ImmunoCAP™ Total IgE

Fluoroenzymeimmunoassay

CLIA Complexity Category = Moderately Complex

Directions for Use 52-5292-EN/08

INTENDED USE

ImmunoCAP Total IgE is an in vitro test system for the quantitative measurement of circulating total IgE in human serum or plasma. It is intended for in vitro diagnostic use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings, and is to be used in clinical laboratories. ImmunoCAP Total IgE is to be used with the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 1000, Phadia 2500 or Phadia 5000.

SUMMARY AND EXPLANATION OF THE TEST

Since 1967, when the first assays for serum immunoglobulin E (1-3) were described, these measurements have become well established components of the investigation of allergic patients. The serum concentration of IgE is significantly elevated in patients suffering from extrinsic asthma, hayfever or atopic eczema. The increase during childhood is slow. Adult values are not stabilized until 15-20 years of age (6-7).

PRINCIPLE OF THE PROCEDURE

Anti-IgE, covalently coupled to ImmunoCAP, reacts with the total IgE in the patient sample. After washing, enzyme labeled antibodies against IgE are added to form a complex. Following incubation, unbound enzyme-anti-IgE is washed away and the bound complex is then incubated with a developing agent. After stopping the reaction, the fluorescence of the eluate is measured. The fluorescence is directly proportional to the concentration of IgE in the sample. The higher the response, the more IgE is present in the sample. To evaluate the test results, the responses for the patient samples are transformed to concentrations with the use of a calibration curve.

REAGENTS AND MATERIAL

Reagents are packaged as described below, each purchased separately. The two digit suffix (-xx) on the article number may vary between countries. All kits are not available in all countries.

The expiration date and storage temperature are stated on the labels. Do not use reagents beyond their expiration dates.

Note: It is not recommended to pool any reagents.

Keep the ImmunoCAP carrier closed to avoid evaporation of buffer.

Reagents for Phadia 100

- **ImmunoCAP Total IgE** (Art No 10-9517-01: for 96 determinations)
  - Total IgE Conjugate (1 vial)
  - Total IgE Curve Control 1 (CC-1) (4 single dose vials)
  - Total IgE Curve Control 2 (CC-2) (4 single dose vials)
- **ImmunoCAP Total IgE Curve Controls** (CC-1 and CC-2) (Art No 10-9257-01: for 3 additional assay runs)
- **ImmunoCAP Total IgE Calibrators** (Cal-xx) (Art No 10-9252-01: for 1 calibration curve)
- **ImmunoCAP Total IgE Anti-IgE** (a-IgE) (Art No 14-4509-01: carrier of 16 ImmunoCAP)
- **Development Solution** (Art No 10-9478-01: for 600 determinations)
- **Stop Solution** (Art No 10-9479-01: for 600 determinations)
- **Washing Solution** (Art No 10-9422-01: 6 x 1 l)
  - Washing Solution Additive, 6 x 17.2 ml
  - Washing Solution Concentrate, 6 x 80 ml
- **Washing Solution** (Art No 10-9202-01: 2 x 5 l)
  - Washing Solution Additive, 2 x 86 ml
  - Washing Solution Concentrate, 2 x 400 ml
- **ImmunoCAP Total IgE Control LMH** (Art No 10-9447-01: for 3 x 2 x 4 determinations)

Reagents for Phadia 200

- **ImmunoCAP Total IgE Conjugate 100** (Art No 10-9319-01: for 6 x 100 determinations)
- **ImmunoCAP Total IgE Conjugate 400** (Art No 10-9480-01: for 6 x 400 determinations)
- **ImmunoCAP Total IgE Curve Control Strip** (CC-1 and CC-2) (Art No 10-9325-01: for 5 x 3 curve controls)
- **ImmunoCAP Total IgE Calibrator Strip** (Art No 10-9387-01: for 5 calibration curves)
- **ImmunoCAP Total IgE Anti-IgE** (a-IgE) (Art No 14-4509-01: carrier of 16 ImmunoCAP)
- **Development Solution** (Art No 10-9441-01: for 6 x 200 determinations; Art No 10-9440-01: for 6 x 315 determinations)
- **Stop Solution** (Art No 10-9442-01: for 6 x 185 determinations; Art No 10-9479-01: for 6 x 100 determinations)
- **Washing Solution** (Art No 10-9422-01: 6 x 1 l)
  - Washing Solution Additive, 6 x 17.2 ml
  - Washing Solution Concentrate, 6 x 80 ml
- **Washing Solution** (Art No 10-9202-01: 2 x 5 l)
  - Washing Solution Additive, 2 x 86 ml
  - Washing Solution Concentrate, 2 x 400 ml
- **ImmunoCAP Total IgE Control LMH** (Art No 10-9447-01: for 3 x 2 x 4 determinations)

