CLINICAL CHEMISTRY

ARCHITECT / AEROSET

IMMUNOGLOBULIN G

This package insert contains information to run the Immunoglobulin G 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

NAME

IMMUNOGLOBULIN G

INTENDED USE

The Immunoglobulin G (IgG) assay is used for the quantitation of IgG in human serum or plasma.

SUMMARY AND EXPLANATION OF TEST

IgG is the major immunoglobulin in the blood and is produced in copious amounts during secondary immune responses. IgG molecules bind to specific receptors on phagocytic cells, such as macrophages and polymorphonuclear leukocytes, thereby increasing the efficiency with which the phagocytic cells can ingest and destroy infecting microorganisms that have become coated with IgG antibodies in response to the infection. Additionally, IgG molecules can bind to and thereby activate the first component of the complement system, which under these circumstances unleashes a biochemical attack that kills the microorganisms. IgG molecules are the only antibodies that can pass from mother to fetus. The ability of IgG to cross the placenta provides a major line of defense against infection for the first weeks of an infant's life. IgG is the predominant extravascular immunoglobulin and functions to neutralize bacterial toxins and bind most types of microorganisms to facilitate phagocytosis. Additionally, IgG antibodies can bind to target cells such as tumor cells to sensitize them for destruction by killer (K) cells that have IgG-specific receptor sites.[1]

Quantitation of IgG can be used to evaluate humoral immunity; establish diagnosis and monitor therapy in IgG myeloma; and evaluate patients, especially children and those with lymphoma, with propensity to infections. Reduction of IgG, usually less than 300 mg/dL (3.0 g/L), leads to susceptibility to infection due to encapsulated bacteria.[2]

IgG deficiencies may be genetic or acquired. Conditions associated with acquired IgG deficiency include thermal burns, pemphigus, nephrotic syndrome, protein-losing enteropathies, non-IgG myelomas or macroglobulinemia, pregnancy, Wiskott-Aldrich syndrome, myotonic dystrophy, anti-immunoglobulin antibodies, immunosuppressive therapy, and monoclonal gammopathies involving non-IgG immunoglobulins. IgG values in AIDS and AIDS-related complex can span the range from severe immunodeficiency to hyperimmunoglobulinemia, depending on clinical state and disease stage.

Elevated IgG levels can be polyclonal, oligoclonal, or monoclonal. Elevated polyclonal IgG levels are associated with autoimmune diseases (systemic lupus erythematosus, rheumatoid arthritis, Sjogren's syndrome), sarcoidosis, chronic liver disease, some parasitic diseases, chronic or recurrent infections, and intrauterine contraceptive devices. Increased oligoclonal IgG levels are associated with malignancies, infections (especially in the elderly), some dysgammaglobulinemias, and autoimmune disorders. Increased monoclonal IgG levels are associated with multiple myeloma (IgG type), lymphomas, and leukemia.[3]

PRINCIPLES OF PROCEDURE

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

Methodology: Immunoturbidimetric

REAGENTS

Reagent Kit

REF 9D99 Immunoglobulin G is supplied as a liquid, ready-to-use, two-reagent kit which contains:

R1 4 x 20 mL
R2 4 x 20 mL

Estimated tests per kit: 388

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 IgG goat serum	20%
	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 23 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 are 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. This product contains sodium azide. For a specific listing, refer to the REAGENTS section of this package insert. 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.

- **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. When processing samples, separate serum from blood cells or gel according to the specimen collection tube manufacturer's instructions.

  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. When processing samples, separate plasma from blood cells or gel according to the specimen collection tube manufacturer's instructions.

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
20 to 25˚C	4 months	8
2 to 8˚C	8 months	8, 9
-20˚C	8 months	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 9D99 Immunoglobulin G 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

The IgG assay uses a standard undiluted sample. Samples with low IgG concentrations are rerun using a 3:1 dilution (three times the sample volume).

IgG is analyzed as follows:

- The sample is run undiluted.
- If the patient result flag "<" (ARCHITECT *c* Systems) or an LL result error code (AEROSET) is generated, the system can be configured to automatically rerun the sample 3:1.

