

Total IgE

For the Quantitative Determination of Circulating Total Human IgE

Cat. No. KAI-092

INTENDED USE

The **K-ASSAY**® Total IgE is an *in vitro* diagnostic reagent for the quantitative determination of circulating total IgE in human serum or plasma by immunoturbidimetric assay for use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings. FOR *IN VITRO* DIAGNOSTIC USE.

PRINCIPLE OF TEST

Latex particles coated with antibody specific to human IgE form immune complexes in the presence of IgE from the sample. The immune complexes cause an increase in light scattering that is proportional to the concentration of IgE in the serum or plasma sample. The light scattering is measured by reading turbidity at 570 nm. The sample IgE concentration is determined versus IgE calibrators of known concentrations.

KIT COMPOSITION

Reagents (Liquid Stable)

R1: Buffer Reagent
0.1 M Tris hydrochloride buffer

R2: Antiserum Reagent
Latex particles coated with goat anti-human IgE antibody

WARNINGS AND PRECAUTIONS

FOR *IN VITRO* DIAGNOSTIC USE. Rx only.

Not to be used internally in humans or animals. Normal precautions exercised in handling laboratory reagents should be followed. Do not mix or use reagents from one test kit with those from a different lot number. Do not use reagents past their expiration date stated on each reagent container label.

Do not pipette by mouth. Avoid ingestion and contact with skin.

Reagents in this kit contain sodium azide as a preservative. Sodium azide may form explosive compounds in metal drain lines. When disposing of reagents through plumbing fixtures, flush with copious amounts of water. For further information, refer to "Decontamination of Laboratory Sink Drains to Remove Azide Salts," in the Manual Guide-Safety Management No. CDC-22 issued by the Centers for Disease Control, Atlanta, Georgia.

REAGENT PREPARATION

Reagents are ready to use and do not require reconstitution. Mix before using by gently inverting the bottles. After opening, gently invert Reagent 2 once a week.

STORAGE AND STABILITY

All reagents should be stored at 2-8°C and protected from light. Unopened reagents can be used for one year from the date of manufacture as indicated on the expiration date on the package and bottle labels if stored at 2-8°C. Once the reagent vials have been opened, store tightly capped at 2-8°C and use within 1 month. Discard reagents if they become contaminated. Evidence of obvious precipitation in reagent 2 (R-2) solution is cause to discard.

SPECIMEN COLLECTION AND PREPARATION

Serum

Blood should be collected from a patient and the serum separated as soon as possible. Soon after the blood is drawn, it should be allowed to clot, centrifuged, and the serum separated from the clot to a tube. It is recommended that specimen collection be carried out in accordance with NCCLS document M29-A2. Serum samples can be stored for 1 week at 4°C, or at -20°C for longer storage. Avoid repeated freeze/thaw cycles.

Plasma

Whole blood is collected in sodium citrate anticoagulant. After collection, immediately centrifuge. In the U.S., follow NCCLS guideline H3-A2. Plasma samples can be stored for 1 week at 4°C, or at -20°C for longer storage. Avoid repeated freeze/thaw cycles.

AUTOMATED ANALYZER APPLICATION

Suitable for two-reagent automated analyzers that can measure a rate reaction at an absorbance of 570 nm. Performance assessment was determined using the Hitachi 917. Customers should contact KAMIYA BIOMEDICAL COMPANY for information regarding performance verification of applications for other analyzers.

Refer to the instrument manual from the manufacturer regarding the following:

- Use or function
- Installation procedures and requirements
- Principles of operation
- Performance characteristics, operating instructions
- Calibration procedures including materials and / or equipment to be used
- Operational precautions, limitations, and hazards
- Service and maintenance information

PROCEDURE

Materials Supplied

KAI-092	
Reagent 1 (R-1) Buffer Reagent	2 x 20 mL
0.1 M Tris hydrochloride buffer	
Reagent 2 (R-2) Antiserum Reagent	1 x 6.6 mL
Latex suspension with goat anti-human IgE antibodies	

Materials Required But Not Supplied

Calibrators: **K-ASSAY**® Total IgE Calibrator, Cat. No. KAI-093C

Purified water.

Two Reagent Clinical Chemistry Analyzer:
Capable of accurate absorbance readings at 570 nm
Capable of accurately dispensing the required volumes
Capable of maintaining 37°C

Plastic tubes.

Sample dilution: Saline with 0.09% Sodium Azide and 1% BSA.

Assay Procedure

Example of an automated application:

Sample	8.0 µL
↓	
• ← R1 (Buffer Reagent)	300 µL
↓	37°C, 300 seconds
• ← R2 (Antiserum Reagent)	50 µL
↓	37°C, 300 seconds
Measure 2 Point End at 570 nm main, 800 nm sub	

Note: Allow all reagents and specimens to warm to room temperature (18-25°C). Mix all reagents gently before using.

Automated Method (Example)

Chemistry Parameters for Automatic Analyzer

INSTRUMENT	Hitachi 717
TEMPERATURE	37°C
TEST	(IgE)
ASSAY CODE	(2 POINT) : (27) - (50)
SAMPLE VOLUME	(8) ()
R1 VOLUME	(300) () (NO)
R2 VOLUME	(50) () (NO)
WAVELENGTH	(800) (570)
CALIB. METHOD	(NONLINEAR) (4) (5)
STD.(1) Conc.-POS.	(*1) - (1)
STD.(2) Conc.-POS.	(*2) - (2)
STD.(3) Conc.-POS.	(*3) - (3)
STD.(4) Conc.-POS.	(*4) - (4)
STD.(5) Conc.-POS.	(*5) - (5)
STD.(6) Conc.-POS.	() - ()
SD LIMIT	(999)
DUPLICATE LIMIT	(10000)
SENSITIVITY LIMIT	(0)
ABS. LIMIT (SLOPE)	(32000) (INCREASE)
PROZONE LIMIT	(-32000) (LOWER)
EXPECTED VALUE	(-99999) (99999)
PANIC VALUE	(-99999) (99999)
INSTRUMENT FACTOR	(1.00)

* 1-5 Input concentration of calibrators

Parameters for other automated analyzers are available.

