

AIA-360 Assay Specifications

ST IgE II Test Code 077

No.	Item	Data
1	Calib. Req	Show
2	Cal 1	0 IU/mL
3	Cal 2	50 IU/mL (example)
4	Cal 3	300 IU/mL (example)
5	Cal 4	1000 IU/mL (example)
6	Cal 5	2500 IU/mL (example)
7	Cal 6	4000 IU/mL (example)
8	Cal Lot L	
9	Cal Lot R	
10	Unit	IU/mL
11	Smpl. Vol	10
12	Dil. Vol	100
13	Assay L	3.0
14	Assay H	4000
15	Ref. L	
16	Ref. H	
17	Decimal	1

Visible only in Test Mode

18	Test Name	#IgE2
19	Calib. No	6
20	Calib. Mul	3
21	Calib. Equ	3
22	Calib. CV	90
23	Assay Prtl	1
24	Factor1 A	1.000000
25	Factor1 B	0.000000
26	Factor2 A	1.000000
27	Factor2 B	0.000000
28	V. Conc	0.000000
29	G Origin	0.000000

AIA-900 Assay Specifications

ST IgE II Test Code 077

No.	Item	Data
1	Code	77
2	ACT	1
3	Analyte	#IgE2
4	Lot	***Enter current cal lot no.
5	CAL 1	0 IU/mL
6	CAL 2	50 IU/mL (example)
7	CAL 3	300 IU/mL (example)
8	CAL 4	1000 IU/mL (example)
9	CAL 5	2500 IU/mL (example)
10	CAL 6	4000 IU/mL (example)
11	Cal lot L	
12	Cal lot R	
13	Unit	IU/mL
14	Decimal	1
15	Assay Low	3.0
16	Assay High	4000
17	Reference Low	
18	Reference High	
19	Reschedule Low	3.0
20	Reschedule High	4000
21	Factor A	1
22	Factor B	0
23	Sample Volume	10
24	Diluent Volume	100
25	2 Step reagent dispensing volume	0
26	Calibration code	94
27	CAL. No.	6
28	CAL. MUL.	3
29	CAL. EQU.	3
30	CAL. CV	90
31	DIL. SP1	1
32	DIL. SP2	1
33	DIL. CAL. (Calculation of dil ratio of conc.)	1
34	DIL. CNTL.	1
35	DIL. DO	10
36	DIL. AH.	5
37	DIL. CALC.	1
38	DIL. CODE	94
39	DIL. NAME	IgE2
40	DIL. PRTY	3
41	PRE. SPVOL (Vol. of pretreated sample)	0
42	PRE. 1VOL (Vol. of pretreatment sol-1)	0
43	PRE. 2 VOL (Vol. of pretreatment sol-2)	0
44	PRE. CODE (pretreated sol. code)	0
45	PRE. NAME (pretreated sol. name)	0
46	Protocol	1
47	SYS. F_A	1
48	SYS. F_B	0
49	V. CONC.	0
50	G. ORIGIN	0

AIA-2000 Assay Specifications

ST IgE II Test Code 077

No.	Item	Data
1	Unit	IU/mL
2	Decimal places	1
3	Reference low	
4	Reference high	
5	Reschedule low	3.0
6	Reschedule high	4000
7	Assay range low	3.0
8	Assay range high	4000
9	Specimen diluent code	94
10	Specimen diluent name	IgE2
11	Dilution factor for Sp. 1	1
12	Dilution factor for Sp. 2	1
13	Dilution factor for Control	1
14	Default multiplier for DO	100
15	Default multiplier for >H	10
16	Factor A	1.00000e+000
17	Factor B	0.00000e+000
18	Calibration code	3
19	Calibrator replicates	3
20	Calibrator lot	***Enter current cal. lot no,
21	Calibrator Concentration	
22	Cal - 01	0 IU/mL
23	Cal - 02	50 IU/mL (example)
24	Cal - 03	300 IU/mL (example)
25	Cal - 04	1000 IU/mL (example)
26	Cal - 05	2500 IU/mL (example)
27	Cal - 06	4000 IU/mL (example)
28		
29		
30		
31		
32		
33		
34	Dilution factor for calibrator	1
35	Calibration period	90
36	Incubation time (10/40)	10
37	Assay protocol	1
38	Specimen volume	10
39	Diluent volume	100
40	Conjugate volume	0
41	Diluted conjugate volume	0
42	Pretreatment	0
43	Pretreatment specimen volume	0
44	Pretreatment Reagent code	0
45	Pretreatment Reagent name	0
46	Pretreatment Reagent 1 volume	0
47	Pretreatment Reagent 2 volume	0
48	System Factor	1
49	Calibration Code Check	094
50	Virtual Concentration	0.0
51	Graph Origin	0.0
52	Calculation with Dilution Factor	Yes