  Refer to the instrument-specific Configuration instructions that follow and *Section 2* of the instrument-specific operations manual.
- If the system is not configured to automatically rerun the sample, a rerun must be ordered by the operator using 3:1 (ARCHITECT *c* Systems) or Dil 1 (AEROSET) dilution protocol.

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

Configuration

To automatically rerun the sample 3:1, perform the following instrument-specific steps. Refer to *Section 2* of the instrument-specific operations manual for additional information.

ARCHITECT *c* Systems—Configure Retest Rules

1. Select **System** from the menu bar, and then select **Configuration**.
2. Select the **Assay settings** option.
   The Configuration screen - Assay settings - Assay Parameters view displays.
3. Select **Retest rules** from the **Assay categories** list on the Configuration screen.
4. Select **IgG** from the **Assays** list, and then select **F6 - Configure**.
5. Select **Add rule**.
6. Enter a name in the **Rule name** data entry box.
7. Enter the number of replicates in the **Replicates** data entry box, or leave as 1.
8. Ensure that the **Result range** option is selected.
   - Edit the first **Result range** data entry box to be blank.
   - Enter **320** mg/dL (**3.20** g/L) in the second **Result range** data entry box.

NOTE: If the reporting units are changed, the Result range values must be edited with the appropriate conversion factor.

9. Select **STANDARD** as the **Original dilution** option.
10. Select **3:1** as the **Retest dilution** option.
11. Select **Done** to return to the Add / edit assay retest rules window.
12. Select **Done** to save your changes.

PROCEDURE (Continued)

AEROSET System—Configure Auto Rerun

1. Select <**RUN**> in the Action Area of the Main Display. The **RUN OPTIONS** screen displays.
2. Select <**SysCfg**> in the right column of the **RUN OPTIONS** screen. The **SYSTEM CONFIGURATION** screen displays.
3. Select the Auto Rerun option.
4. Select <**OK**> to save the settings.

Refer to the AEROSET SYSTEM ASSAY PARAMETERS section of this package insert for IgG Rerun Rules configuration.

NOTE: Samples are not automatically returned to the sample arm unless the Auto Return option is selected on the **RUN OPTIONS** screen.

NOTE: For AEROSET Software v1.03ER000 or higher, Auto Rerun is not performed on non-bar code labeled samples; reruns must be requested manually.

Specimen Dilution Procedures (for samples above the reportable range)

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 IgG values exceeding the highest calibrator are flagged and may be diluted by following either 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 using 1:4 (ARCHITECT *c* Systems) or Dil 2 (AEROSET) 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 EXT and LH result error codes (AEROSET) may indicate antigen excess. Dilute sample and rerun. Samples were tested for antigen excess up to 9,482 mg/dL (94.82 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 23 days (552 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 IgG on an analyzer other than the ARCHITECT *c* Systems or the AEROSET System must be validated and verified.

Results from samples containing paraproteins (abnormal monoclonal antibodies) may incorrectly fall within the reference range. Samples with elevated total protein concentrations or samples from patients with suspected paraproteinemia can be screened using other laboratory methods such as protein electrophoresis. In addition, analysis of one or more diluted samples should be performed to ensure that consistent results are obtained.[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)
0 to 1 month		
Male	397 to 1,765	3.97 to 17.65
Female	391 to 1,737	3.91 to 17.37
> 1 month to 1 year		
Male	205 to 948	2.05 to 9.48
Female	203 to 934	2.03 to 9.34
> 1 to 2 years		
Male	475 to 1,210	4.75 to 12.10
Female	483 to 1,226	4.83 to 12.26
> 2 to 80 years		
Male	540 to 1,822	5.40 to 18.22
Female	552 to 1,631	5.52 to 16.31

* Reference ranges are based on a 90% confidence interval for a large North American caucasian population.

