**Immunocap™ Total IgE**

**Fluoroenzymeimmunoassay**

**CLIA Complexity Category: Moderately Complex**

**INSTRUMENTS**

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

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.

**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%

Ready for use. Store at 2 – 8 °C until expiration date.

Total IgE Control H (High); Sodium azide 0.05%

Ready for use. Store at 2 – 8 °C until expiration date.

**Immunocap™ E/C/EPT/Trystate Sample Diluent**

(buffer solution with Bovine Serum Albumin)

Preservative* <0.003%

Ready for use. Store at 2 – 8 °C until expiration date.

**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 HIV-1, HIV-2 and hepatitis C virus and found to be negative. Nevertheless, all recommended precautions for the handling of blood derivatives should be observed.

Blood Culture Health Service (HHS) Publication No. (CDC) R3-8395 or other local/national guidelines on laboratory safety procedures.

Reagents containing >0.01% mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC no.247-500-7] and 2-methyl-2H-isothiazolin-3-one [EC no.220-239-6] (3:1).

**Additional material**

- Immunocap™ E/C/EPT/Trystate Sample Diluent (10-8256-0110-9360-108541-01)

Materials required but not provided by Phadia AB:

- Measuring cylinder 1000 ml

- Purified water (10, 11) or Clinical Laboratory Reagent Water (CLRW, 12)

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**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 (9).

**Handling of control specimen**
- IgE/ECP/Tryptase Sample Diluent.
- Fordetermination ofvalues higher than 5000kU/l IgE, dilutethesampleswithImmunoCAP Solution.

**Procedure**
- Patientsamplesareruninsingledeterminations.
- TotalIgEControlsshouldbetreatedinthesamewayasapatientsampleintheprocedure.
- ImmunoCAPTotalIgEControlsarereadyforuseandmustnotbefurtherdiluted. ImmunoCAP It is recommended to remove and recap the control vials from the instrument as soon as 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 expressed 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.

**Procedure steps**
- TotalIgEControlsthemselves (14).
- It is 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 expressed 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 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 all immunoassays the results are affected by the testing procedures and equipment used by different laboratories. Therefore it is 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 expressed 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 (9). Phadia 100 is programmed to automatically calculate all results (9). 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**
Good laboratory practice recommends that each laboratory establishes its own expected range of values.

**PERFORMANCE CHARACTERISTICS**

**Instrument comparison**
Comparison studies (12) have been performed with different combinations of Phadia instruments, including more than 85 patient samples. The results obtained show good concordance between instruments.

**Precision**
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.

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

**Analytical sensitivity**
The detection limit is 2 kU/l.

**Analytical specificity**
The cross-reactivity with other human immunoglobulins is not detectable at physiological concentrations of IgA, IgG, IgM and IgE.

**Recovery**
Mean recovery is 98%.
REFERENCES


Notes

*More information, see Phadia 100, Phadia 200, Phadia 250, Phadia 1000 and/or Phadia 2500/Phadia User Manual.

Patents/Trademarks

The following designations are trademarks belonging to Phadia AB:

- ImmunoCAP
- Phadia Quality Club

Trademark changes: Phadia AB has changed the trademarks of the instrument platforms from "ImmunoCAP®" and "ImmunoCAP™" to "Phadia®TM." 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.