Immunoglobulin E

ST AIA-PACK IgE II

Name and Intended Use

ST AIA-PACK IgE II is designed for IN VITRO DIAGNOSTIC USE ONLY for the quantitative measurement of Immunoglobulin E (IgE) in human serum or heparinized plasma on specific Tosoh AIA System analyzers.

Summary and Explanation of Test

Like the other immunoglobulin classes, IgE exhibits the typical four chain structure consisting of two light chains and two heavy chains. The two light chains and the variable portion of the heavy chain are common to all immunoglobulin classes. This portion of the molecule also contains the antigen recognition site. The IgE class specificity is contained within the constant region of the molecule which is comprised of approximately three quarters of each heavy chain from the carboxyl-terminal end. ¹ IgE is capable of binding to receptors on mast cells and basophils. Through a series of complex and poorly understood reactions, an IgE-antigen complex is triggered to release certain vasoactive agents, such as histamine, into the blood stream producing the symptoms characteristic of "allergies". ²

Total serum IgE levels are of value in differentiating the allergic individual from non-allergic patients. ³ Significantly elevated IgE concentrations are reported in allergic rhinitis, extrinsic asthma, urticaria and atopic eczema. ⁴⁻⁷ Other conditions associated with elevated levels of IgE have also been reported. ⁸⁻¹¹

Principle of the Assay

The ST AIA-PACK IgE II is a two-site immunoenzymometric assay which is performed entirely in the AIA-PACK. Human IgE present in the test sample is bound with monoclonal antibody immobilized on a magnetic solid phase and enzyme-labeled monoclonal antibody in the AIA-PACK. The magnetic beads are washed to remove unbound enzyme-labeled monoclonal antibody and are then incubated with a fluorogenic substrate, 4-methylumbelliferyl phosphate (4MUP). The amount of enzyme-labeled monoclonal antibody that binds to the beads is directly proportional to the IgE concentration in the test sample. A standard curve is constructed, and unknown sample concentrations are calculated using this curve.

Material Provided (ST AIA-PACK IGE II, Cat. No. 0025295)

5 trays x 20 test cups (ST AIA-PACK IgE II Test Cup)

Plastic test cups containing lyophilized magnetic beads coated with mouse anti-human IgE monoclonal antibody and monoclonal antibody (to human IgE) conjugated to bovine alkaline phosphatase with 0.1% sodium azide as a preservative.

Materials Required But Not Provided

The following materials are not provided but are required to perform Immunoglobulin E analysis using the ST AIA-PACK IgE II (Cat. No. 0025295) on specific Tosoh AIA Systems. They are available separately from Tosoh.

Materials	Cat. No.
AIA-SYSTEMS:	
AIA-360	0019945
AIA-900	0022930
AIA-900 9tray Sorter	0022931
AIA-900 19tray Sorter	0022932
AIA-2000 ST	0022100
AIA-2000 LA	0022101
AIA-PACK:	
AIA-PACK Substrate Set II	0020968
AIA-PACK Substrate/Reconstituent	
AIA-PACK IGE II Calibrator Set	0020395
Calibrator #1 0 IU/mL	
Calibrator #2 50 IU/mL (approx.)	
Calibrator #3 300 IU/mL (approx.)	
Calibrator #4 1000 IU/mL (approx.)	
Calibrator #5 2500 IU/mL (approx.)	
Calibrator #6 4000 IU/mL (approx.)	
AIA-PACK IGE II Sample Diluting Solution	0020595
AIA-PACK Wash Concentrate Set	0020955
AIA-PACK Diluent Concentrate Set	0020956
AIA-PACK Detector Standardization Test Cups	0020970
AIA-PACK Sample Treatment Cups	0020971
Sample Cups	0018581
ADDITIONAL REQUIREMENTS: (Except AIA-360)	
Pipette Tips (1000/Pkg)	019215
Tip Rack (Empty)	019216
Preloaded Pipette Tips (96 Tips X 50 Racks)	996010
Preloaded Pipette Tips (96 Tips X 5 Racks)	996005

Only materials obtained from Tosoh should be used. Materials obtained elsewhere should not be substituted since assay performance is characterized based strictly on Tosoh materials.