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.[12] From this study, 95% of all specimens fell within 757.8 to 1,941.1 mg/dL (7.58 to 19.41 g/L), with samples ranging from 652.2 to 2,105.8 mg/dL (6.52 to 21.06 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 IgG assay reportable range is from 109 mg/dL (1.09 g/L) to 320 mg/dL (3.20 g/L) using the Dil 1 sample mode and from 320 mg/dL (3.20 g/L) to the highest calibrator concentration when using the Standard sample mode. Human serum containing a known concentration of IgG was diluted with saline and the resulting samples were analyzed. Observed mean results across the reportable range were within 16 mg/dL (0.16 g/L) or 8%, whichever is greater, of the target concentrations. Representative data are summarized below.

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

Sample	Target Concentration (mg/dL)	Observed Mean (mg/dL)	Delta* (mg/dL)	Percent (%) Recovery*
1**	93.6	80.9	-12.8	86.4
2**	124.8	114.9	-9.9	92.1
3**	187.2	184.6	-2.7	98.6
4**	249.6	244.6	-5.0	98.0
5	312.0	288.9	-23.1	92.6
6	386.7	369.6	-17.0	95.6
7	773.3	750.5	-22.8	97.1
8	1,546.6	1,576.2	29.6	101.9
9	2,080.0	2,109.9	29.9	101.4
10	2,319.9	2,384.8	64.9	102.8
11	3,093.2	3,184.3	91.1	103.0
12	3,866.5	4,012.2	145.7	103.8

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

** Run with 3:1 sample ratio.

Limit of Quantitation

The LOQ for IgG is ≤ 61 mg/dL (0.61 g/L). The LOQ is the analyte concentration at which the CV = 20%. Performance studies produced an LOQ of 8.5 mg/dL (0.085 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	695.7	98.18
	60 mg/dL (1,026 µmol/L)	4	695.7	96.32
Hemoglobin	1,000 mg/dL (10.0 g/L)	4	582.9	98.70
	2,000 mg/dL (20.0 g/L)	4	582.9	96.64
Human triglyceride	750 mg/dL (8.5 mmol/L)	4	875.8	99.99
	1,000 mg/dL (11.3 mmol/L)	4	875.8	99.35
Intralipid	1,000 mg/dL (10.0 g/L)	4	668.0	100.7
	2,000 mg/dL (20.0 g/L)	4	668.0	101.3

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	1,934.1	98.62
	60 mg/dL	(1,026 µmol/L)	4	1,934.1	98.19
Hemoglobin	1,000 mg/dL	(10.0 g/L)	4	1,624.2	101.00
	2,000 mg/dL	(20.0 g/L)	4	1,624.2	101.41
Human triglyceride	750 mg/dL	(8.5 mmol/L)	4	2,025.2	95.90
	1,000 mg/dL	(11.3 mmol/L)	4	2,025.2	92.97
Intralipid	1,000 mg/dL	(10.0 g/L)	4	1,849.2	100.7
	2,000 mg/dL	(20.0 g/L)	4	1,849.2	100.5

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 IgG assay is ≤ 3.4% 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)		948.3	1,639	2,993.1
Within Run	SD	10.08	22.64	81.93
	%CV	1.1	1.4	2.7
Between Run	SD	16.10	20.29	5.94
	%CV	1.7	1.2	0.2
Between Day	SD	6.70	5.19	38.88
	%CV	0.7	0.3	1.3
Total	SD	20.14	30.84	90.88
	%CV	2.1	1.9	3.0

Method Comparison

Correlation studies were performed using CLSI protocol NCCLS EP9-A.[16] Serum results from the IgG assay on the AEROSET System were compared with those from a commercially available immunoturbidimetric methodology.

