

# Sample Quality Assessment of the Serumbank@UZA

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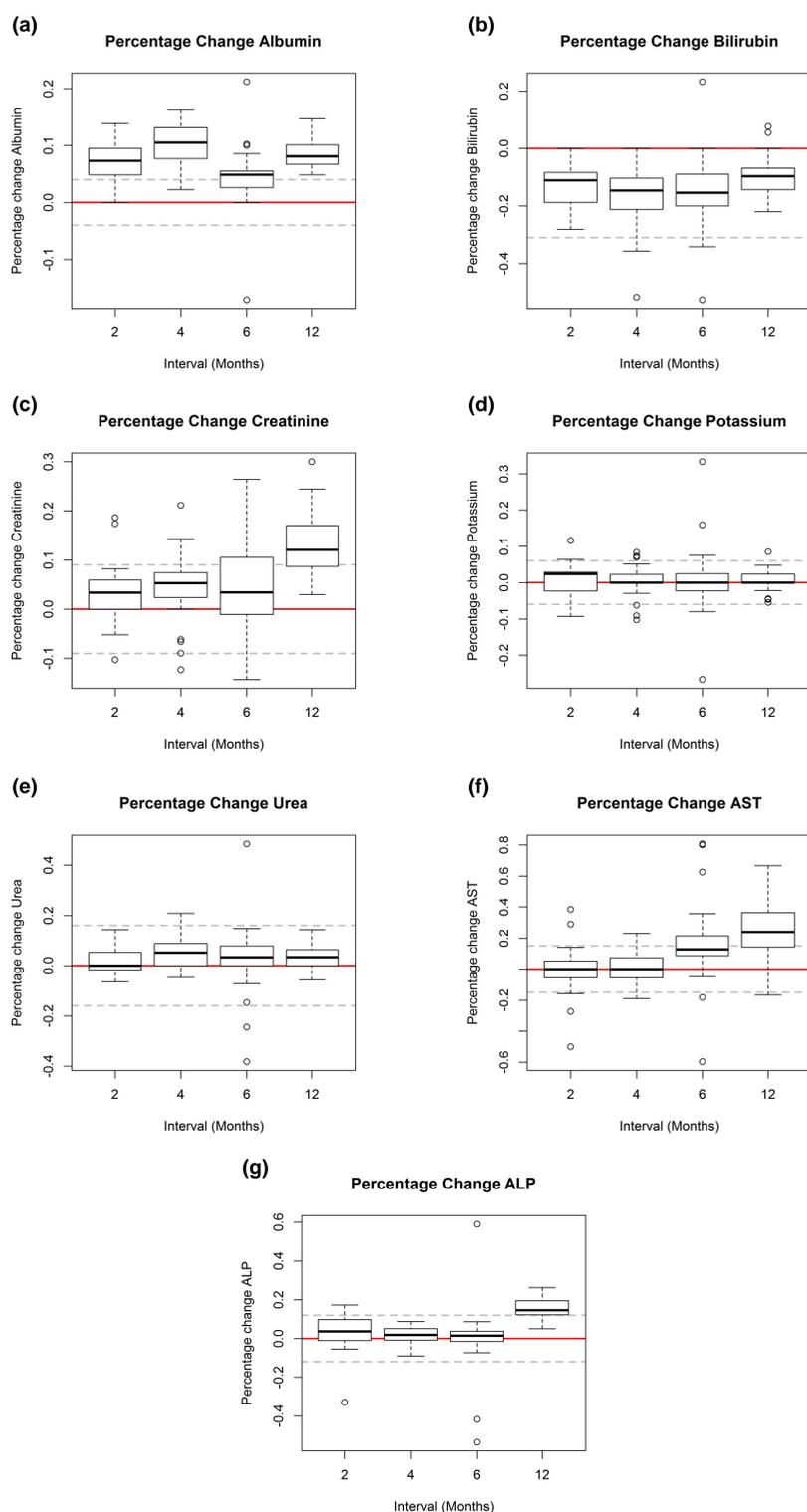
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## Introduction & Aim

Serumbank@UZA is side-project of the Tumorbank@UZA-initiative, focussing on the systematic collection of residual sera from oncological subjects obtained from routine blood check-ups. The serumbank is established by a close collaboration between the department of Oncology, department of Clinical Chemistry and Tumorbank@UZA. Specimens are obtained in a semi-automated manner, by which eligible samples are labelled, automatically analyzed and fractionated, and subsequently manually stored at -80 °C. Technical specifications and laboratory results are uploaded into the sample management system (Slims, Genohm). Since the start in early 2012, the serumbank has collected over 7900 serum specimens. In order to proof the usefulness of these specimens for scientific research, sample quality of residual sera was assessed at different time-intervals based on several routine serum parameters.