Warnings and Precautions

- The ST AIA-PACK IgE II is intended for in vitro diagnostic use only.
- **Rx** only. US Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
- Inspect the packaging and the exterior of the aluminum pouch or the vials for any sign of damage before use. If any damages are visible, contact your local Tosoh sales representative.
- Test cups from different lots should not be mixed within a tray.
- The ST AIA-PACK IgE II contains sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
- Human sera is not used in the preparation of this product, however, since human specimens will be used for samples and other quality control products in the lab may be derived from human serum, please use standard laboratory safety procedures in handling all specimens and controls.
- For safe waste disposal, it is recommended that each laboratory complies with established laboratory procedures and local, state, and federal regulations.
- Do not use beyond the expiration date.
- The ST AIA-PACK IgE II has been designed so that the high dose “hook effect” is not a problem for the vast majority of samples. Samples with IgE concentrations between 4000 and 100,000 IU/mL will read > 4000 IU/mL. The “hook effect” phenomenon may occur at IgE concentrations > 100,000 IU/mL.
- Serum, dust, metal, or microorganism contamination may cause degradation of reconstituted substrate solution. Store in a clean environment, away from direct sunlight and ultraviolet light.
- Tosoh Automated Immunoassays utilizing alkaline phosphatase-based technologies should not be used with samples from patients under Asfotase Alfa treatment.

Storage and Stability

All unopened materials are stable until the expiration date on the label when stored at the specified temperature.

Materials	Cat. No.
Refrigerator Temperature (2 - 8 °C):	
ST AIA-PACK IgE II	0025295
AIA-PACK IgE II Calibrator Set	0020395
AIA-PACK IgE II Sample Diluting Solution	0020595
AIA-PACK Substrate Set II	0020968
AIA-PACK Wash Concentrate	0020955
AIA-PACK Diluent Concentrate	0020956
Room Temperature (18 - 25 °C):	

ST AIA-PACK IgE II test cups may be stored at room temperature (18° - 25 °C) for up to 24 hours. Calibrators must be kept tightly sealed and refrigerated at (2 - 8 °C). After opening or reconstituting, calibrators should be used within 7 days. After opening, Sample Diluting Solution is stable for a minimum of 7 days. Reconstituted substrate solution is stable for 3 days at 18 - 25 °C or 30 days at 2 - 8 °C. Working diluent and wash solutions are stable for 30 days at room temperature (18 - 25 °C). Reagents should not be used if they appear cloudy or discolored.

Specimen Collection and Handling

Serum or heparinized plasma is required for the assay. EDTA and citrated plasma **SHOULD NOT BE USED**.

No special patient preparation is necessary. When using serum, a venous blood sample is collected aseptically without additives. Store at 18 - 25 °C until a clot has formed (usually 15 - 45 minutes), then centrifuge to obtain the serum specimen for assay.

To use heparinized plasma, a venous blood sample is collected aseptically with the designated additive. Centrifuge and separate plasma from the packed cells as soon as possible.

Samples may be stored at 2 - 8 °C for up to 24 hours prior to analysis. If the analysis cannot be done within 24 hours, the sample should be stored frozen at -20 °C or below for up to 60 days.

Repeated freeze-thaw cycles should be avoided. Turbid serum samples or samples containing particulate matter should be centrifuged prior to testing. Prior to assay, bring frozen samples to room temperature (18 - 25 °C) slowly and mix gently.

The sample required for analysis is 10 µL.

Procedure

1) Reagent Preparation

1a) Substrate Solution

Bring all reagents to room temperature (18 - 25 °C) before preparing the working reagent. Add the entire contents of the Substrate Reconstituent (100 mL) to the lyophilized Substrate and mix thoroughly to dissolve the solid material.

1b) Wash Solution

Add the entire content of the Wash Concentrate (100 mL) to approximately 2.0 L of CAP Class I water or the clinical laboratory reagent water, mix well, and adjust the final volume to 2.5 L.