CALIBRATION

A multi-point calibration curve should be made using the **K-ASSAY**® Total IgE Calibrator. It is recommended that the user determine calibration curve frequency as this depends on the instrument and type/number of other assays being performed. Initially, calibration should be performed each day.

QUALITY CONTROL

It is recommended that at least two levels of control (with known concentrations of IgE) be included in all assay runs.

CALCULATIONS

IgE levels are determined by the analyzer using the prepared calibration curve.

LIMITATIONS OF PROCEDURE

Performance of this assay has only been evaluated on adult specimens. Since a reference range is only available for adult specimens, this assay should only be used for adults. The reference range was calculated using Japanese adults.

If IgE value of sample is greater than highest calibrator value, dilute with saline (containing 0.09% sodium azide and 1% BSA) and re-assay.

PERFORMANCE

Sensitivity

When a diluent blank is used as a sample, the absorbance \leq 0.002/min. When a calibrator having an IgE concentration of around 500 IU/mL is assayed, the absorbance (after subtracting the diluent blank) is within the range of 0.005 to 0.055/ min., and at 2000 IU/mL is between 0.020 to 0.200/min.

Specificity

When a sample with a known value is assayed, the result is within \pm 10% of the assigned value.

Precision Assay

(Within Run)
The following results were obtained on a Hitachi 917 analyzer with pooled human serum:

	SERUM				
	Sample I	Sample II	Sample III	Sample IV	Sample V
N	10	10	10	10	10
Mean	105.3 IU/mL	174.1 IU/mL	350.5 IU/mL	1117.8 IU/mL	1908.6 IU/mL
Std. Dev.	1.06	2.85	7.68	13.26	30.25
CV	1.01%	1.63%	2.2%	1.2%	1.6%

(Between Runs)
The following results were obtained on a Hitachi 917 analyzer with pooled human serum:

	SERUM				
	Sample I	Sample II	Sample III	Sample IV	Sample V
N	10	10	10	10	10
Mean	105.4 IU/mL	177.6 IU/mL	663.7 IU/mL	2147.5 IU/mL	3304.7 IU/mL
Std. Dev.	2.72	3.24	11.22	33.56	16.67
CV	2.58%	1.82%	1.69%	1.56%	0.50%

Accuracy / Correlation

A comparison of the **K-ASSAY**® Total IgE reagent and the Company X's Total IgE reagent was performed with the following results:

$y = 0.9851x + 10.618$
 $r = 0.9928$
 $n = 80$
 $x =$ Company X's Total IgE
 $y =$ **K-ASSAY**® Total IgE

Assay Range

10 - 2000 IU/mL (or value of highest calibrator)

Lower Limit of Detection

The lower limit of detection is 10 IU/mL.

MATRIX COMPARISON

A comparison of serum vs. plasma was performed with the following results:

$y = 1.2072x + 10.297$
 $r = 0.9989$
 $n = 57$
 $x =$ Plasma IgE values (IU/mL)
 $y =$ Serum IgE Values (IU/mL)

INTERFERENCE

Bilirubin F	No interference up to 18.5 mg/dL
Bilirubin C	No interference up to 21.6 mg/dL
Hemoglobin	No interference up to 467 mg/dL
RF	No interference up to 500 IU/mL
Sodium Citrate	No interference up to 15 mg/mL
Sodium Heparin	No interference up to 150 U/mL
EDTA-2Na	No interference up to 1.5 mg/mL
Chyle (Formazine Turb.)	No interference up to 2,120

EXPECTED VALUES











It is recommended that each laboratory establish its own expected range to reflect its patient population.

In our laboratory, the expected value of IgE in adults is less than 178 IU/mL for 413 normal plasma samples. The top 149 of the 413 samples were excluded due to the statistical prevalence of allergies in the normal population. The reference range cited in the Laboratory Test Handbook for U.S. populations is <300 IU/mL.¹

REFERENCE

1. Jacobs DS, *et al*, eds, "Laboratory Test Handbook, 4th Edition" Hudson, OH: Lexi-Comp Inc., 1996, p. 409.

LABELING SYMBOLS

	Lot Number
	Reagent
	Expiration or "Use By" Date
	Catalog Number
	For <i>In Vitro</i> Diagnostic Use
	Temperature Limitation. Store between 2 and 8 degrees C
	Potential Human Biohazard
	Manufacturer
	Consult Package Insert for Instructions for Use
	Authorized Representative in the European Community

EU AUTHORIZED REPRESENTATIVE



 **EC/REP**

Advena Ltd.

Tower Business Centre, 2nd Flr.,
Tower Street, Swatar, BKR 4013 Malta

ORDERING / PRICING / TECHNICAL INFORMATION



KAMIYA BIOMEDICAL COMPANY

12779 Gateway Drive
Seattle, WA 98168 USA
TEL: (206) 575-8068 / (800) 526-4925
FAX: (206) 575-8094