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

	AEROSET vs. Comparative Method	ARCHITECT vs. AEROSET
N	73	97
Y - Intercept	40.56	-8.76
Correlation Coefficient	0.997	0.999
Slope	0.96	0.99
Mean %Bias	-1.2	-1.5
Range (mg/dL)	401.6 to 2,943.6	123.8 to 3,856.2

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ARCHITECT

Immunoglobulin G Serum/Plasma—Conventional and SI Units

Configure assay parameters — General

● General O Calibration O SmartWash O Results O Interpretation

Assay: **IgG** Type: **Photometric** Version: †
Number: **1058**

● Reaction definition O Reagent / Sample O Validity checks

Reaction mode: **End up**
Primary Secondary Read times
Wavelength: **700** / **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:	**IGG00**	Reagent volume:	**160**	**160**
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 :	**2.7**	___	___	___ =	**1:1.00**	●
3:1 :	**8.1**	___	___	___ =	**1:0.34**	O
1:4 :	**25.0**	**2.7**	**75**	___ =	**1:4.00**	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: **IgG** 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**	**2.7**	___	___	___
Cal 1: **SP1**	**2.7**	___	___	___
Cal 2: **SP2**	**2.7**	___	___	___
Cal 3: **SP3**	**2.7**	___	___	___
Cal 4: **SP4**	**2.7**	___	___	___
Cal 5: **SP5**	**2.7**	___	___	___

O Calibrators O Volumes ● Intervals O Validity checks

Calibration intervals:
Full interval: **552** (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: **IgG**

COMPONENT	REAGENT / ASSAY	WASH	Volume	Replicates
R1	**DIG00**	**Detergent A**	**345**	**1**
R1	**AMIK9**	**Detergent A**	**345**	**1**
R1	**VANCO**	**Detergent A**	**345**	**1**
R1	**GENT9**	**Detergent A**	**345**	**1**
R1	**TOBRA**	**Detergent A**	**345**	**1**
R1	**DGT0B**	**Detergent A**	**345**	**1**
R2	**DIG00**	**Detergent A**	**345**	**1**
R2	**AMIK9**	**Detergent A**	**345**	**1**
R2	**VANCO**	**Detergent A**	**345**	**1**
R2	**GENT9**	**Detergent A**	**345**	**1**
R2	**TOBRA**	**Detergent A**	**345**	**1**
R2	**DGT0B**	**Detergent A**	**345**	**1**
Cuvette	**Trig**	**10% Detergent B**	**345**	

Immunoglobulin G Serum/Plasma—Conventional Units

Configure assay parameters — Results

O General O Calibration O SmartWash ● Results O Interpretation

Assay: **IgG** Assay number: **1058**
Dilution default range: Result units: **mg/dL**
Low-Linearity: **320**
High-Linearity: **3825**‡‡
Gender and age specific ranges:*

GENDER	AGE (UNITS)	NORMAL**	EXTREME
Male	**0 – 130 (Y)**	**540 – 1822**	
Female	**0 – 130 (Y)**	**552 – 1631**	
Either	**0 – 130 (Y)**	**540 – 1822**	

Configure result units

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

Immunoglobulin G Serum/Plasma—SI Units

Configure assay parameters — Results

O General O Calibration O SmartWash ● Results O Interpretation

Assay: **IgG** Assay number: **1058**
Dilution default range: Result units: **g/L**
Low-Linearity: **3.20**
High-Linearity: **38.25**‡‡
Gender and age specific ranges:*

GENDER	AGE (UNITS)	NORMAL**	EXTREME
Male	**0 – 130 (Y)**	**5.40 – 18.22**	
Female	**0 – 130 (Y)**	**5.52 – 16.31**	
Either	**0 – 130 (Y)**	**5.40 – 18.22**	

Configure result units

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

† 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 the concentration specified in the calibrator value sheet. In ARCHITECT software version 5.00 and above, these values are defined on the ‡ Configure calibrator screen.
‡‡ Edit to highest calibrator concentration specified in the calibrator value sheet.
* User defined.
** Reference range is from > 2 years to 80 years of age.