1c) Diluent

Add the entire contents of the Diluent Concentrate (100 mL) to approximately 4.0 L of CAP Class I water or the clinical laboratory reagent water, then adjust the final volume to 5.0 L.

2) Calibration

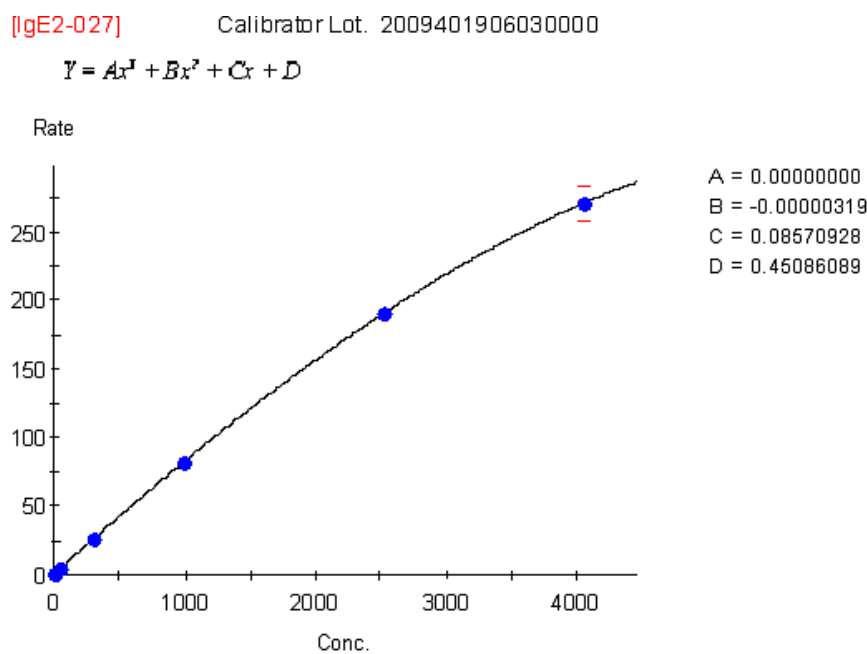
2a) Calibration Curve

The calibrators for use with the ST AIA-PACK IgE II have been standardized against WHO 2nd IRP 75/502 (1980).

The calibration curve for the ST AIA-PACK IgE II has been shown to be valid for a period of 90 days, provided the reagents are handled in accordance with the manufacturer's instructions and the AIA System is maintained as instructed.

Recalibration may be necessary more frequently if controls are out of the established range for this assay, if certain service procedures are performed (e.g. temperature adjustment, sampling mechanism changes, or detector lamp adjustment or change). For further information regarding instrument operation, consult the AIA Systems Operator's Manual.

The sample calibration curve below shows the algorithm used to calculate the results. This is an example only. Actual results will vary depending on the Instrument type and lot number used.



2b) Calibration Procedure

Refer to the appropriate AIA System Operator's Manual for procedural instructions.

- i) Verify that both the calibrator lot and concentration numbers have been correctly entered into the software.
- ii) Calibrators for ST AIA-PACK IgE II are provided ready to use. Tosoh recommends that all calibrators be run in triplicate.

2c) Calibration Acceptability criteria

- i) The mean rate for the zero calibrator should be < 3.0 nM/sec.
- ii) Since there is a direct relationship between concentration and rate, the rates should increase as the concentration increases.
- iii) The replicate values should be within a 10% range.

2d) Calibration Review and Acceptance

- i) Review the calibration curve carefully, using the criteria listed above.
- ii) Edit the calibration if necessary, then accept the calibration.
- iii) For further information regarding calibration, consult the specific AIA System Operator's Manual.

3) Quality Control

3a) Commercially Available Controls

Commercially available controls should be run at least once per day. It is recommended that at least two (2) levels of controls be used with target concentrations of IgE of approximately 100 and 300 IU/mL, respectively. Laboratory policy for this particular assay designates the following:

Control Material: _____
Frequency: _____

Lot number of control material, acceptable limits, and corrective action to be taken if controls do not meet laboratory criteria will be found in a separate quality control document.

