COMPLEMENT C3

This package insert contains information to run the Complement C3 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 1-5	Calibrators 1 through 5	REF	Catalog number/List number
CONC	Concentration	SN	Serial number
EC REP	Authorized Representative in the European Community		Consult instructions for use
INGRED	Ingredients		Manufacturer
IVD	In vitro diagnostic medical device		Temperature limitation
LOT	Batch code/Lot number		Use by/Expiration date
R1	Reagent 1		
R2	Reagent 2		

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Abbott Diagnostics

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NAME

COMPLEMENT C3

INTENDED USE

The Complement C3 (C3) assay is used for the quantitation of C3 in human serum or plasma.

SUMMARY AND EXPLANATION OF TEST

All complement proteins are acute phase reactants and rise rapidly in concentrations during inflammatory episodes. Conversely, the rates of complement protein catabolism may greatly increase in various autoimmune diseases. Because complement component determinations represent a static measurement of the net concentrations that result from a dynamic balance between component synthesis and catabolism, serial sample quantitations are more clinically useful.[1]

In most disease states, complement functions "normally" in producing inflammation and tissue damage. When complement plays a role in the development of a disease, it is often due to activation by an "abnormal" antibody, immune complex, or foreign material.[2]

Increased C3 levels are associated with acute phase reaction, rheumatic disease, viral hepatitis, myocardial infarction, cancer, diabetes, pregnancy, sarcoidosis, amyloidosis, thyroiditis, inflammatory bowel disease, typhoid fever, and pneumococcal pneumonia. The magnitude of C3 increase is rarely more than two-fold and may mask decreases in levels due to concurrent consumption.[3]

Decreased levels of C3 occur in individuals with congenital deficiency or immunologic diseases (where complement is consumed at an increased rate). C3 and/or complement C4 (C4) levels may be decreased in cases of: systemic lupus erythematosus (SLE) (especially with lupus nephritis), acute and chronic hypocomplementemic nephritis, infective endocarditis, disseminated intravascular coagulation (DIC) (especially with hemolytic uremic syndrome form), and partial lipodystrophy (with associated nephritis-like activity in serum). Cases of hereditary C3 deficiency, while rare, are characterized clinically by recurrent infection and by immune complex disease, in particular, membranoproliferative glomerulonephritis. The central role of C3 in both classical and alternate pathways, results in C3 deficient patients being at risk for especially severe infections by encapsulated bacteria such as *S. pneumoniae*, *H. influenzae*, and *N. meningitidis*. Bacteremia, sinopulmonary infections, meningitis, paronychia, and impetigo may occur. Deficient C3 levels have also been found in cases of uremia, chronic liver diseases, anorexia nervosa, and celiac disease.[1]

Refer to the following table for a general guide to evaluation of C3 and C4 protein levels in the presence of decreased hemolytic complement activity:[1]

	Normal C4	Decreased C4
Normal C3	• Alterations in vitro (e.g., improper specimen handling) • Coagulation-associated complement consumption • Inborn errors (other than C3 or C4)	• Immune complex disease • Hypergammaglobulinemic states • Cryoglobulinemia • Hereditary angioedema • Inborn C4 deficiency
Decreased C3	• Acute glomerulonephritis • Membranoproliferative glomerulonephritis • Immune complex disease • Active SLE • Inborn C3 deficiency	• Active SLE • Serum sickness • Autoimmune/chronic active hepatitis • Infective endocarditis • Immune complex disease

PRINCIPLES OF PROCEDURE

The C3 assay is an immunoturbidimetric procedure that measures increasing sample turbidity caused by the formation of insoluble immune complexes when antibody to C3 is added to the sample. Sample containing C3 is incubated with a buffer R1 and a sample blank determination is performed prior to the addition of C3 antibody R2. In the presence of an appropriate antibody in excess, the C3 concentration is measured as a function of turbidity.

Methodology: Immunoturbidimetric

REAGENTS

Reagent Kit

REF 9D96 Complement C3 is supplied as a liquid, ready-to-use, two-reagent kit which contains:

R1 3 x 20 mL
R2 3 x 8 mL

Estimated tests per kit: 279

Calculation is based on the minimum reagent fill volume per kit.