AEROSET SYSTEM ASSAY PARAMETERS

AEROSET

Immunoglobulin G Serum/Plasma—Conventional Units

Assay Configuration: Outline Page

Assay Name	Assay #	Line
IgG	58	A-Line

Quantitative Ranges

Min Text	Min	Panic-L	L-Reference-H**	Panic-H	Max	Max Text
*	0.0*	0.0	540	1822	0.0	0.0*	*
		320	L-Linear Range-H	3825‡‡		

Reference Ranges*

Age	Male	Female
0 Year	540 – 1822	552 – 1631
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	700 / ___	31 – 33 / 0 – 0	0.0
Sample Blank Test	**Blank Read Time**	**Abs Window**	**Abs Limits**
IgG (58)	14 – 16	0 – 0	0.0 – 0.0

	S.Vol	DS.Vol	D.Vol	W.Vol		Rgt Name/Pos
Standard	2.7	0.0	0	0		
Dil 1	8.1	0.0	0	0	Diluent:	DILUENT C–10*
Dil 2	25.0	2.7	75	0	Type#	0

	Rgt Name/Pos	R.Vol	W.Vol	Type#
Reagent 1	IGG0011 – ___*	160	0	0
Reagent 2	IGG0012 – ___*	160	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					552	
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	2.7	0.0	0	0	0.0 – 0.0
C1	SP 1	2.7	0.0	0	0	**Cal Deviation**
C2	SP 2	2.7	0.0	0	0	0.0
C3	SP 3	2.7	0.0	0	0	**FAC Limit (%)**
C4	SP 4	2.7	0.0	0	0	10
C5	SP 5	2.7	0.0	0	0	

Assay Configuration: SmartWash Page

Rgt Probe

Reagent	Wash	Vol
DIG0051	AlkW	345
DIG0012	AlkW	345
AMIK941	AlkW	345
AMIK942	AlkW	345
VANCO51	AlkW	345
VANCO52	AlkW	345
TOBRA41	AlkW	345
TOBRA42	AlkW	345
DGT0B11	AlkW	345
DGT0B12	AlkW	345

Cuvette

Assay Name	Wash	Vol
—	—	—

Sample Probe

Wash
—

Assay Configuration: Rerun Rules Page

LL : Linear Low Dil 1

Immunoglobulin G Serum/Plasma—SI Units

Assay Configuration: Outline Page

Assay Name	Assay #	Line
IgG	58	A-Line

Quantitative Ranges

Min Text	Min	Panic-L	L-Reference-H**	Panic-H	Max	Max Text
*	0.0*	0.0	5.40	18.22	0.0	0.0*	*
		3.20	L-Linear Range-H	38.25‡‡		

Reference Ranges*

Age	Male	Female
0 Year	5.40 – 18.22	5.52 – 16.31
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	700 / ___	31 – 33 / 0 – 0	0.0
Sample Blank Test	**Blank Read Time**	**Abs Window**	**Abs Limits**
IgG (58)	14 – 16	0 – 0	0.0 – 0.0

	S.Vol	DS.Vol	D.Vol	W.Vol		Rgt Name/Pos
Standard	2.7	0.0	0	0		
Dil 1	8.1	0.0	0	0	Diluent:	DILUENT C–10*
Dil 2	25.0	2.7	75	0	Type#	0

	Rgt Name/Pos	R.Vol	W.Vol	Type#
Reagent 1	IGG0011 – ___*	160	0	0
Reagent 2	IGG0012 – ___*	160	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					552	
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	2.7	0.0	0	0	0.0 – 0.0
C1	SP 1	2.7	0.0	0	0	**Cal Deviation**
C2	SP 2	2.7	0.0	0	0	0.0
C3	SP 3	2.7	0.0	0	0	**FAC Limit (%)**
C4	SP 4	2.7	0.0	0	0	10
C5	SP 5	2.7	0.0	0	0	

Assay Configuration: SmartWash Page

Rgt Probe

Reagent	Wash	Vol
DIG0051	AlkW	345
DIG0012	AlkW	345
AMIK941	AlkW	345
AMIK942	AlkW	345
VANCO51	AlkW	345
VANCO52	AlkW	345
TOBRA41	AlkW	345
TOBRA42	AlkW	345
DGT0B11	AlkW	345
DGT0B12	AlkW	345

Cuvette

Assay Name	Wash	Vol
—	—	—

Sample Probe

Wash
—

Assay Configuration: Rerun Rules Page

LL : Linear Low Dil 1

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 > 2 years to 80 years of age.

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