424	424	424	424	424
x	XXXXX	XXXXX	Concentration†	0					
x	XXXXX	XXXXX	Position††						
x	XXXXX	XXXXX	Sample Volume	6.0	5.0	5.0	10.0	10.0	20.0
x	XXXXX	XXXXX	Diluent S.Vol	0.0	3.0	3.0	6.0	6.0	6.0
x	XXXXX	XXXXX	Diluent Volume	0	250	125	200	150	160
x	XXXXX	XXXXX							
x	XXXXX	XXXXX							
x	XXXXX	XXXXX							
x	XXXXX	XXXXX							
x	XXXXX	XXXXX							

Delete	Read
--------	------

\* User-definable.

\*\* Enter the calibrator code in the Calibration menu, Install screen, Add Calibrator window.

† Enter the calculated lot-specific calibrator values in the Calibration menu, Install screen, Edit Calibrator window.

†† When running non-barcoded calibrators, enter the standard positions in the Calibration menu, Calibrators screen, Assign Position window.

# Roche/Hitachi Instrument Settings

(917 continued)

## Procedure

### **Calibrators**

STD 1: Use 0.9% NaCl

Calibrator Code: 501

STD 2-6: Use C.f.a.s. Lipids

Calibrator Code: 424

(Multi-point calibration is achieved by instrument parameter settings.)

**NOTE:** Multiply the value in the C.f.a.s. Lipids calibrator package insert by the following factors to determine the calibrator values to enter in the Calibration menu, Install screen, Edit Calibrator window.

STD 2: 0.208

STD 3: 0.408

STD 4: 1.000

STD 5: 1.312

STD 6: 2.334

### **Calibration Frequency**

Calibration is automatically performed by the analyzer. A Full calibration occurs with each reagent lot change and should be requested as required following quality control procedures.

## Extended Reportable Range

The extended reportable range using automatic rerun is 10 - 400 mg/dL.

# Roche/Hitachi Instrument Settings

## MODULAR P

Application Code 168

Utility/Application Screen

Test		Analyze	Calib	Range	Others
1*	APOA1 Ser/Pl	<b>Assay/Time/Point</b>	2 Point End	10	16 25 0 0
2	xxxxx xxxxx	<b>Wavelength (2nd/Primary)</b>	700 340		
3	xxxxx xxxxx	<b>Sample Volume</b>			
4	xxxxx xxxxx	<b>Normal</b>	10.0 6.0 200		
5	xxxxx xxxxx	<b>Decrease</b>	10.0 6.0 200		
6	xxxxx xxxxx	<b>Increase</b>	20.0 6.0 200		
7	xxxxx xxxxx	<b>Reagent Volume</b>			
8	xxxxx xxxxx	<b>R1</b>	250 0 168 42	<b>Timing</b>	
9	xxxxx xxxxx	<b>R2</b>	0 0 168 0		T2
10	xxxxx xxxxx	<b>R3</b>	50 0 168 42		T3
11	xxxxx xxxxx	<b>R4</b>	0 0 168 0		
		<b>Diluent</b>			
		<input type="radio"/> Water			
		<input checked="" type="radio"/> Diluent	951 99		
		<b>Abs. Limit</b>	0 Increase		
		<b>Prozone Limit</b>	32000 0 0 0 0 Upper		
		<b>Cell Detergent</b>	Detergent 1		
		<b>Twin Test</b>	Cancel		

Utility/Application Screen

Test		Analyze	Calib	Range	Others
1*	APOA1 Ser/Pl	<b>Calibration Type</b>	Logit-Log (4P)		
2	xxxxx xxxxx	<b>Point</b>	6		
3	xxxxx xxxxx	<b>Span</b>	6		
4	xxxxx xxxxx	<b>Weight</b>	0		
5	xxxxx xxxxx	<b>Update Type</b>	None		
6	xxxxx xxxxx	<b>Isozyme Q Channel</b>	Cancel		
7	xxxxx xxxxx	<b>Auto Calibration</b>			
8	xxxxx xxxxx	<b>Timeout</b>			
9	xxxxx xxxxx	<input type="checkbox"/> Blank	1		
10	xxxxx xxxxx	<input type="checkbox"/> Span	1		
11	xxxxx xxxxx	<input type="checkbox"/> 2 Point	1		
		<input type="checkbox"/> Full	1		
		<b>Changeover</b>			
		<b>Module</b>	Cancel		
		<b>Lot</b>	Full		
		<b>Bottle</b>	Cancel		
		<b>SD Limit</b>	150		
		<b>Duplicate Limit</b>	10 % 30 Abs.		
		<b>Sensitivity Limit</b>	6 17		
		<b>S1Abs. Limit</b>	-32000 32000		

\* User-definable.