3b) Quality Control Procedure

- i) Assay quality control specimens as instructed in the specific Operator's Manual for your analyzer. In addition, refer to the AIA System Operator's Manual for detailed instructions on defining and editing the files.
- ii) Quality control material to be run with this assay is defined by individual laboratory policy.

4) Specimen Processing

4a) Preparation

Following specific instructions in the Operator's Manual for the analyzer, place samples on the instrument appropriately.

4b) Assay Procedure

- i) Ensure a sufficient quantity of ST AIA-PACK IgE II test cups for the number of samples to be run.

- ii) Load patient samples as instructed in the Operator's Manual and proceed with analysis. Note: The AIA-900 and AIA-2000 will require AIA-PACK Sample Treatment Cups if onboard dilutions are utilized.

Procedural Notes

- Lyophilized Substrate must be completely dissolved.
- Ligand assays performed by the Tosoh AIA System Analyzer require that the laboratory use water designated by the CAP Class I or by the clinical laboratory reagent water. Water should be tested at least once per month and should be free of particulate matter including bacteria. The pH of the water should also be routinely tested. For further information, consult the CLSI document GP40-A4-AMD, Preparation and Testing of Reagent Water in the Clinical Laboratory; Approved Guideline - Fourth Edition.
- If a specimen Immunoglobulin E concentration is found to be greater than 4000 IU/mL, the specimen should be diluted with the AIA-PACK IgE II Sample Diluting Solution and re-assayed according to the Assay Procedure. The recommended dilution for samples containing greater than 4000 IU/mL is 1:10 or 1:100. It is desirable to dilute the sample so that the diluted sample reads between 10 and 3000 IU/mL. The dilution factor should be entered into the software. For further information on the dilution of specimens, refer to the AIA System Operator's Manual.
- The AIA systems can store two different calibration curves for each analyte at one time. Therefore, up to two different lots of ST AIA-PACK IgE II Test cups can be used during the same run.
- If the assay specifications for this test are not already in the system software, the specifications must be entered under test code 077.

Calculation of Results

The AIA Systems perform all sample and reagent handling operations automatically. The AIA Systems read the rate of fluorescence produced by the reaction and automatically convert the rate to Immunoglobulin E concentration in IU/mL.

For samples requiring dilution, the AIA 900 and AIA-2000 will automatically perform dilutions and calculate results if the dilution factors are entered into the software. For detailed information regarding programming dilutions, consult the appropriate Operator's Manual.

Evaluation of Results

Quality Control

In order to monitor and evaluate the precision of the analytical performance, it is recommended that commercially available control samples be assayed daily.

The minimum recommendations for the frequency of running internal control material are:

- After calibration, two levels of controls are run in order to accept the calibration curve.
- The two levels of controls are also repeated after calibration when certain service procedures are performed (e.g. temperature adjustment, sampling mechanism changes, maintenance of the wash probe or detector lamp adjustment or change).
- After daily maintenance, at least two levels of the control should be run in order to verify the overall performance of the Tosoh AIA System Analyzers.

If one or more control sample value(s) is out of the acceptable range, it will be necessary to investigate the validity of the calibration curve before reporting patient results.

Standard laboratory procedures should be followed in accordance with the strictest regulatory agency under which the laboratory operates.

Limitations of the Procedure

For diagnostic purposes, the results obtained from this assay should be used in conjunction with other data (eg, symptoms, results of other tests, clinical impressions, therapy, etc.).

Using ST AIA-PACK IgE II, the highest concentration of Immunoglobulin E measurable without dilution is approximately 4000 IU/mL, and the lowest measurable concentration is 3 IU/mL (assay sensitivity).

Although the approximate value of the highest calibrator is 4000 IU/mL, the exact concentration may be slightly different. The assay specification, Assay Range High, should be defined as the upper limit of the assay range, 4000 IU/mL.

Although hemolysis has an insignificant effect on the assay, hemolyzed samples may indicate mistreatment of a specimen prior to assay and results should be interpreted with caution.

Lipemia has an insignificant effect on the assay except in the case of gross lipemia where spatial interference may occur.

Certain medications may interfere with assay performance. Specimens from patients taking medicines and/or medical treatment may show erroneous results. All results should be interpreted with respect to the clinical picture of the patient.

For a more complete understanding of the limitations of this procedure, please refer to the Specimen Collection and Handling, Warnings and Precautions, Storage and Stability, and Procedural Notes sections in this insert sheet.