	Reactive Ingredients	Concentration
R1	TRIS	100 mmol/L
	Polyethylene Glycol	40 g/L
	Sodium Azide	0.1%
R2	Anti-human complement C3 goat serum	35%
	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.[4] Biosafety Level 2[5] or other appropriate biosafety practices[6,7] should be used for materials that contain or are suspected of containing infectious agents.
6. R1 and R2 contain 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 reagents 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.

- **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 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	8 days	8, 9
-20°C	8 days	8

Guder et al.[8] 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 9D96 Complement C3 Reagent Kit

Materials Required but not Provided

- REF 1E78 Specific Proteins Multiconstituent Calibrator, CAL 1-5 1 x 1 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 C3 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 1:2 dilution of the specimen and automatically corrects the concentration by multiplying the result by the appropriate dilution factor.

PROCEDURE (Continued)

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 1,065 mg/dL (10.65 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 57 days (1,368 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 (Spline) curve is generated using Specific Proteins Multiconstituent 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 Specific Proteins Multiconstituent 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 C3 on an analyzer other than the ARCHITECT *c* Systems or the AEROSET System must be validated and verified.

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.[10]

Turbidity and particles in the samples can interfere with the assay. Therefore, particulate matter should be removed by centrifugation prior to running the assay.

EXPECTED VALUES

Reference Range

Serum/Plasma[11]

	Range* (mg/dL)	Range* (g/L)
1 to 14 years		
Male	80 to 170	0.80 to 1.70
Female	82 to 173	0.82 to 1.73
> 14 to 80 years		
Male	82 to 185	0.82 to 1.85
Female	83 to 193	0.83 to 1.93

* Reference ranges are based on a 95% confidence interval for a large North American caucasian population.

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

Confirmation of the reference ranges for individuals between the ages of 14 and 80 years was conducted using serum samples from 25 males and 52 females, based on Clinical and Laboratory Standards Institute (CLSI) protocol NCCLS C28-A2.[12]

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 C3 assay reportable range is from 11 mg/dL (0.11 g/L) to the highest calibrator concentration. Human serum containing a known concentration of C3 was diluted with saline and the resulting samples were analyzed. Observed mean results across the reportable range were within 5 mg/dL (0.05 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*
3.5	3.2	-0.3	91.7
4.6	4.9	0.3	106.7
10.6	10.5	-0.1	99.1
17.7	17.9	0.2	101.1
35.4	33.3	-2.1	94.0
141.6	135.1	-6.6	95.4
212.4	205.9	-6.5	96.9
283.2	282.1	-1.1	99.6
354.1	350.7	-3.4	99.1

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

Limit of Quantitation (LOQ)

The LOQ for C3 is ≤ 5 mg/dL (0.05 g/L). The LOQ is the analyte concentration at which the CV = 20%. Performance studies produced an LOQ of 1.4 mg/dL (0.014 g/L).

Interfering Substances

Interference studies were conducted using CLSI protocol NCCLS EP7-P.[13] Interference effects were assessed by Dose Response and Paired Difference methods, at two medical decision levels of the analyte.

Medical Decision Level 1

Interfering Substance	Interferent Concentration	N	Target (mg/dL)	Observed (% of Target)
Bilirubin	30 mg/dL (513 µmol/L)	4	72.4	97.6
	60 mg/dL (1,026 µmol/L)	4	72.4	96.1
Hemoglobin	1,000 mg/dL (10.0 g/L)	4	60.4	94.0
	2,000 mg/dL (20.0 g/L)	4	60.4	95.9
Human triglyceride	750 mg/dL (8.5 mmol/L)	4	75.7	104.8
	1,000 mg/dL (11.3 mmol/L)	4	75.7	102.2
Intralipid	1,000 mg/dL (10.0 g/L)	4	63.4	98.0
	2,000 mg/dL (20.0 g/L)	4	63.4	89.0

SPECIFIC PERFORMANCE CHARACTERISTICS (Continued)

Interfering Substances (Continued)

Medical Decision Level 2

Interfering Substance	Interferent Concentration	N	Target (mg/dL)	Observed (% of Target)
Bilirubin	30 mg/dL (513 µmol/L)	4	174.7	99.9
	60 mg/dL (1,026 µmol/L)	4	174.7	97.8
Hemoglobin	1,000 mg/dL (10.0 g/L)	4	187.1	98.5
	2,000 mg/dL (20.0 g/L)	4	187.1	99.4
Human triglyceride	750 mg/dL (8.5 mmol/L)	4	182.7	99.6
	1,000 mg/dL (11.3 mmol/L)	4	182.7	98.4
Intralipid	1,000 mg/dL (10.0 g/L)	4	170.8	100.2
	2,000 mg/dL (20.0 g/L)	4	170.8	97.8

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 C3 assay is ≤ 3.9% Total CV. Representative data from studies using CLSI protocols NCCLS EP5-T2[14] and EP5-A[15] are summarized below.

