Abstract:
Objective: The healthcare quality debate is centered on innovative processes to achieve better outcomes. Our objective was to review the error rate in clinical diagnostic laboratories in sigma levels to understand causes of errors and opportunities for improvement in the process.

Design / Methods: Six-sigma is a valuable guideline in achieving quality goals. A sigma value indicates the frequency of defects occurring in a process. We conducted a review of studies that investigated the rate of errors in clinical laboratory and process improvement strategies using six sigma.

Results: The present day healthcare services are only functioning at three-sigma and, in some cases, four-sigma levels. Despite low error rates, the magnitude of usage of clinical laboratories is so high that even the low variances translate into a very high number of defects. The results from studies on errors in clinical diagnostic laboratories give a wide range of rate of errors, varying from 0.1% to 9.36%. Various reasons like variability in the process itself or imperfect error detection methods, may be attributed to this difference in the rates of error.

Conclusion: Quality in clinical laboratories is driven by application of data driven approaches and evidence based practices. This approach aids in setting up professional quality standards, coupled with education and training which helps transform a laboratory culture into a ‘Quality Conscious’ setting. A six-sigma concept aims at an overall improvement in the quality of the process as a fundamental goal in healthcare services thereby improving the performance of the process exponentially.

Keywords- Six-sigma, quality healthcare, quality standards, clinical laboratories, culture of safety.

Invitation Status: I accept
2014 (N = 136,864), 2015 (N = 153,329), 2016 (N = 106,687) and 2017 (N = 75,774) were retrospectively reviewed. THCA had a positive/negative screening cut-off concentration of 40 ng/mL. Positivity rates were calculated annually and partitioned by gender and age (19 y, 20 to 29 y, 30 to 39 y, 40 to 49 y, 50 to 59 y, 60 to 69 y, 70 to 79 y and 70 y). 

**Results:** Overall THCA positivity rates in 2014, 2015, 2016 and 2017 were 29.6%, 28.9%, 29.4% and 28.6%, respectively. With the exception of the 70 y cohort, males had relatively higher THCA positivity rates than females in all age partitions. THCA positivity rates for both genders were highest amongst 20 to 29 y (46.4% and 34.1%) in all males and females tested from 2014 to 2017, respectively and steadily decreased with age. This trend was consistent in each of the testing years examined. From 2014 to 2017, the THCA positivity rates for males and females 719 y were 39.0% and 30.6%, respectively.

**Conclusions:** Age and gender specific information on cannabinoid use was obtained through a multi-year retrospective review of THCA urine drug screening positivity rates. This study may be used to evaluate the relative impact of cannabis legalization in Canada on cannabinoid use within this population.

4 Alkaline Phosphatase Isoenzymes (isoALP) Prevalence in Community-Based Patients with Elevated Total ALP Levels in Ontario

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**Abstract:**

**Objective:** To identify prevalence of ALP isoenzymes in community-based patients with elevated total ALP levels in Ontario.

**Design and Method:** ALP isoenzymes results from 2937 patients (n = 1911 females, aged 5 to 101 yrs; n = 1026 males, aged 1 to 104 yrs) with elevated ALP (>120 U/L) between January 2015 to November 2017 were retrospectively reviewed.

**Results:** Seven patterns of elevated isoALP were routinely recognized and reported. The prevalence of these patterns in descending order: liver isoALP (64%), bone (18%), liver + bone (10%), liver + intestine (7%), bone + intestine (4%), and intestine (3%). Similar prevalence of each isoALP was observed in female and male patients, with the exception of two cases of placental isoALP and two cases of macro liver isoALP being observed in females only. Highest average total ALP levels was observed with macro liver isoALP (342 U/L), followed by placental (320 U/L), bone (252 U/L), liver + bone (220 U/L), liver (214 U/L), intestine (175 U/L), liver + intestine (174 U/L), and bone + intestine (172 U/L). Highest average patient age was associated with the macro liver isoALP (77), followed by liver (65), liver + intestine (65), liver + bone (63), intestine (61), bone + intestine (56), bone (55) and placental (34). In these patients, a positive correlation was observed between concentrations of total ALP and GGT, but not ALT or AST. Higher phosphorus levels were observed in samples with Bone isoALP, but no difference in calcium levels was noted in samples with different isoALPs.

**Conclusions:** This study may provide useful information to assist laboratory scientists and clinicians to interpret elevated ALP and isoALP patterns.

5 VALIDATION of BD Barricor plasma tube on Beckman-Coulter AU5800 and DXI under different centrifugation conditions.

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**Abstract:**

**Objectives:** Routine and STAT orders are often processed on the same system, which increases the turnaround time. To optimize laboratory automation efficiency, a shorter centrifugation time is warranted. Although the recommended centrifugation parameters are 10 minutes at 1890 to 2500xg, we evaluated performance of BD Barricor™ tubes for high volume chemistry analytes on the Beckman-Coulter Power Express centrifuged 5 minutes at 1952xg.

**Design and methods:** Fiftieth paired specimens (Barricor™) were obtained from healthy subjects. First set of samples were centrifuged 10 minutes and the second set 5 minutes at the same speed (1952xg) Each plasma sample was analysed on AU 5800 and DXI for selected routine chemistry analytes and immunoassays. Data were analyzed using weighted Deming regression analysis and comparison acceptability criteria was based on mean bias (clinical acceptance limits) and correlation coefficient (r < 0.975).

**Results:** Biochemistry panel including Na, K, Cl, creatinine, urea, glucose, ALT, ALP, TBIL, calcium, phosphorus, albumin, total CO2, Mg, CK, LD, GGT, AMY, total proteins, cholesterol, HDL-C, Tg, lipase, uric acid, CRP (> 1 mg/L), iron, transferrin, IgG and IgA showed mean bias less than 5%. Immunoassays including TSH, T4, T3, FSH, LH, cortisol and prolactin showed bias less than 7%. Lipemia, icteric and hemolysis index remained unchanged. All the parameters examined were judged clinically acceptable.

**Conclusion:** Alternative centrifugation time of BD Barricor™ tube showed clinically equivalent results compared to the recommended 10 minutes while improving total automation time.

6 COMPARISON of the BD Barricor Tube with BD serum separator tube (SST) for selected chemistry analytes on Beckman-Coulter AU 5800 and DXI.

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**Abstract:**

**Objectives:** The use of plasma has important advantages for laboratory professionals: among them reduced turnaround time and no interference induced by microfibrin. Moreover, it is desirable to consolidate a number of analytes on the same tube. The aim of this study is to evaluate the performance of the BD Barricor™ tube in comparison with the BD SST™ tube for selected chemistry analytes.

**Design and methods:** Samples from 119 volunteers were collected in the two different tubes (SST™ and Barricor™). Each sample was analysed on AU 5800 and DXI for selected routine chemistry analytes and immunoassays. Data were analyzed using weighted Deming regression analysis and comparison acceptability criteria was based on mean bias (clinical acceptance limits) and correlation coefficient (r < 0.975).

**Results:** A total of 34 routine biochemical analytes, 14 endocrinology analytes and 7 tumour markers were tested. The correlation data were good with r > 0.975 for all the tested parameters except for some analytes, such as calcium, electrolytes and free T4. However, all the tested analytes were deemed clinically acceptable, even when the correlation coefficient was below 0.975.

**Conclusion:** The use of BD Barricor™ tube showed clinically acceptable equivalence to the SST tube for the studied parameters resulting in an shorter turnaround time and an improved analytes consolidation.

7 Reference laboratory-controlled interventions are successful in reducing unnecessary test ordering: AST and folate testing in Ontario, Canada.