Reagents for Phadia 250

- **ImmunoCAP Total IgE Conjugate 100** (Art No 10-9319-01: for 6 x 100 determinations)
- **ImmunoCAP Total IgE Conjugate 400** (Art No 10-9480-01: for 6 x 400 determinations)
- **ImmunoCAP Total IgE Curve Control Strip** (CC-1 and CC-2) (Art No 10-9325-01: for 5 x 3 curve controls)
- **ImmunoCAP Total IgE Calibrator Strip** (Art No 10-9387-01: for 5 calibration curves)
- **ImmunoCAP Total IgE Anti-IgE** (a-IgE) (Art No 14-4509-01: carrier of 16 ImmunoCAP)
- **Development Solution** (Art No 10-9441-01: for 6 x 200 determinations; Art No 10-9440-01: for 6 x 315 determinations)
- **Stop Solution** (Art No 10-9442-01: for 6 x 185 determinations)
- **Washing Solution** (Art No 10-9422-01: 6 x 1 l)
  - Washing Solution Additive, 6 x 17.2 ml
  - Washing Solution Concentrate, 6 x 80 ml
- **Washing Solution** (Art No 10-9202-01: 2 x 5 l)
  - Washing Solution Additive, 2 x 86 ml
  - Washing Solution Concentrate, 2 x 400 ml
- **ImmunoCAP Total IgE Control LMH** (Art No 10-9447-01: for 3 x 2 x 4 determinations)

Reagents for Phadia 1000

- **ImmunoCAP Total IgE Conjugate 100** (Art No 10-9319-01: for 6 x 100 determinations)
- **ImmunoCAP Total IgE Conjugate 400** (Art No 10-9480-01: for 6 x 400 determinations)
- **ImmunoCAP Total IgE Curve Control Strip** (CC-1 and CC-2) (Art No 10-9325-01: for 5 x 3 curve controls)
- **ImmunoCAP Total IgE Calibrator Strip** (Art No 10-9387-01: for 5 calibration curves)
- **ImmunoCAP Total IgE Anti-IgE** (a-IgE) (Art No 14-4509-01: carrier of 16 ImmunoCAP)
- **Development Solution** (Art No 10-9439-01: for 6 x 1200 determinations; Art No 10-9314-01: for 6 x 2000 determinations)
- **Stop Solution** (Art No 34-2271-51: for 1200 determinations)
- **Washing Solution** (Art No 10-9202-01: 2 x 5 l)
  - Washing Solution Additive, 2 x 86 ml
  - Washing Solution Concentrate, 2 x 400 ml
- **ImmunoCAP Total IgE Control LMH** (Art No 10-9447-01: for 3 x 2 x 4 determinations)

Reagents for Phadia 2500 and Phadia 5000

- **ImmunoCAP Total IgE Conjugate 100** (Art No 10-9319-01: for 6 x 100 determinations)
- **ImmunoCAP Total IgE Conjugate 400** (Art No 10-9480-01: for 6 x 400 determinations)
- **ImmunoCAP Total IgE Curve Control Strip** (CC-1 and CC-2) (Art No 10-9325-01: for 5 x 3 curve controls)
- **ImmunoCAP Total IgE Calibrator Strip** (Art No 10-9387-01: for 5 calibration curves)
- **ImmunoCAP Total IgE Anti-IgE** (a-IgE) (Art No 14-4509-01: carrier of 16 ImmunoCAP)
- **Development Solution** (Art No 10-9314-01: for 6 x 2000 determinations)
- **Stop Solution** (Art No 34-2337-11: for 4600 determinations)
- **Washing Solution Additive** (Art No 10-9518-01: 4 x 850 ml)
- **Washing Solution Concentrate** (Art No 34-2337-21: 1 x 2800 ml)
- **ImmunoCAP Total IgE Control LMH** (Art No 10-9447-01: for 3 x 2 x 4 determinations)

Details of reagents

ImmunoCAP Total IgE Conjugate/Conjugate 100/Conjugate 400	
ß-Galactosidase-anti-IgE Approximately 2 µg/ml (mouse monoclonal antibodies) Sodium azide 0.06%	Ready for use. Store at 2 – 8 °C until expiration date. **Do not freeze!**

ImmunoCAP Total IgE Curve Controls/Curve Control Strip	
(human IgE in buffer) Preservative* <0.003%	Ready for use. Store at 2 – 8 °C until expiration date.