Control		Level 1	Level 2	Level 3
N		80	80	80
Mean (mg/dL)		68.3	138.5	201.7
Within Run	SD	1.53	1.73	2.51
	%CV	2.2	1.3	1.2
Between Run	SD	0.41	0.14	2.15
	%CV	0.6	0.1	1.1
Between Day	SD	1.40	0.67	5.60
	%CV	2.0	0.5	2.8
Total	SD	2.11	1.85	6.50
	%CV	3.1	1.3	3.2

Method Comparison

Correlation studies were performed using CLSI protocol NCCLS EP9-A.[16]

Serum results from the C3 assay on the AEROSET System were compared with those from a commercially available immunoturbidimetric methodology.

Serum results from the C3 assay on an ARCHITECT *c* System were compared with the C3 assay on the AEROSET System.

	AEROSET vs. Comparative Method	ARCHITECT vs. AEROSET
N	80	99
Y - Intercept	7.73	3.97
Correlation Coefficient	0.994	0.999
Slope	1.03	0.94
Mean %Bias	8.3	-2.7
Range (mg/dL)	27.8 to 235.6	12.0 to 357.1

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16. Kennedy JW, Carey RN, Coolen RB, et al. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline (EP9-A)*. Wayne, PA: The National Committee for Clinical Laboratory Standards, 1995.

TRADEMARKS

ARCHITECT®

Complement C3 Serum/Plasma—Conventional and SI Units

Configure assay parameters — General

● General O Calibration O SmartWash O Results O Interpretation

Assay: **C3** Type: **Photometric** Version: †
Number: **1055**

● 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:	**C3000**			Reagent volume:		**167**	**47**
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 :	**3.0**	___	___	___	=	**1:1.00**	●
1:2 :	**25.0**	**6.0**	**75**	___	=	**1:2.03**	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: **C3** Calibration method: **Spline**

● Calibrators O Volumes O Intervals O Validity checks

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

Calibrator level:	Concentration:
Blank: **Water**	**0**††
Cal 1: **SP1**	‡
Cal 2: **SP2**	‡
Cal 3: **SP3**	‡
Cal 4: **SP4**	‡
Cal 5: **SP5**	‡

O Calibrators ● Volumes O Intervals O Validity checks

Calibrator: **SP**

Calibrator level	Sample	Diluted sample	Diluent	Water
Blank: **Water**	**3.0**	___	___	___
Cal 1: **SP1**	**3.0**	___	___	___
Cal 2: **SP2**	**3.0**	___	___	___
Cal 3: **SP3**	**3.0**	___	___	___
Cal 4: **SP4**	**3.0**	___	___	___
Cal 5: **SP5**	**3.0**	___	___	___

O Calibrators O Volumes ● Intervals O Validity checks

Calibration intervals:
Full interval: **1368** (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: **C3**

COMPONENT	REAGENT / ASSAY	WASH	Volume	Replicates
Cuvette	**Trig**	**10% Detergent B*** **	**345**	

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

Complement C3 Serum/Plasma—Conventional Units

Configure assay parameters — Results

O General O Calibration O SmartWash ● Results O Interpretation

Assay: **C3** Result units: **mg/dL**
Assay defaults:
Low-Linearity: **11**
High-Linearity: **315**‡‡
Gender and age specific ranges:*

GENDER	AGE (UNITS)	NORMAL**	EXTREME
Male	**0 – 130 (Y)**	**82 – 185**	
Female	**0 – 130 (Y)**	**83 – 193**	
Either	**0 – 130 (Y)**	**82 – 193**	