MODULAR P continued on next page

# Roche/Hitachi Instrument Settings

## MODULAR P

Utility/Application Screen

Test	
1*	APOA1 Ser/Pl
2	xxxxx xxxxx
3	xxxxx xxxxx
4	xxxxx xxxxx
5	xxxxx xxxxx
6	xxxxx xxxxx
7	xxxxx xxxxx
8	xxxxx xxxxx
9	xxxxx xxxxx
10	xxxxx xxxxx
11	xxxxx xxxxx

Analyze Calib **Range** Others

**Application Code** 168  
**Unit** mg/dL  
**Report Name** APOAT  
**Data Mode** Active  
**Technical Limit** 20 400  
**Repeat Limit\*** -99999 999999  
 **Control Interval Time** 0  
 **Qualitative**

(1)	0	--
(2)	0	-
(3)	0	+ -
(4)	0	++
(5)	0	+++
(6)		++++

**Expected Values**

**Male**

100	Years	-99999	999999**
100	Years	-99999	999999**
		-99999	999999**

**Female**

100	Years	-99999	999999**
100	Years	-99999	999999**
		-99999	999999**

**Default**

**Sex**

Male  Female

**Range**

Range 1  Range 2  Range 3

Utility/Application Screen

Test	
1*	APOA1 Ser/Pl
2	xxxxx xxxxx
3	xxxxx xxxxx
4	xxxxx xxxxx
5	xxxxx xxxxx
6	xxxxx xxxxx
7	xxxxx xxxxx
8	xxxxx xxxxx
9	xxxxx xxxxx
10	xxxxx xxxxx
11	xxxxx xxxxx

Analyze Calib **Range** Others

**Standards**

	(1)	(2)	(3)	(4)	(5)	(6)
<b>Calibrator Code†</b>	501	424	424	424	424	424
<b>Concentration††</b>	0					
<b>Rack No. - Pos.‡</b>						
<b>Sample Volume</b>	6.0	5.0	5.0	10.0	10.0	20.0
<b>Diluent S. Volume</b>	0.0	3.0	3.0	6.0	6.0	6.0
<b>Diluent Volume</b>	0	250	125	200	150	160

\* User definable.

\*\* If desired, the values of 104 - 202 for Male and 108 - 225 for Female may be entered.

† Enter the calibrator codes in the Calibration menu, Install screen, Add Calibrator window.

†† Enter the calculated lot-specific calibrator values in the Calibration menu, Install screen, Edit Calibrator window.

‡ When running a non-barcoded calibrator, enter the calibrator position in the Calibration menu, Calibrators screen, Calibrator Rack Assignment window.

MODULAR P continued on next page

# Roche/Hitachi Instrument Settings

(MODULAR P continued)

## Procedure

### **Calibrators**

STD 1: Use 0.9% NaCl

Calibrator Code: 501

STD 2-6: Use C.f.a.s. Lipids

Calibrator Code: 424

(Multi-point calibration is achieved by instrument parameter settings.)

**NOTE:** Multiply the value in the C.f.a.s. Lipids calibrator package insert by the following factors to determine the calibrator values to enter in the Calibration menu, Install screen, Edit Calibrator window.

STD 2: 0.208

STD 3: 0.408

STD 4: 1.000

STD 5: 1.312

STD 6: 2.334

### **Calibration Frequency**

Calibration is automatically performed by the analyzer. A Full calibration occurs with each reagent lot change and should be requested as required following quality control procedures.

## Extended Reportable Range

The extended reportable range using automatic rerun is 10 - 400 mg/dL.

