Introduction

The novel cobas® pure integrated solutions (Roche Diagnostics International Ltd, Rotkreuz, Switzerland) is a serum work area laboratory analyzer developed to quantify ion selective electrolyte (ISE), immunochrometry, and clinical chemistry parameters in serum, plasma, cerebrospinal fluid, and urine samples.

A multicenter study to evaluate cobas pure integrated solutions was conducted at five sites in Europe and Asia (Heidelberg & Ludwigshafen, Germany; Visp, Switzerland; Wroclaw, Poland; Seoul, Republic of Korea).

Objectives

To evaluate the analytical performance, functionality, reliability, comparability, practicability, and usability of cobas pure integrated solutions under routine-like conditions.

Here, we report the comparability of cobas pure integrated solutions versus respective routine analyzers at four sites.*

*Results for exploratory performance and system validation are presented in Appendix M040 and M041 respectively of this congress.

Methods

In total, 47 selected analytes with 53 applications were assessed; here, we present 18 of the most common analytes:

- Electrolytes: chloride, potassium, and sodium.
- Immunochrometry: free thyroid hormone thyroxine, NT-proBNP, and vitamin B12.
- Clinical chemistry: albumin, alanine aminotransferase, aspartate aminotransferase, calcium, cholesterol, creatinine, C-reactive protein, glucose, hemoglobin A1c, and phosphorous.

We conducted routine simulation method comparison experiments using routine leftover samples (pooled and stored at 2–8°C) to evaluate the comparability of cobas pure integrated solutions with the following routine analyzers at the following sites:

- Visp, Switzerland: cobas INTEGRA 400 plus and cobas e 411.
- Ludwigshafen, Germany: cobas pro and cobas 8000.
- Heidelberg, Germany: cobas 8000.

Available results from routine samples in the Laboratory Information Systems (LIS) Host were transferred to data capture software WinCAEv and then measurement requests were transferred by WinCAEv to cobas pure integrated solutions (Figure 1). Following sample measurement, cobas Passing-Bablok regression analyses were performed; slopes, intercepts, and correlations were calculated and compared with pre-defined acceptance criteria.

Results

More than 35,000 result pairs were included in the analysis.

For the 53 applications, 90% of the method comparisons with Roche methods met the Passing-Bablok slope and intercept acceptance criteria, as applied for standard method comparisons. The 18 most common analytes are presented in Figure 2.

A total of 218 method comparisons generated a median Passing-Bablok regression slope of 1.00 (67% of comparisons were between 0.95 and 1.05), a median bias at the medical decision point of −0.1% (87% ≤ ±5%), and a median Pearson’s r of 0.998 (Tables 1–3).

Conclusion

The results of this study demonstrate that cobas pure integrated solutions deliver comparable and accurate results versus commercially available analyzers at four different evaluation sites across a selection of 47 analytes under routine-like conditions.

Table 1. cobas pure integrated solutions versus respective routine analyzers: ISE analytes

| Parameter | Site and analyzer | cobas pure INTEGRA 4000R | cobas pro | cobas e 411 | cobas INTEGRA 400 plus | cobas 8000 | Heidelberg/linke +
|-----------|------------------|---------------------------|----------|------------|------------------------|------------|------------------|
| Slope     | y = 0.968 * x + 0.04 | y = 0.986 * x + 0.03     | y = 0.98  | y = 0.98   | y = 0.98               | y = 0.99   | Heidelberg/linke +
| Intercept | -0.02            | -0.01                      | -0.01     | -0.01      | -0.01                  | -0.01      | Heidelberg/linke +

Table 2. cobas pure integrated solutions versus respective routine analyzers: clinical chemistry analytes

| Parameter | Site and analyzer | cobas pure INTEGRA 4000R | cobas pro | cobas e 411 | cobas INTEGRA 400 plus | cobas 8000 | Heidelberg/linke +
|-----------|------------------|---------------------------|----------|------------|------------------------|------------|------------------|
| Slope     | y = 0.968 * x + 0.04 | y = 0.986 * x + 0.03     | y = 0.98  | y = 0.98   | y = 0.98               | y = 0.99   | Heidelberg/linke +
| Intercept | -0.02            | -0.01                      | -0.01     | -0.01      | -0.01                  | -0.01      | Heidelberg/linke +

Table 3. cobas pure integrated solutions versus respective routine analyzers: immunochromology analytes

| Parameter | Site and analyzer | cobas pure INTEGRA 4000R | cobas pro | cobas e 411 | cobas INTEGRA 400 plus | cobas 8000 | Heidelberg/linke +
|-----------|------------------|---------------------------|----------|------------|------------------------|------------|------------------|
| Slope     | y = 0.968 * x + 0.04 | y = 0.986 * x + 0.03     | y = 0.98  | y = 0.98   | y = 0.98               | y = 0.99   | Heidelberg/linke +
| Intercept | -0.02            | -0.01                      | -0.01     | -0.01      | -0.01                  | -0.01      | Heidelberg/linke +

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