Configure result units

Assay: **C3**
Version: †
Result units: **mg/dL**
Decimal places: **0** [Range 0 – 4]
Correlation factor: **1.0000**
Intercept: **0.0000**

Complement C3 Serum/Plasma—SI Units

Configure assay parameters — Results

O General O Calibration O SmartWash ● Results O Interpretation

Assay: **C3** Result units: **g/L**
Assay defaults:
Low-Linearity: **0.11**
High-Linearity: **3.15**‡‡
Gender and age specific ranges:*

GENDER	AGE (UNITS)	NORMAL**	EXTREME
Male	**0 – 130 (Y)**	**0.82 – 1.85**	
Female	**0 – 130 (Y)**	**0.83 – 1.93**	
Either	**0 – 130 (Y)**	**0.82 – 1.93**	

Configure result units

Assay: **C3**
Version: †
Result units: **g/L**
Decimal places: **2** [Range 0 – 4]
Correlation factor: **1.0000**
Intercept: **0.0000**

* User defined.
** Reference range is from > 14 years to 80 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®

Complement C3 Serum/Plasma—Conventional Units

Assay Configuration: Outline Page

Assay Name	Assay #	Line
C3	55	A-Line

Quantitative Ranges

Min Text	Min	Panic-L	L-Reference-H**	Panic-H	Max	Max Text
*	0.0*	0.0	82	193	0.0	0.0*	*
		11	L-Linear Range-H	315‡‡		

Reference Ranges*

Age	Male	Female
0 Year	82 – 185	83 – 193
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**
C3 (55)	14 – 16	0 – 0	0.0 – 0.0

	S.Vol	DS.Vol	D.Vol	W.Vol		Rgt Name/Pos
Standard	3.0	0.0	0	0		
Dil 1	25.0	6.0	75	0	**Diluent:**	DILUENT C–10*
Dil 2	3.0	0.0	0	0	**Type#**	0

	Rgt Name/Pos	R.Vol	W.Vol	Type#
Reagent 1	C300011 – ___*	167	0	0
Reagent 2	C300012 – ___*	47	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)	
Spline					1368	
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	3.0	0.0	0	0	0.0 – 0.0
C1	SP 1	3.0	0.0	0	0	**Cal Deviation**
C2	SP 2	3.0	0.0	0	0	0.0
C3	SP 3	3.0	0.0	0	0	**FAC Limit (%)**
C4	SP 4	3.0	0.0	0	0	10
C5	SP 5	3.0	0.0	0	0	

Assay Configuration: SmartWash Page

Rgt Probe	Reagent	Wash	Vol
	—	—	—

Cuvette	Assay Name	Wash	Vol
	—	—	—

Sample Probe	Wash
	—

Complement C3 Serum/Plasma—SI Units

Assay Configuration: Outline Page

Assay Name	Assay #	Line
C3	55	A-Line

Quantitative Ranges

Min Text	Min	Panic-L	L-Reference-H**	Panic-H	Max	Max Text
*	0.0*	0.0	0.82	1.93	0.0	0.0*	*
		0.11	L-Linear Range-H	3.15‡‡		

Reference Ranges*

Age	Male	Female
0 Year	0.82 – 1.85	0.83 – 1.93
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**
C3 (55)	14 – 16	0 – 0	0.0 – 0.0

	S.Vol	DS.Vol	D.Vol	W.Vol		Rgt Name/Pos
Standard	3.0	0.0	0	0		
Dil 1	25.0	6.0	75	0	**Diluent:**	DILUENT C–10*
Dil 2	3.0	0.0	0	0	**Type#**	0

	Rgt Name/Pos	R.Vol	W.Vol	Type#
Reagent 1	C300011 – ___*	167	0	0
Reagent 2	C300012 – ___*	47	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)	
Spline					1368	
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	3.0	0.0	0	0	0.0 – 0.0
C1	SP 1	3.0	0.0	0	0	**Cal Deviation**
C2	SP 2	3.0	0.0	0	0	0.0
C3	SP 3	3.0	0.0	0	0	**FAC Limit (%)**
C4	SP 4	3.0	0.0	0	0	10
C5	SP 5	3.0	0.0	0	0	

Assay Configuration: SmartWash Page

Rgt Probe	Reagent	Wash	Vol
	—	—	—

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 > 14 years to 80 years of age.

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