# General Description of the Automated Immunochemical Analyzer, PAMIA-40*i*

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*This analyzer has been developed as a desk-top, compact automated immunochemical analyzer. Several innovative features characterize the PAMIA-40i, including an unique reagent container/holder for easier reagent handling, automatic reagent cap opener/closure, and reagent identification (by bar code). This new model adds functionality by its acceptance of open-topped test tube, network compatibility, and whole blood analysis capability. In addition, it also allows setting of seven parameters for special RANREAM reagents, and has random access and automatic dilution measuring functions.*

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**Key Words** Automated Immunochemical Analyzer, PAMIA-40*i*, Rapid Measurement, Network, Particle Counting Immunoassay

NOTE: This product is not available in some area. Please contact your local sales representative for any inquiry.

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## INTRODUCTION

The PAMIA, automated immunochemical analyzer, with Particle Counting Immunoassay (PCIA) as the principle measurement realizes random access measurement with 15-minute reaction time by utilizing the characteristics of homogeneous assay. PAMIA also has rapid and easy measurement with the apparatus and reagents, and is widely used for testing for infection. We developed the automated immunochemical analyzer, PAMIA-40*i* (hereinafter, PAMIA-40*i*, ***Fig. 1***) equipped with an added function, whole blood analysis capability.
Herein, we report the outline of the PAMIA-40*i*.

## DEVELOPMENTAL CONCEPTS

To meet the diversified needs for imaging in laboratory systems required for health care in the 21st century, the PAMIA-40*i* has been developed with the following concepts.
1) Compact and desk-top type apparatus
2) Within-20-minute reaction time
3) High sensitivity despite homogeneous assay system
4) Additional new functions
(whole blood analysis capability)
5) Rapid and easy for emergent testing
6) Equipped with easy-to-use functions
(reagent ID, automatic reagent cap opener/closure)
7) Additional new function utilizing network

## TECHNOLOGY

### Principle of measurement

This method is based on the principle of latex aggregation, and the target compound is detected by the counting of latex particles. That is, the reactants of antibodies in samples and antigen-sensitized latex particles are introduced to the center of flow cell according to the sheath flow mechanism passing through in a line. A laser beam is used to count aggregated latex (P: Polymer) and non-aggregated latex (M: Monomer). The aggregation ratio P/T (T=P+M) is calculated. Concentrations depending on aggregation ratios are calculated from the calibration curve using the standard sample (calibrator) with known concentration (use antibody-sensitized latex in assaying antigens in samples).

***Fig. 1*** *PAMIA-40i*

## Whole blood analysis

In the PAMIA, concentrations are determined using scattered light intensity of polymer and monomer generated by the antigen-antibody reaction between sample and latex. Since the scattered light intensity of blood cell components is stronger than that of latex particles when whole blood is used as the sample, blood cells can be counted by discriminating latex particles and blood cells (***Fig. 2***).
In the PAMIA-40*i*, concentrations are corrected from the blood cell counts.

## Function

The special reagents, RANREAM for the PAMIA series basically comprise three reagents (buffer, latex, diluent for sample). When randomly accessing 7 parameters, 21 bottles are fully installed. Integration of reagents for every parameter using PAMIA Caps (***Fig. 3***), makes it easy to set reagents.
The reagents set in the analyzer are automatically read with the bar code to set the information on reagents (parameter name, number of test, expiration date, Lot No.). After completion of measurement, the three reagents are simultaneously removed from the analyzer to be retained.
The PAMIA-40*i* is equipped with automatic opening and closing of PAMIA Caps. The cap is opened before aspiration of reagent, and closed after the reagent is aspirated with a pipette. Therefore, this mechanism enables automatic opening and closing of reagent caps.
Additionally, the PAMIA-40*i* is equipped with the following functions:

- Syringe all-in-one pipette (improvement of assay precision)
- Monitoring of sample aspiration (checks for plugs in pipettes and blank aspirations)
- Built-in sheath liquid tank (reduction of remaining quantity of sheath liquid)
- Automatic switch-off at completion of shutdown

## Precision

When precision was tested using two kinds of samples in 10 consecutive times, excellent results were obtained (CV=1.38-2.92%) (***Table 1***).
When between-day imprecision was continuously tested using sample in 10 consecutive times a day for 10 days, an excellent result was obtained (CV=2.18%) (***Table 2***).

