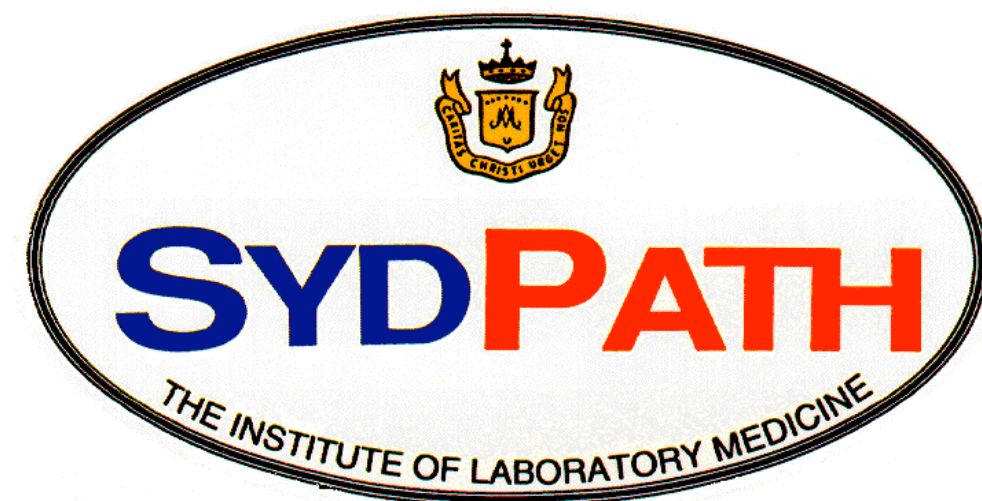




# Stability and Matrix Study: Bayer Centaur and BD tubes.



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## Introduction and Aim

- ❖ Knowledge about acceptable sample types and analyte stability is important for routine laboratories. This information is required to assess the suitability of collection in different tubes; if there are delays prior to analysis; or if requests are made for later addition of tests.
- ❖ Manufacturer's information on these issues is often conservative and limited knowledge about these factors may lead to unnecessary recollections for the patient with consequent delays in producing results.
- ❖ We investigate sample type and storage conditions for the following analytes as measured on a Bayer Centaur: Cortisol, LH, FSH, Prolactin, FT4, FT3 and Ferritin.

## Methods

- ❖ Blood was collected from 5 healthy non-fasting volunteers using the following BD Vacutainer tubes:
  - Serum - SST™ II Advanced (5.0mL).
  - Heparin plasma- LH PST™ II (4.5mL)
  - EDTA Plasma – K2E (4mL)
- ❖ Following centrifugation, the primary tubes were stored at room temperature (RT) or 4°C.
- ❖ Aliquots were taken from the primary tubes at 8, 24 and 32 hours (RT), and 1 and 7 days (4°C), and frozen.
- ❖ The frozen aliquots were thawed, mixed, centrifuged and then measured in the same analytical run.
- ❖ Additional paired samples were used for further investigation of matrix effects on LH measurement.
- ❖ For sample suitability studies results from heparin and EDTA tubes were compared with serum results.
- ❖ Differences were analysed by comparison with the RCPA-QAP Allowable Limits of Performance (ALP) with differences less than 1/3 of the ALP considered acceptable. If this criteria was not met other considerations were made.
- ❖ Manufacturer's recommended sample types and storage conditions were taken from the Bayer product inserts.

## Analyser



Bayer Centaur Analyser

## Results – Tubes Types

- ❖ FSH, Prolactin, FT4, FT3 and ferritin in EDTA or PST showed no results which differed from SST by more than 1/3 of the ALP and thus all sample types were considered acceptable.
- ❖ LH passed the 1/3 ALP criteria for EDTA but not for PST on initial testing with PST showing higher results than SST by an average of 10% (3 – 18%) which was up to 0.7 x ALP. Testing of a further 10 paired SST and PST tubes gave a combined average elevation of 5% with average increase in U/L of 0.4 (-0.4 to 2.1) and as fraction of ALP as 0.13 (-0.2 to 0.7). This was considered acceptable for use.
- ❖ Cortisol showed average decreases of 15% (EDTA) and 21% (PST) and thus only SST was considered acceptable.
- ❖ This data is summarised in figure 1 and was used to make recommendations for practice at SydPath (Table).

