Reagent on-board stability study on the new economic respons®910 clinical analyser

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Introduction

The DiaSys respons®910 system is a compact, economic, fully automated bench-top clinical chemistry analyser designed for small to mid-size workloads.

Key features are the simultaneous 12 wavelength detection and the economic long-term on-board stabilities of reagents on a non-refrigerated reagent rotor tray.

Figure 1: *DiaSys respons®910*

To demonstrate the long-term on-board stability a panel of 28 clinical IVD reagents was evaluated. The panel included tests sensitive to environmental factors, like atmospheric oxygene, carbon-dioxide, temperature or evaporation.

The Creatinine Jaffé method is known to the laboratory for short on-board stability. Cholesterol on the other hand is known to be a very stable reagent. Therefore these two reagents were used as benchmark for the stability under non-cooled reagent storage conditions on the respons®910 instrument.

Results

Table 1 summarizes the results of the on-board stability study under non-refrigerated conditions vs. refrigerated storage. Although the temperature range in the non-cooled reagent compartment was from 25°C to 30°C the notable on-board stabilities for Creatinine Jaffé and Cholesterol reagent are shown in Figures 2 - 5. In particular the Creatinine Jaffé reagent showed a 5-fold extended on-board and nearly a doubled calibration stability compared to the Hitachi 911 refrigerated system.

	confidence limits	respons®910 non-cooled reagent storage		Hitachi 911 cooled reagent storage	
assay	± x%	on-board	calibration	on-board	calibration
AMY	10	4 w	2 w	4 w	4 w
ALP	10	3 w	7 d	8 d	8 d
ALT	10	4 w	4 w	4 w	4 w
ALT + p5p	10	4 w	4 w	6 d	6 d
AST	10	6 w	6 w	4 w	4 w
AST + p5p	10	10 d	10 d	6 d	6 d
Ca P	6	10 d	10 d	8 w	8 w
CHOL	7	8 w	4 w	4 w	4 w
CK NAC	10	6 w	3 w	4 w	4 w
CK-MB	10	4 w	1w	6 w	6 w
CREA (Jaffé)	10	3 w	1 w	4 d	4 d
CRP	10	4 w	1 w	4 w	4 w
DBIL	10	6 w	3 w	4 w	4 w
FE	10	6 w	1 w	6 w	6 w
GGT	10	2 w	1 w	4 w	4 w
GLUC (HK)	10	6 w	6 w	4 w	4 w
HbA1c	10	4 w	10 d	8 w	8 w
HCO3	10	3 w	2 w	3 w	3 w
HDL	10	4 w	2 w	4 w	4 w
LDH	9	5 w	4 d	10 d	5 d
LDL	10	4 w	10 d	4 w	4 w
LPS	10	6 w	1 w	6 w	6 w
PO3	9	3 w	1 w	4 w	4 w
TBIL	10	4 W	3 d	4 w	4 w
TP	6	10 d	7 d	10 d	7 d
TRIG	9	4 w	7 d	4 w	2 w
UA (TOOS)	10	6 w	3 w	6 w	6 w
UREA	10	4 w	7 d	6 w	6 w

Table 1: *Summary of the on-board stability study results. Legend: w = weeks; d = days*

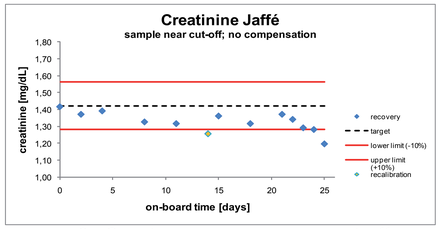

Figure 2: *Creatinine sample near cut-off*

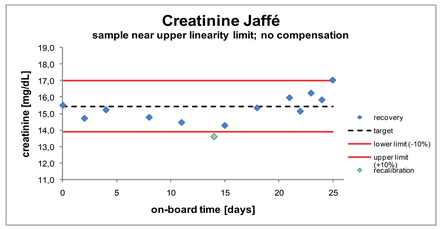

Figure 3: *Creatinine sample near upper linearity limit*

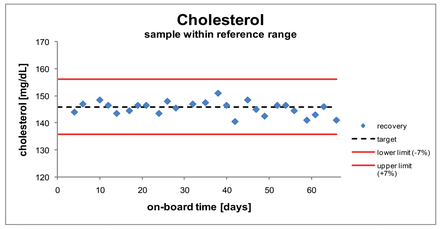

Figure 4: *Cholesterol sample within reference range*

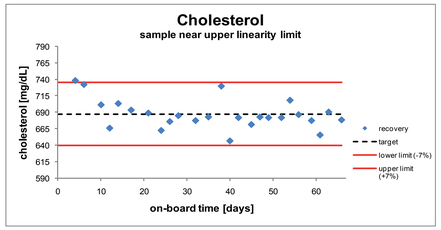

Figure 5: *Cholesterol sample near upper linearity limit*

Materials & Methods

On-board and calibration stability tests for 28 assays have been carried out on two respons®910 systems in parallel.

All reagents, calibrators and controls were commercial available products of DiaSys Diagnostic Systems GmbH.

Three different levels, one within normal range, one pathological sample and one near the upper linearity limit of the assay, were measured in each assay at least twice a week over a total period of nine weeks. The sample at the upper linearity limit verifies the validity of the measuring range.

Acceptance criterion was the recovery of each assigned target value within ±10% limits. For parameters where the Guidelines of the German Federal Medical Society [3], requires deviations below ±10% limits, these criteria were used for result assessment.

In case the result missed the target criteria, the assay was re-calibrated. If the limit was failed again after re-calibration, the study for that dedicated clinical parameter was terminated.

Conclusion

The in-use stability under non-refrigerated conditions was shown for a panel of representative clinical assays. All reagents on board of the system showed calibration and in-use stabilities comparable to modern analysers with refrigerated reagent compartments. It was demonstrated that the respons®910 is an economic, robust system, which meets the demands of a state-of-the-art clinical laboratory.

References

[[1] La Penberthy. A Users Guide to Statistics in Clinical Chemistry. *J Clin Biochem Revs* (1986);7:3947.

[2] CLSI. Evaluation of Stability of In Vitro Diagnostic Reagents; approved guideline. CLSI Document EP25-A. Wayne (PA): CLSI; 2009.

[3] „Richtlinie der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen“. Deutsches Ärzteblatt (2008); Jg. 105:Heft 7.