ImmunoCAP Total IgE Calibrators/Calibrator Strip	
(human IgE in buffer) Conc. 2; 10; 50; 200; 1000 and 5000 kU/l Preservative* <0.003%	Ready for use. Store at 2 – 8 °C until expiration date.

ImmunoCAP Total IgE Anti-IgE	
(mouse monoclonal antibodies) Preservative* <0.0015%	Ready for use. Store at 2 – 8 °C until expiration date.

Development Solution	
4-Methylumbelliferyl-ß-D-galactoside 0.01% Preservative* <0.0010%	Ready for use. Store at 2 – 8 °C until expiration date. **Do not freeze!**

Stop Solution	
Sodium carbonate 4%	Ready for use. Store at 2 – 32 °C until expiration date.

Washing Solution
For information, see separate Directions for Use for Washing Solution.

ImmunoCAP Total IgE Control LMH	
Total IgE Control L (Low); Sodium azide 0.05%	Ready for use. Store at 2 – 8 °C until expiration date.
Total IgE Control M (Medium); Sodium azide 0.05%	
Total IgE Control H (High); Sodium azide 0.05%	
ImmunoCAP Total IgE Controls LMH are prepared from selected pooled human samples.	

ImmunoCAP IgE/ECP/Tryptase Sample Diluent	
(buffer solution with Bovine Serum Albumin) Preservative* <0.003%	Ready for use. Store at 2 – 8 °C until expiration date.

***Preservative:** Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2*H*-isothiazol-3-one [EC no. 220-239-6] (3:1).

Additional material

- ImmunoCAP IgE/ECP/Tryptase Sample Diluent (10-9256-01/10-9360-01/10-9541-01)

Materials required but not provided by Phadia AB:

- Measuring cylinder 1000 ml
- Purified water (10, 11) or Clinical Laboratory Reagent Water (CLRW, 12)

Precautions

- For in vitro diagnostic use. Not for internal or external use in humans or animals.
- Some reagents are manufactured from human blood components. The source materials have been tested by immunoassay for hepatitis B surface antigen, for antibodies to HIV1, HIV2 and hepatitis C virus and found to be negative. Nevertheless, all recommended precautions for the handling of blood derivatives should be observed. Please refer to Human Health Service (HHS) Publication No. (CDC) 93-8395 or other local/national guidelines on laboratory safety procedures.
- Reagents containing >0.0015% mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2*H*-isothiazol-3-one [EC no. 220-239-6] (3:1) may cause sensitization by skin contact. Avoid contact with skin. Wear suitable gloves. For more information see Safety Data Sheet.

INSTRUMENTS

Phadia 100 and Phadia 200 process all steps of the assay and print results automatically after the assay is completed[(a)]. Phadia 250, Phadia 1000, Phadia 2500 and Phadia 5000 are continuous random access systems that perform all steps of the assay[(a)].

On board stability

Phadia 100 has no provisions for on board reagent storage. Information on reagent storage for the intended locations on the other Phadia instruments is shown below.

	Phadia 200	**Phadia 250**	**Phadia 1000**	**Phadia 2500, Phadia 5000**
Calibrator/ Curve Control	28 days.			N/A

	Phadia 200	Phadia 250	Phadia 1000	Phadia 2500, Phadia 5000
Conjugate	4 days. Recap bottles every night.		7 days.	
Development Solution	5 days. Recap bottles every night.		14 days.	5 days.
Stop Solution	14 days. Recap bottles every night.		14 days.	31 days.
Washing Solution *(prepared solution)*	7 days. Discard every seventh day and perform weekly maintenance according to respective instrument user manual.			
Washing Solution Concentrate	N/A			30 days.
Washing Solution Additive	N/A			30 days.
Sample Diluent	7 days. Recap bottles every night.		N/A	
ImmunoCAP Carrier	No provision for on board storage.	Until expiration date.		