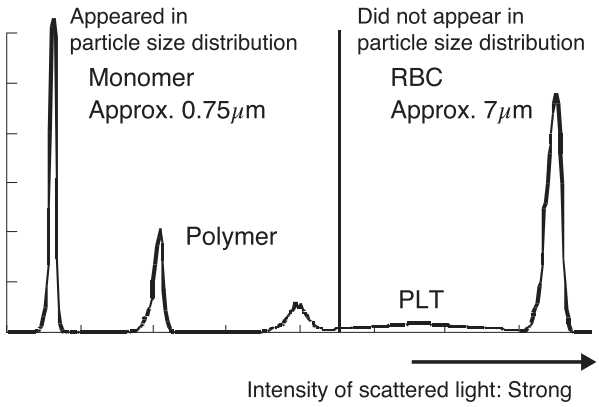


***Fig. 2*** *Intensity of scattered light by latex and blood cells*

***Fig. 3*** *RANREAM reagents installed in PAMIA Cap*

***Table 1*** *Precision of HCVII EX (C.O.I.)*

| n | Sample 1 | Sample 2 |
|---|---|---|
| 1 | 0.99 | 8.93 |
| 2 | 1.03 | 9.05 |
| 3 | 0.97 | 8.81 |
| 4 | 1.01 | 8.92 |
| 5 | 0.99 | 9.00 |
| 6 | 1.06 | 8.89 |
| 7 | 1.01 | 8.98 |
| 8 | 0.97 | 8.89 |
| 9 | 1.02 | 8.60 |
| 10 | 1.04 | 8.91 |
| Mean (C.O.I.) | 1.01 | 8.90 |
| SD (C.O.I.) | 0.03 | 0.12 |
| CV(%) | 2.92% | 1.38% |

C. O. I. = Cut off Index

***Table 2*** *Between-day imprecision of HCVII EX*

| Day No. | C.O.I. | P/T (%) |
|---|---|---|
| 1 | 8.36 | 14.20 |
| 2 | 8.19 | 13.94 |
| 3 | 8.56 | 14.52 |
| 4 | 8.77 | 14.86 |
| 7 | 8.54 | 14.49 |
| 8 | 8.27 | 14.06 |
| 9 | 8.56 | 14.52 |
| 10 | 8.48 | 14.39 |
| Mean (C.O.I.) | 8.47 | 14.37 |
| SD (C.O.I.) | 0.18 | 0.29 |
| CV (%) | 2.18% | 2.05% |

## SPECIFICATIONS

### Name

1) Name : Automated immunochemical analyzer
2) Model : PAMIA-40*i*

### Usage

Quantitative or qualitative determination of trace proteins in human serum, plasma, whole blood, and urine, etc.

### Principle and test parameters

1) Principle: Particle counting immunoassay (PCIA)
2) Test parameters: (serum test parameters)
   - α-Fetoprotein (RANREAM AFP)
   - Caricinoembryonic antigen (RANREAM CEA)
   - PSA (RANREAM PSA)
   - HCV antibody (RANREAM HCV II EX)
     *Measurable with whole blood
   - HBs antigen (RANREAM HBs Ag)
     *Measurable with whole blood
   - HBs antibody (RANREAM HBs Ab)
   - HBe antigen (RANREAM HBe Ag)
   - HBe antibody (RANREAM HBe Ab)
   - HBc antibody (RANREAM HBc Ab)
   - TP antibody (RANREAM TP)
     *Measurable with whole blood
   - Syphilitic lipid antibody (RANREAM STS)
   - Ferritin (RANREAM FRN)
   - β2-Microglobulin (RANREAM B2M)
     *Measurable with urine
   - IgE (RANREAM IgE)
   - Insulin (RANREAM Insulin)
     *Measurable with plasma

### Throughput

1) Sample processing speed : 70 tests/hr (max.)
2) No. of installations of reagents : 7 parameters
3) No. of installations of samples : Usually: 50 samples, Emergent: 1 sample
4) Reaction time : Approx. 15 minutes

### External output

1) LAN interface
2) Serial interface

### Dimensions and weight

1) Dimensions : 765 (W) × 582 (H) × 566 (D) mm
2) Weight : Approx. 68 kg

### Power source

AC 117/ 220/ 230/ 240V ± 10% (50/60Hz)

### Power Consumption

480VA or less

## CONCLUSIONS

In this study, we reported some of the data on the automated immunochemical analyzer, PAMIA-40*i* we developed. The PAMIA-40*i* provides rapid testing and is easy to use. It can contribute to shortening the Turn Around Time (TAT), and provide new additional functions as a laboratory analyzer required for health care in the 21st century.

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***References***

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