

K962274

UniCAP 100 510(k) Submission
Section 15. Summary of Safety and Effectiveness

SEP 12 1996

15. SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is being submitted in accordance with the requirements of The Safe Medical Devices Act of 1990 (SMDA 1990).

Date of Summary Preparation: May 28, 1996

Distributor: Pharmacia Inc.

Manufacturer: Pharmacia AB
S-751 82 Uppsala, Sweden

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Device Names: UniCAP Specific IgE Assay
UniCAP 100 Instrument
UniCAP RM External Software
Pharmacia Specific IgE Control
Pharmacia Specific IgE Negative Control

Common Name: Automated *in-vitro* diagnostic system
for the determination of specific IgE.

Classification:

<u>Product Name</u>	<u>Product Code</u>	<u>Class</u>	<u>CFR</u>
UniCAP Specific IgE Assay	82DHB	I	866.5750
UniCAP 100 Instrument	75JRD	I	862.2750
UniCAP RM External Software	---	I	Accessory to UniCAP 100 Instrument
Pharmacia Specific IgE Control	82DGC	II	866.5510
Pharmacia Specific IgE Neg. Control	82DGC	II	866.5510

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Substantial Equivalence to:

Pharmacia CAP System:

Assay:

Pharmacia CAP System RAST FEIA

Instrumentation:

Positioning Guide 96

AutoCAP

FluoroCount 96

Software:

MasterCAP

Control Sera:

Pharmacia Specific IgE Control

Phadexact Negative Control

Intended Use Statements:

1. UniCAP Specific IgE Assay is an in vitro semi-quantitative assay for the measurement of allergen specific IgE in human serum or plasma. UniCAP Specific IgE assay is to be used with the instrument UniCAP 100. It is intended for *in vitro* diagnostic use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other findings, and is to be used in clinical laboratories, as well as, physician office laboratories.
2. UniCAP 100 is a fully integrated and automated instrument including software for immunodiagnostic testing. UniCAP 100 is a user friendly instrument designed to handle all steps from sample and reagent handling to processing of results.

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3. UniCAP 100 RM External Software is intended to be used with a Windows-based PC operating up to five UniCAP 100 instruments. The external software creates requests and assay runs, retrieves the test results from the instrument, and prints reports. It can also import requests from, and export requests to, a connected mainframe computer or network server.
4. Pharmacia Specific IgE Control is intended for laboratory use in monitoring the performance of specific IgE measurements as determined by UniCAP™ Specific IgE and Pharmacia CAP System™ RAST® RIA/FEIA.
5. Pharmacia Specific IgE Negative Control is intended for laboratory use in monitoring the performance of specific IgE measurements as determined by UniCAP™ Specific IgE, Pharmacia CAP System™, RAST® RIA/FEIA and Phadebas RAST® RIA/FEIA and Phadebas RAST®/Phadezym®.

General Description:

UniCAP is a fully integrated and automated system for the determination of specific IgE in human blood serum or plasma. The UniCAP system includes the UniCAP 100 instrument with software for immunodiagnostic testing; UniCAP reagents, in this submission reagents for the measurement of allergen specific IgE; UniCAP RM External Software; and Pharmacia Specific IgE positive and negative Controls.

The UniCAP 100 instrument is designed to handle all steps from sample and reagent handling to processing of results. Reagents, requests, samples and ImmunoCAP are loaded into the instrument and the process, which takes 2.5 hours is started. A laboratory report is automatically printed when the process is ended.

UniCAP 100 can store a calibration curve to be used for up to one month. After an initial calibration curve is accepted by the software, subsequent assay runs may use the stored calibration curve for calculation of results. In these runs, Curve Controls are included to validate that the run is on the same response level as the stored curve. Limits for the response of the Curve Controls are defined in the UniCAP 100 Operator and Panel Software. A new calibration curve is run once a month, and/or when a new lot number of Specific IgE Conjugate is introduced.

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Device Comparison:

UniCAP Specific IgE Assay reagents when used with the UniCAP 100 Instrument are substantially equivalent to another commercially available assay and instrumentation system for the measurement of Specific IgE, namely Pharmacia CAP System RAST FEIA used with Pharmacia CAP System instrumentation.

Comparison Data:

Comparison studies were performed to establish the substantial equivalence of results using UniCAP 100 and UniCAP Specific IgE Assay compared to the corresponding instrumentation and reagents in Pharmacia CAP System.

The complete comparison study comprised more than 7,000 patient samples covering 170 single allergens and 16 mixed allergens.

Results were given in kU_A/l and in Classes. The correlation between the methods is presented as:

- 1) Agreement in positive and negative results in the two systems.
- 2) Complete agreement within Classes in both systems.
- 3) Complete agreement ± 1 Class in both systems.

Agreement in positive and negative results between UniCAP 100 and PharmaCAP System is 99.8%; complete agreement within Classes is 70-95% and complete agreement ± 1 Class in both systems is 97-100%.