SPECIMEN COLLECTION AND PREPARATION

Specimen collection

Serum and plasma (EDTA or heparin) samples from venous or capillary blood can be used. Collect blood samples using standard procedures. Keep specimens at room temperature (RT) for shipping purposes only. Store at 2 °C to 8 °C up to one week, or else at –20 °C. Avoid repeated freezing and thawing (9). For further reading on interfering substances, see reference (8).

Note: It is the responsibility of the individual laboratory to use all available references and/or its own studies to determine specific stability criteria for its laboratory. In general, laboratories should perform validation studies before implementing a change in specimen acceptance criteria (14).

Preparation of samples

Sample dilution is usually not required.

For determination of values higher than 5000 kU/l IgE, dilute the samples with ImmunoCAP IgE/ECP/Tryptase Sample Diluent.

Handling of control specimen

It is recommended to remove and recap the control vials from the instrument as soon as the pipetting of the samples is finished and the sample incubation is started. It is also recommended to gently stir the vial before use.

ImmunoCAP Total IgE Controls are ready for use and must not be further diluted. ImmunoCAP Total IgE Controls should be treated in the same way as a patient sample in the procedure.

PROCEDURES

Procedural steps[a]

For procedural steps, see **Notes** a.

Parameters of the procedure

Patient samples are run in single determinations.

Volumes per determination:

Sample	40 µl
Conjugate	50 µl
Development Solution	50 µl
Stop Solution	600 µl

Incubations are performed at 37 °C by Phadia instruments.

Phadia 100: Total time for one assay is 2.5 hours.

Phadia 200: Total time for one assay is up to 4 hours.

Phadia 250, Phadia 1000, Phadia 2500 and Phadia 5000: The process time is 1 hour and 45 minutes from entering the first sample until the result is available.

Calibration[a]

ImmunoCAP Total IgE Calibrators and ImmunoCAP Total IgE Calibrator Strip are run in duplicate to obtain a full calibration curve. The curve can be stored. The software for Phadia instruments has built-in acceptance limits for the calibration curve and the curve controls. Use two curve controls, CC-1 and CC-2, each in single determination to evaluate subsequent runs against the stored curve.

Calibrator range: 2-5000 kU/l.

Reference material: The IgE calibrators are traceable (via an unbroken chain of calibrations) to the 2nd International Reference Preparation (IRP) 75/502, or the equivalent 3rd International Standard 11/234, of Human Serum Immunoglobulin E from World Health Organization (WHO) (13).

QUALITY CONTROL

Record keeping for each assay

It is good laboratory practice to record the lot numbers of the components used, the dates when they were first opened and the remaining volumes.

Control specimen

Good laboratory practice requires that quality control specimen should be included in every run. Any material used should be assayed repeatedly to establish mean values and acceptable ranges.

Controls available from Phadia AB for day to day quality control:

- ImmunoCAP Total IgE Control LMH (10-9447-01)

Intended use

ImmunoCAP Total IgE Controls are used for monitoring ImmunoCAP Total IgE measurements performance in Phadia instruments.

Expected values for ImmunoCAP Total IgE Control LMH

As with all immunoassays the results are affected by the testing procedures and equipment used by different laboratories. It is therefore recommended that each laboratory establishes its own target value for each actual lot of control together with criteria of acceptance (recommended range ± 30%). This established target value is expected to fall within the range for the actual lot stated on the vial label. The range for each specific lot is calculated as a mean ± 3 SD using the expected long term variation. The mean value for each specific lot has been determined from 6 consecutive control assays, each in 6 replicates in ImmunoCAP Total IgE.

Proficiency testing

An external quality assessment program (proficiency testing) is available from Phadia AB for quality assurance purposes (Quality Club):

- Quality Club Total IgE (10-9297-01)

RESULTS

For Phadia instruments using Phadia Information Data Manager Software or Phadia Prime, all calculations are automatically performed[a]. Phadia 100 is programmed to automatically calculate all results[a]. It can also be used with Phadia Information Data Manager Software.

LIMITATIONS OF THE PROCEDURE

A definitive clinical diagnosis should only be made by the physician after all clinical and laboratory findings have been evaluated. It should not be based on the results of any single diagnostic method.

EXPECTED VALUES[b]

Good laboratory practice recommends that each laboratory establishes its own expected range of values.