Expected Values

Each laboratory should determine a reference interval which corresponds to the characteristics of the population being tested. As with all diagnostic procedures, clinical results must be interpreted with regard to concomitant medications administered to the patient.¹⁶

Reference Ranges

Each laboratory should determine a reference interval corresponding to the characteristics of the population being tested. The interval given here was determined from serum samples from 104 apparently healthy individuals.

Number of samples (n) 104

Mean value (x) 77.4 IU/mL

Reference Interval 5.8 - 216 IU/mL

Performance Characteristics

The following performance characteristics were determined using the Tosoh AIA NexIA.

1) Accuracy

1a) Recovery:

Three serum samples were spiked with three different levels of IgE and assayed before and after spiking.

Sample	Initial Value (IU/mL)	IgE Added (IU/mL)	Expected Value (IU/mL)	Measured Value (IU/mL)	Percent Recovery (%)
Sample A1	231.3	480.6	711.9	697.9	98.0
	231.3	961.2	1192.5	1184.2	99.3
	231.3	1922.3	2153.6	2047.5	95.1
Sample B1	163.5	480.6	644.1	646.4	100.4
	163.5	961.2	1124.7	1099.9	97.8
	163.5	1922.3	2085.8	2031.1	97.4
Sample C1	193.9	480.6	674.5	675.0	100.1
	193.9	961.2	1155.1	1157.4	100.2
	193.9	1922.3	2116.2	2032.0	96.0

1b) Dilution:

Three serum samples containing high concentrations of IgE were serially diluted with IgE II Sample Diluting Solution and assayed.

Sample	Dilution Factor	Expected Value (IU/mL)	Measured Value (IU/mL)	Percent Recovery (%)
Sample A2	none		3196.0	
	7.5/10	2397.0	2415.9	100.8
	5.0/10	1598.0	1713.9	107.3
	2.5/10	799.0	829.1	103.8
	1.0/10	319.6	328.0	102.6
Sample B2	none		3461.1	
	7.5/10	2595.8	2710.9	104.4
	5.0/10	1730.5	1847.9	106.8
	2.5/10	865.3	887.0	102.5
	1.0/10	346.1	351.4	101.5
Sample C2	none		3325.7	
	7.5/10	2494.3	2622.3	105.1
	5.0/10	1662.9	1801.7	108.3
	2.5/10	831.4	891.4	107.2
	1.0/10	332.6	356.7	107.2

2) Precision

2a) Intra-assay precision

The intra-assay (within run) precision was determined using three controls in a total of 20 runs. Within each run, one set of duplicates per control was assayed. The mean of each duplicate was used to obtain the pooled standard deviation (SD), which was then used to calculate the coefficient of variation.

Sample	Mean (IU/mL)	Pooled SD (IU/mL)	Coefficient of Variation (%)
Serum A3	44.1	0.9	2.1
Serum B3	262.8	6.2	2.4
Serum C3	1754.0	48.2	2.8

2b) Inter-assay precision

The inter-assay (between run) precision coefficient of variation was evaluated at two different concentrations by analyzing control samples in 20 separate runs over 20 days.

Sample	Number of Replicates	Mean (IU/mL)	Standard Deviation (IU/mL)	Coefficient of Variation (%)
Serum A3	20	43.6	0.6	1.4
Serum B3	20	260.5	7.0	2.7
Serum C3	20	1733.1	60.4	3.5

2c) Total precision

Total precision was determined by the duplicate assay of three controls in 20 separate runs. The means of each run were used to calculate the standard deviation (SD) and coefficient of variation (CV).

Sample	Mean (IU/mL)	Standard Deviation (IU/mL)	Coefficient of Variation (%)
Serum A3	44.1	1.2	2.8
Serum B3	262.8	8.2	3.1
Serum C3	1754.0	54.6	3.1

Specificity

The following substances were tested for cross-reactivity. The cross-reactivity (%) is the percent of the compound which will be identified as IgE. If these compounds are present in the specimen at the same concentration as IgE, the final result will be increased by these percentages.

Compound	Concentration	Cross-reactivity (%)
IgM lamda	1 mg/mL	0
IgM kappa	1 mg/mL	0
IgG	10 mg/mL	0
IgA	2.9 mg/mL	0

Sensitivity

The minimal detectable concentration (MDC) of Immunoglobulin E is estimated to be 3.0 IU/mL. The MDC is defined as that concentration of IgE which corresponds to the rate of fluorescence that is two standard deviations from the mean rate of fluorescence of 20 replicate determinations of a zero calibrator.

