Quality Club™ ECP

Directions for Use 52-5213-EN/14

INTENDED USE

Quality Club ECP is a quality assessment program for ImmunoCAP ECP users. The individual laboratory's continuous performance is monitored by comparison of test results generated from other ImmunoCAP ECP users.

PRINCIPLE OF THE PROCEDURE

This kit includes reagents for a period of four months. Each month two of the control samples are assayed and the results are registered online. After a statistical evaluation of all the results, a laboratory specific report is made available.

REAGENTS AND MATERIAL

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. Make sure to check the expiration date of **all** reagents before use.

Reagents for Phadia instruments

- **Quality Club ECP** (Art No 10-9344-01: 8 vials)

Details of reagents

Quality Club ECP	
Sodium azide <0.05%	**
Quality Club ECP Controls are prepared from selected pooled human sera. They are lyophilized to ensure maximum stability. **Reconstitution** Reconstitute the content of a vial by adding exactly 300 µl purified water (1, 2) or Clinical Laboratory Reagent Water (CLRW, 3). Let the vial stand for one minute, then mix gently until the content is completely dissolved. **Shelf-life and storage** **Lyophilized serum: Store at 2 – 8 °C until expiration date Reconstituted serum: Store at -20 °C or 2 – 8 °C for 1 week Repeated freezing and thawing should be avoided.	

Precautions

- For in vitro diagnostic use. Not for internal or external use in humans or animals.
- The 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.

PROCEDURES

Quality Club control samples should be treated in the same way as patient samples and run in accordance with the Directions for Use valid for the assay used. Make sure to transfer the Quality Club controls to the same type of tubes that are used for the patient samples.

The original Quality Club control vials must not be used in the instrument.

The kit contains eight vials of control sample, two vials for each month during the cycle period of four months. The month during which the analysis should be performed is printed on the vial labels.

The results obtained should be registered online before the last day of the month.

Technical support

If you need any technical support, please contact our local sales office or Phadia AB at qualityclub.idd@thermofisher.com.

LIMITATIONS OF THE PROCEDURE

This program is intended for Quality Assessment of the individual laboratory's performance compared to other laboratories and not for control of day-to-day variation.

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	IVD	In vitro diagnostic medical device
LOT	Batch code		Temperature limitation
	Caution		Consult instructions for use
	Manufacturer		Biological Risks
Σ	Sufficient for		

REFERENCES

1. US Pharmacopeia & National Formulary, current edition.
2. European Pharmacopoeia, current edition.
3. CLSI C3-A4, Preparation and Testing of Reagent Water in the Clinical Laboratory, Approved Guideline-Fourth Edition, Clinical and Laboratory Standards Institute, 2006.

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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