The results below have been obtained using Phadebas IgE PRIST. The exptected values for Phadebas IgE PRIST can be used for ImmunoCAP Total IgE as comparison studies[b] have shown good concordance between ImmunoCAP Total IgE and Pharmacia CAP System IgE FEIA, as well as between Pharmacia CAP System IgE FEIA and Phadebas PRIST.

Adults: Total IgE levels have been determined using Phadebas IgE PRIST in serum of 412 adult patients with respiratory symptoms, of which 160 were classified non-atopic and 252 had atopic disease, and showed the following distribution pattern between atopic and non-atopic individuals (7): below 25 kU/l - 84% non-atopic, above 100 kU/l - 78% atopic. When determined using Phadebas IgE PRIST (7), the geometric mean calculated from the total IgE levels in serum of 175 non-atopic adults was 13.2 kU/l, + 2 SD = 114 kU/l.

Children: The data from two independent studies using Phadebas IgE PRIST for the determination of total IgE in serum of 466 carefully selected healthy children (4,5), have been used for calculations leading to the following summary of development of serum total IgE levels during childhood (6). After the peak at the age of 10 years, serum total IgE levels decline to adult values.

Age	Geometric mean (kU IgE/l)	+1 SD (kU IgE/l)
6 weeks	0.6	2.3
3 months	1.0	4.1
6 months	1.8	7.3
9 months	2.6	10
12 months	3.2	13
2 years	5.7	23
3 years	8.0	32
4 years	10	40
5 years	12	48
6 years	14	56
7 years	16	63
8 years	18	71
9 years	20	78
10 years	22	85

PERFORMANCE CHARACTERISTICS

Instrument comparison

Comparison studies[b] have been performed with different combinations of Phadia instruments, including more than 85 patient samples. The results obtained show good concordance between instruments.

Precision[b]

For Phadia 100

The following pooled coefficients of variation have been obtained. Each sample has been assayed in 4 replicates on 18 different occasions, using stored calibration curves.

Sample level (kU/l)	Coefficients of variation (%)	
	Within assay	Between assay
13	3	9
75	2	5
640	3	9

For Phadia 200, Phadia 250, Phadia 1000, Phadia 2500 and Phadia 5000

The following pooled coefficients of variation have been obtained with Phadia 1000. Each sample has been assayed in 2 replicates on 24 different occasions, using the same lot of reagents. Each level contains 3 samples. The values are also representative for Phadia 200, Phadia 250, Phadia 2500 and Phadia 5000.

Sample level (kU/l)	Coefficients of variation (%)	
	Within assay	Between assay
15-60	3	5
75-430	3	4
600-1840	3	7

Analytical sensitivity[b]

The detection limit is 2 kU/l.

Analytical specificity[b]

The cross-reactivity with other human immunoglobulins is non-detectable at physiological concentrations of IgA, IgD, IgM and IgG.

Recovery[b]

Mean recovery is 98%.

WARRANTY

The performance data presented here was obtained using the procedure indicated. Any change or modification in the procedure not recommended by Phadia AB may affect the results, in which event Phadia AB disclaims all warranties expressed, implied or statutory, including the implied warranty of merchantability and fitness for use. Phadia AB and its authorized distributors, in such event, shall not be liable for damages indirect or consequential.

SYMBOLS

	Use-by date		Contains sufficient for <*n*> tests
	Batch code		*In vitro* diagnostic medical device
	Date of manufacture		Temperature limit
	Catalogue number		Consult instructions for use
	Caution		Biological risks
	Manufacturer		

Full symbol glossary is available at: https://symbols_glossary.phadia.com.

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Notes

[a]For more information, see Phadia 100, Phadia 200, Phadia 250, Phadia 1000 and/or Phadia 2500/Phadia 5000 User Manual.

[b]Studies performed at Phadia AB, Uppsala, Sweden.

Patents/Trademarks

The following designations are trademarks belonging to Phadia AB:

ImmunoCAP, Phadia, Quality Club.

Trademark change: Phadia AB has changed the trademarks of the instrument platforms from "UniCAP™" and "ImmunoCAP™" to "Phadia™". The new name has been applied to the instruments and related items, e.g. Software and User Manuals. The trademark "ImmunoCAP™" has been removed from the System Reagents. This is a trademark change only; the change has no impact on performance or safety.

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