Laboratory evaluation of the COBAS MIRA S random access analyser

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The random access analyser COBAS MIRA S (Roche Diagnostics) was evaluated for two months. The instrument is a computer-controlled discrete analyser which can be run in a combination profile and/or single test mode. This instrument has special features, including an automatic cuvette segment changer, a reagent rack cooling system, an external keyboard and monitor, as well as a bar-code facility for the entry of test parameters, worklists and sample identification numbers. Study of within-run and between-run precision gave values of % CV = 0.54–3.37 and 0.61–3.65, respectively, for a variety of assays. Linearity testing to the upper limit of each test was also studied and were found to cover the necessary pathological range. Within the two-month period, no major problems were encountered. The instrument required minimum operator attention during operation. Correlation studies with the Hitachi 705 using six clinical chemistry tests (glucose, cholesterol, triglyceride, ALP, AST, ALT) gave correlation coefficients ranging from 0.95–0.99 and slopes of 0.91–1.17.

Materials and methods

In this paper, the results of an assessment on the analytical performance of COBAS MIRA S are reported. Six routine chemistry tests were selected (table 1) for use in the study of its suitability and usefulness in small- to medium-sized laboratories where routine service and statistic tests in both batch and random access mode are performed. The evaluation studies performed included within-run and between-run precision at four analyte concentrations, method linearity and relative accuracy (comparison studies).

Table 1. Methods and volumes used on the COBAS MIRA S.

| Test     | Method basis                  | Sample vol. (µl) | Total reagent vol. (µl) |
|----------|-------------------------------|-----------------|------------------------|
| Glucose  | UNI-KIT: Hexokinase (UV endpoint) | 4.0             | 200                    |
| Cholesterol | UNI-KIT: Cholesterol oxidase (PAP) | 4.0             | 350                    |
| Triglyceride | UNI-KIT: Colorimetric end-point (PAP) | 4.0             | 300                    |
| ALP      | UNI-KIT: Kinetic at 405 nm (IFCC, 37 °C) | 6.0             | 250                    |
| AST      | UNI-KIT: Kinetic at 340 nm (IFCC, 37 °C) | 16.0            | 145                    |
| ALT      | UNI-KIT: Kinetic at 340 nm (IFCC, 37 °C) | 16.0            | 145                    |

*All reagents were supplied by Roche Diagnostics.
Table 3. Within-run precision at four analyte concentrations. Coefficients of variation (CV) are given in % (N = 20).

| Sample          | Glucose (mmol/l) | Cholesterol (mmol/l) | Triglyceride (mmol/l) | ALP (I.U./l) | AST (I.U./l) | ALT (I.U./l) |
|-----------------|------------------|----------------------|-----------------------|--------------|-------------|-------------|
|                 | Mean CV          | Mean CV              | Mean CV               | Mean CV      | Mean CV     | Mean CV     |
| Control N*      | 5.58 1.47        | 1.96 1.68            | 0.29 1.81             | 63.08 1.48   | 150.10 0.63 | 39.11 0.97  |
| Control P       | 11.96 1.58       | 2.61 1.94            | 0.37 2.11             | 191.80 0.89  | 189.30 0.54 | 91.53 0.72  |
| Ciba-Corning    | 4.31 1.30        | 3.34 0.75            | 0.96 1.53             | 72.74 1.65   | 26.47 2.81  | 23.19 2.36  |
| Lyophil        | 4.66 0.70        | 3.73 0.99            | 1.34 1.20             | 67.43 0.76   | 45.13 0.81  | 21.67 3.67  |

* Lot K 1736.

Table 4. Between-run precision at four analyte concentrations. Coefficients of variation (CV) are given in % (N = 20).

| Sample          | Glucose (mmol/l) | Cholesterol (mmol/l) | Triglyceride (mmol/l) | ALP (I.U./l) | AST (I.U./l) | ALT (I.U./l) |
|-----------------|------------------|----------------------|-----------------------|--------------|-------------|-------------|
|                 | Mean CV          | Mean CV              | Mean CV               | Mean CV      | Mean CV     | Mean CV     |
| Control N*      | 5.08 1.00        | 1.70 1.33            | 0.27 3.17             | 64.85 3.65   | 134.55 0.61 | 33.00 0.98  |
| Control P       | 12.68 1.44       | 1.81 1.93            | 0.39 3.15             | 211.55 1.48  | 194.30 1.11 | 90.85 1.02  |
| Ciba-Corning-N  | 4.80 1.33        | 3.49 1.74            | 0.94 1.86             | 84.25 3.51   | 27.20 2.82  | 24.90 2.81  |
| Lyophil        | 5.08 0.62        | 3.89 1.22            | 1.36 1.21             | 78.10 2.78   | 46.25 1.38  | 24.90 3.17  |

* Lot K 1440.