Interference

Interference is defined, for purposes of this study, to be recovery outside of 10% of the known specimen mean concentration.

- Hemoglobin (up to 430 mg/dL), free bilirubin (up to 17 mg/dL) and conjugated bilirubin (up to 19 mg/dL) do not interfere with the assay.
- Lipemia, as indicated by triglyceride concentrations (up to 1660 mg/dL), does not interfere with the assay.
- Protein, as indicated by human albumin concentrations (up to 5 g/dL), does not interfere with the assay.
- Ascorbic acid (up to 20 mg/dL) does not interfere with the assay.
- Tosoh Automated Immunoassays utilizing alkaline phosphatase-based technologies should not be used with samples from patients under Asfotase Alfa treatment.

References

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5. Wittig, H.J., Belloit, J., De Fillippi, I., Royal, G. Age-related serum immunoglobulin E levels in healthy subjects and in patients with allergic disease. *J. Allergy Clin. Immunol.* 66:305, 1980.
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10. Waldmann, T.A., Polmar, S.H., Balestra, S.T., et al., Immunoglobulin E in immunologic deficiency diseases. II. Serum IgE concentration of patients with acquired hypogammaglobulinemia, thymoma, and hypogammaglobulinemia, myotonic dystrophy, intestinal lymphangiectasia and Wiskott-Aldrich Syndrome. *J. Immunol.* 109:304, 1972.
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European Conformity



In vitro diagnostic medical device



Consult instructions for use



Temperature limitation



Batch code / Lot number



Manufacturer

Authorized representative
in the European Community

Use by date

Catalogue number
/ Part number

Supplied by



Sufficient for

US: For prescription use only

AIA-PACK

IgE II Calibrator Set

Intended Use

The AIA-PACK IgE II Calibrator Set is intended for IN VITRO diagnostic use only for the calibration of the ST AIA-PACK IgE II Assays.

Summary and Explanation

The AIA-PACK IgE II Calibrator Set contains a protein matrix with assigned levels of Immunoglobulin E. Calibration should be performed according to the schedule indicated in the AIA System Operator's Manual. The calibrators in this set have been standardized against WHO 2nd IRP 75/502 (1980).

Material Provided (Cat. No. 0020395)

2 x 1mL	Calibrator #1	0 IU/mL
	Bovine serum albumin matrix containing no detectable concentration of IgE (0 IU IgE/mL), and 0.1% sodium azide as preservative. (Ready to Use)	

2 x 1mL	Calibrator #2	50 IU/mL (approx.)
	Calibrator #3	300 IU/mL (approx.)
	Calibrator #4	1000 IU/mL (approx.)
	Calibrator #5	2500 IU/mL (approx.)
	Calibrator #6	4000 IU/mL (approx.)
	Bovine serum albumin matrix containing the assigned concentration of IgE (described on each vial) and 0.1% sodium azide as preservative. (Ready to Use)	

Warnings and Precautions

- The AIA-PACK IgE II Calibrator Set is for IN VITRO diagnostic use.
- These materials contain sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
- Although material derived from human blood is not used for IgE II Calibrators, it is recommended that this product be handled with the same precautions used for patient samples..
- Do not use beyond the expiration date.

Preparation and Storage

The calibrators are provided ready to use. The calibrators should be at room temperature (18 - 25 °C) prior to assay.

Always store the Calibrator Set in an upright position at 2 - 8 °C when not in use.

Stability

When stored unopened and refrigerated at 2 - 8 °C, the AIA-PACK IGE II Calibrator Set is stable until the expiration date on the label. After opening, the calibrators should be used within 7 days.

Procedure

Refer to the CALIBRATION PROCEDURE in the AIA-PACK section of this analyst application. For additional procedural instructions regarding calibration, refer to the AIA System Operator's Manual.

- 1) Verify that both the calibrator lot and concentrations have been correctly entered into the analyzer software.
- 2) Add the appropriate amounts of each calibrator to sample cups (refer to the instrument worklist for the amount required in each sample cup).
- 3) Place the sample cups and the test cups on the analyzer as indicated on the worklist.
- 4) Tosoh recommends that all calibrators be run in triplicate.