Overall Changes	TEa	95% CI Difference	Inequality*	Equivalence*
Albumin	0.04	0.07 [0.06; 0.08]	< 0.0001	1.000
Total bilirubin	0.31	-0.14 [-0.15; -0.1]	< 0.0001	< 0.0001
Creatinine	0.09	0.05 [0.04; 0.06]	< 0.0001	< 0.0001
Potassium	0.06	0.01 [0.00; 0.01]	0.0959	< 0.0001
Urea	0.16	0.02 [0.01; 0.03]	0.0003	< 0.0001
AST	0.15	0.08 [0.05; 0.11]	< 0.0001	< 0.0001
ALP	0.12	0.04 [0.02; 0.05]	< 0.0001	< 0.0001

**Table 1. Overall results of 7 serum parameters.** Total allowable error (TEa) (www.westgard.com); confidence interval (CI). \*Statistical significance was considered at a p-value  $\leq 0.05$ .



**Figure 1. Percentage change at 2, 4, 6 and 12 months compared to baseline:** Albumin (a), total bilirubin (b), creatinine (c), potassium (d), urea (e), AST (f) and ALP (g). Dashed line represents total allowable error (allowable change) and red line represents 0.0% (no change).

## Materials & Methods

**Specimens:** Sample vials (0.5 mL) containing residual sera were selected after storage for 2 months (n = 30), 4 months (n = 30), 6 months (n = 30) and 12 months (n = 31). Samples were defrosted at room temperature and reanalyzed (Dimension Vista® 1500, Siemens) at the department of Clinical Chemistry for: Albumin, total bilirubin, creatinine, potassium, urea, aspartate transaminase (AST) and alkaline phosphatase (ALP).

**Statistics:** Difference between baseline value (prior to storage at -80 °C) and new values at 2, 4, 6 and 12 months were expressed in percentage change. Changes were tested for inequality with 95% confidence interval (CI) and equivalence using a two-one-sided T-test and the total allowable error (TEa = allowable bias + 1.65 x allowable imprecision). A p-value of less than or equal to 0.05 was considered statistically significant.

## Results

**Overall Results:** Test of inequality showed a statistically significant increase for albumin, creatinine, urea, AST and ALP, and a statistically significant decrease for total bilirubin (p < 0.05). No changes were observed for potassium (p = 0.10). Despite statistical changes, equivalence was maintained in all parameters (p < 0.0001), except for albumin (table 1).

**2 Months:** Changes were observed for albumin, total bilirubin, creatinine and ALP (p  $\leq 0.05$ ), while equivalence was maintained for total bilirubin (-0.15; -0.1), creatinine (0.01; 0.05), potassium (0.00; 0.03), urea (0.00; 0.04), AST (-0.07; 0.05) and ALP (0.00; 0.07) (p < 0.0001) (Figure 1).

**4 Months:** Changes were observed for albumin, total bilirubin, creatinine and urea (p < 0.05), while equivalence was maintained for total bilirubin (-0.2; -0.15), creatinine (0.02; 0.07), potassium (-0.01; 0.02), urea (0.03; 0.07), AST (-0.03; 0.04) and ALP (0.00; 0.03) (p < 0.001) (Figure 1).

**6 Months:** Changes were observed for albumin, total bilirubin, creatinine and AST (p < 0.01), while equivalence was maintained for total bilirubin (-0.2; -0.1), creatinine (0.02; 0.08), potassium (-0.03; 0.04), urea (-0.03; 0.08) and ALP (-0.07; 0.07) (p < 0.01) (Figure 1).

**12 Months:** Changes were observed for all parameters (p  $\leq 0.0001$ ), except potassium, while equivalence was maintained in total bilirubin (-0.12; -0.07), potassium (0.00; 0.02), urea (0.02; 0.05) (p < 0.0001) (Figure 1).

## Conclusions

In general, the observed serum parameters were well preserved after storage at -80 °C given that the overall changes remained within the allowable errors. The collection of residual sera is absolutely useful and further characterization and quality measurements enable optimization of their usage in scientific research.

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