# APO A-1 ver.2

Catalog No.

3032612

## Intended Use

Tina quant @ Apolipoprotein A-1 ver.2 is an immunoturbidimetric assay for the in vitro quantitative determination of apolipoprotein A-1 in human serum and plasma on automated clinical chemistry analyzers.

## Working Solution Preparation

R1 Stable 42 days refrigerated on the analyzer.

1 Ready for use.

R2 Stable 42 days refrigerated on the analyzer.

2 Ready or use.

## Specimen Collection and Preparation

**Serum/Plasma:** Use serum/plasma collected by standard venipuncture technique. Use Li-heparin, Na-heparin, NH<sub>4</sub>-heparin, Na<sub>2</sub>-EDTA, K<sub>2</sub>-EDTA or K<sub>3</sub>-EDTA plasma. Centrifuge samples containing precipitate before performing the assay.

**Storage:** 1 day at 20-25 °C, 3 days at 4-8 °C, or 2 months at -20 °C (only freeze once).

### Interference

Icterus: No significant interference from unconjugated and conjugated bilirubin up to an I index of 60.  
Hemolysis: No significant interference from hemoglobin up to an H index of 1000.  
Lipemia (Intralipid): No significant interference from lipemia up to an L index of 1000.

Refer to the Limitations section of this application sheet for additional information.

Take the following corrective action if a specimen is considered unacceptable:

\_\_\_\_\_  
\_\_\_\_\_

## Procedure

### Calibrators

STD 1/Blank: Use 0.9% NaCl  
Calibrator Code: 501  
STD 2-6: Use C.f.a.s. Lipids  
Calibrator Code: 424  
Cat. No. 2172623

### Calibration Frequency

Refer to the individual Instrument Settings pages of this application sheet for analyzer-specific calibration instructions.

Refer to the appropriate operator's manual for detailed calibration instructions. Take the following corrective action if calibration is unacceptable:

\_\_\_\_\_  
\_\_\_\_\_

### Quality Control

Precinorm L Catalog No. 781827  
Precipath L Catalog No. 1285874

Two levels (normal and abnormal) of other commercially available control material or laboratory-prepared control material may also be used.

\_\_\_\_\_  
\_\_\_\_\_

Refer to the appropriate value sheets/package inserts for additional information.

Each laboratory should establish its own control interval. Quality control should be performed a minimum of once daily and after every calibration.

\_\_\_\_\_  
\_\_\_\_\_

If controls do not recover within the specified limits, take the following corrective action:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## Reportable Range

20 - 400 mg/dL

### Extended Reportable Ranges

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

FOLD HERE

FOLD HERE

If manual dilution is necessary, dilute the specimen with 0.9% NaCl and reassay using routine (normal) sample volume. Multiply the result obtained from the manual dilution by the appropriate manual dilution factor.

### Laboratory Specific Expected Values

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

### Critical Values

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Follow this protocol if you obtain a critical value result:

\_\_\_\_\_  
\_\_\_\_\_

### Backup Methodology

\_\_\_\_\_  
\_\_\_\_\_

### Confirmatory Testing

\_\_\_\_\_  
\_\_\_\_\_

### Reviewed by

Name \_\_\_\_\_

Title \_\_\_\_\_

Date \_\_\_\_\_

Name \_\_\_\_\_

Title \_\_\_\_\_

Date \_\_\_\_\_

Name \_\_\_\_\_

Title \_\_\_\_\_

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Date \_\_\_\_\_

Name \_\_\_\_\_

Title \_\_\_\_\_

Date \_\_\_\_\_

Name \_\_\_\_\_

Title \_\_\_\_\_

Date \_\_\_\_\_

### Application Revision Record

Revision Number	Analyzers affected by the latest revision			
	911	912	917	MODULAR P
03515559001	.	.	.	.

The box above indicates the most current revision level of an application sheet applicable for a particular analyzer. When a change to an application sheet occurs, the revision number changes. However, the change in the application sheet may not be applicable to all analyzers. Therefore, the dots designate to which analyzer the revised application sheet pertains.

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03515559001-0103

This document complies with suggested guidelines recommended by current NCCLS GP-2 Standards.