Assignment of Values

The AIA-PACK IgE II Calibrator Set contains assigned concentrations of Immunoglobulin E. The assigned value is determined on a lot-to-lot basis and is designed to provide an assay calibration range of approximately 0 to 4000 IU/mL of Immunoglobulin E. The calibrators in this set have been standardized against WHO 2nd IRP 75/502 (1980).

Results

- The mean rate for the zero calibrator should be < 3.0 nM/sec.
- Since there is a direct relationship between concentration and rate, the rates should increase as the concentration increases.
- The replicate values should be within a 10% range.

Limitations

The AIA-PACK IgE II Calibrator Set is designed solely for use with AIA-PACK assay procedures.

References

1. AIA Analyte Application Manual (AAM). Tosoh Bioscience, Inc., Grove City, OH.
2. AIA System Operator's Manual. Tosoh Bioscience, Inc., Grove City, OH.



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European Conformity


In vitro diagnostic medical device


Consult instructions for use


Temperature limitation


Batch code / Lot number


Manufacturer


Authorized representative
in the European Community

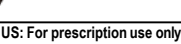

Use by date


Catalogue number
/ Part number

Supplied by


Supplied by


Sufficient for


US: For prescription use only

AIA-PACK

IgE II Sample Diluting Solution

Intended Use

The AIA-PACK IgE II Sample Diluting Solution is intended for IN VITRO DIAGNOSTIC USE ONLY to dilute patient samples that have concentrations of Immunoglobulin E above the linear range of the assay on the AIA Systems.

Summary and Explanation

The AIA-PACK IgE II Sample Diluting Solution contains a bovine serum albumin matrix with no detectable concentration of Immunoglobulin E. This Sample Diluting Solution is to be used only with samples that are being tested for Immunoglobulin E concentrations using the ST AIA-PACK IgE II Assays.

Material Provided (Cat. No. 0020595)

4 x 4mL Sample Diluting Solution

A bovine serum albumin matrix containing no detectable concentration of Immunoglobulin E (0 mIU IgE/mL), and 0.1% sodium azide as a preservative.

Warnings and Precautions

- The AIA-PACK IgE II Sample Diluting Solution is for IN VITRO diagnostic use.
- These materials contain sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
- Although material derived from human blood is not used for AIA-PACK IgE II Sample Diluting Solution, it is recommended that this product be handled with the same precautions used for patient samples.
- Do not use beyond the expiration date.

Preparation and Storage

- The AIA-PACK IgE II Sample Diluting Solution is provided ready to use.
- Always store the Sample Diluting Solution at 2 - 8 °C when not in use.

Stability

When stored unopened and refrigerated at 2 - 8 °C, the AIA-PACK IgE II Sample Diluting Solution is stable until the expiration date on the label. After opening, the Sample Diluting Solution is stable for up to 7 days when refrigerated at 2 - 8 °C.

Procedure

Refer to the AIA System Operator's Manual for additional procedural instructions regarding sample dilution.

1. If a specimen is found to contain greater than the linearity limit of approximately 4000 IU/mL, the specimen should be diluted with the Sample Diluting Solution and assayed according to the Assay Procedure in the AIA-PACK section of the instructions for use.
2. The AIA 900 and AIA-2000 will perform dilutions automatically if the dilution factors are entered into the software prior to assaying the diluted sample.
3. The recommended dilution for specimen containing greater than 4000 IU/mL is 1:10 or 1:100. However, it is desirable to dilute the samples that contain more than 4000 IU IgE/mL so that the diluted sample reads between 10 and 3000 IU IgE/mL.

Results

When an auto-dilution is performed, the AIA instrument will calculate the final result.

Limitations

The AIA-PACK IgE II Sample Diluting Solution is designed solely for use with AIA-PACK assay procedures.

References

1. AIA Analyte Application Manual (AAM). Tosoh Bioscience, Inc., Grove City, OH.
2. AIA System Operator's Manual Tosoh Bioscience, Inc., Grove City, OH.

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European Conformity



In vitro diagnostic medical device



Consult instructions for use



Temperature limitation



Batch code / Lot number



Manufacturer

Authorized representative
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Use by date

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Sufficient for

US: For prescription use only