Table 5. Linearity of assays as performed by the COBAS MIRA S.

| Test           | Determined range of linearity |
|----------------|------------------------------|
| Glucose        | 0.56-26.42 mmol/l            |
| Cholesterol    | 0.0-18.10 mmol/l             |
| Triglyceride   | 0.0-6.58 mmol/l              |
| ALP            | 0-975 I.U./l                 |
| AST            | 0-397 I.U./l                 |
| ALT            | 0-428 I.U./l                 |

Table 6. Linear regression statistics for the COBAS MIRA S (y-axis) against the Hitachi 705 (x-axis).

| Test  | Slope  | y-intercept | Correlation coefficient | N  |
|-------|--------|-------------|-------------------------|----|
| Glucose | 0.91   | 14.18       | 0.98                    | 126|
| Cholesterol | 0.98  | -11.76      | 0.99                    | 127|
| Triglyceride | 1.00  | -0.79       | 0.99                    | 147|
| ALP    | 1.17   | -2.36       | 0.99                    | 120|
| AST    | 1.04   | 1.44        | 0.99                    | 121|
| ALT    | 1.01   | 0.27        | 0.99                    | 124|

Specimens

The following commercially available control sera were used in the precision studies according to the manufacturer’s instructions: (1) control serum N: lot K 1736 and lot K 1440 and control serum P: lot C 2741 Roche Diagnostics; (2) Ciba-Corning: lot Ch-B: 036701, USA and (3) Lyophil: lot 018605 (locally produced, distributed by the faculty of Medical Technology, Mahidol University).

More than 120 patient samples (low, normal and above-normal levels) were selected for comparison studies. Half of each specimen was used for assays in the COBAS MIRA S, while the other half was used for assays in the Hitachi 705. The above-normal concentration specimens were used in the linearity studies.

Calibration

The COBAS MIRA S and the Hitachi 705 were calibrated with Roche Diagnostics calibration material.

Results

Precision

The evaluation of the performance of COBAS MIRA S took two months. Close supervision and appropriate training were given initially by Roche Diagnostics (Thailand) Ltd. Within-run and between-run precisions were assessed. Six clinical chemical analytes were selected: glucose, cholesterol, triglyceride, alkaline phosphatase (ALP), aspartate aminotransferase (AST) and alanine aminotransferase (ALT). For within-run studies, four commercially available control sera were analysed 20 times each in single batches, while the between-run...
Figure 1. Comparison of results for the six analytes determined on the COBAS MIRA S (y-axis) and the Hitachi 705 (x-axis). Refer to tables 1 and 2 for the details of the methods used in the analysis.
precision was estimated by running the same sera on 20 separate days. The values of the imprecision within-run and between-run obtained are shown in tables 3 and 4, respectively. The overall % CV of both precision studies gave values of not greater than 3%.

Linearity

High value samples that greatly exceed the upper limit of determinations were appropriately diluted with isotonic saline for use in linearity studies of each method. The upper limit of each analyte obtained from the study is shown in table 5. The upper limits were in close agreement with the expected range for each analyte as claimed by the manufacturer.

Accuracy

More than 120 serum samples, representing both normal and abnormal levels were divided and run simultaneously in the COBAS MIRA S and the Hitachi 705. The comparison data which comprise slopes, intercepts and correlation coefficients are shown in table 6 and figure 1. The Hitachi 705 is the independent variable and COBAS MIRA S is the dependent variable. Good agreement was found in all cases.

Discussion

The purpose of this study was to assess the overall performance of the COBAS MIRA S in a clinical laboratory performing routine tests.

The precision data in table 3 and 4 show that the range of precision determined from COBAS MIRA S is within the acceptable limits. The good precision with % CV, in the range of 0.5–3.6, may be due to the pipetting system, where the reagent and sample probe are washed, and to the individual reaction cuvette used in the test measurement.

The comparison of the test results obtained on serum samples with COBAS MIRA S and with the Hitachi 705 shows that the degree of correlation was very good (r ranging from 0.95–0.99).

In laboratories where ambient controlled temperature is often in the range of 25–30 °C, the rack cooling device is a very useful compartment to hold temperature-sensitive reagents, especially where large batch of reagents are needed to facilitate the ‘true walk-away’ facility (provided by the manufacturers for 312 analyses to be determined in one run and facilitated by the automatic cuvette segment changer).

The instrument performed well over the evaluation period. No major problems with regards to instrument failure occurred during the study. The operator’s manual and guidelines for trouble-shooting were easy to follow.

In conclusion, the COBAS MIRA S is a flexible, convenient and easy-to-use analyser for either batch or random access work. Its design and operational simplicity provides reliable analytical data, as demonstrated by good correlation with the existing instrument. Unique, cooled reagent reservoirs and sealed serum cups make the COBAS MIRA S an ideal instrument for use in small to medium-sized laboratories where efficient output of laboratory data is required.

Acknowledgement

The authors wish to express their sincere thanks to Roche Diagnostics (Thailand) for the reagents and technical support.

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