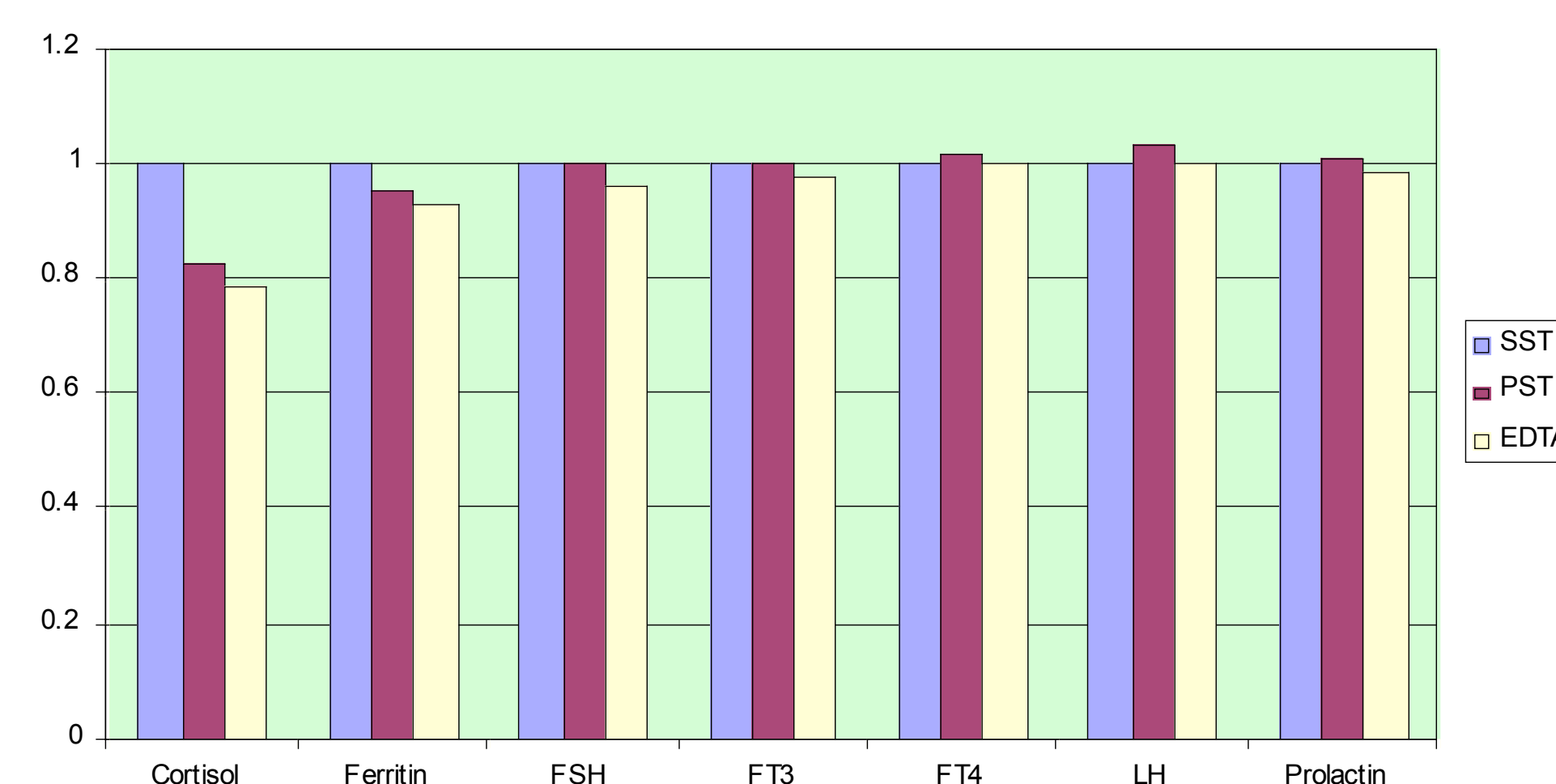


Figure 1. Average effects of sample type for each analyte relative to Serum tubes (SST) for the initial 5 sample sets.

## Results: Stability

- ❖ FSH, prolactin and FT3 was stable at all time points and both temperatures when using 1/3 of the ALP as the criteria.
- ❖ All ferritin results were acceptable using the same criteria except for one result (32 hours at RT in SST tube).
- ❖ Cortisol, FT4 and LH did not meet the 1/3 ALP criteria but showed average stability in all suitable matrices less than the 1 x CV for within-subject biological variation (CVwi), and maximal variation less than 1/3 of the total variability due to this source (4 x CVwi) for cortisol and FT4 and less than 1/2 this variability for LH. Thus the variation seen on storage, which includes within-run analytical imprecision, is small compared to the differences seen due to biological variation. Example data for Cortisol in serum is shown in figure 2.

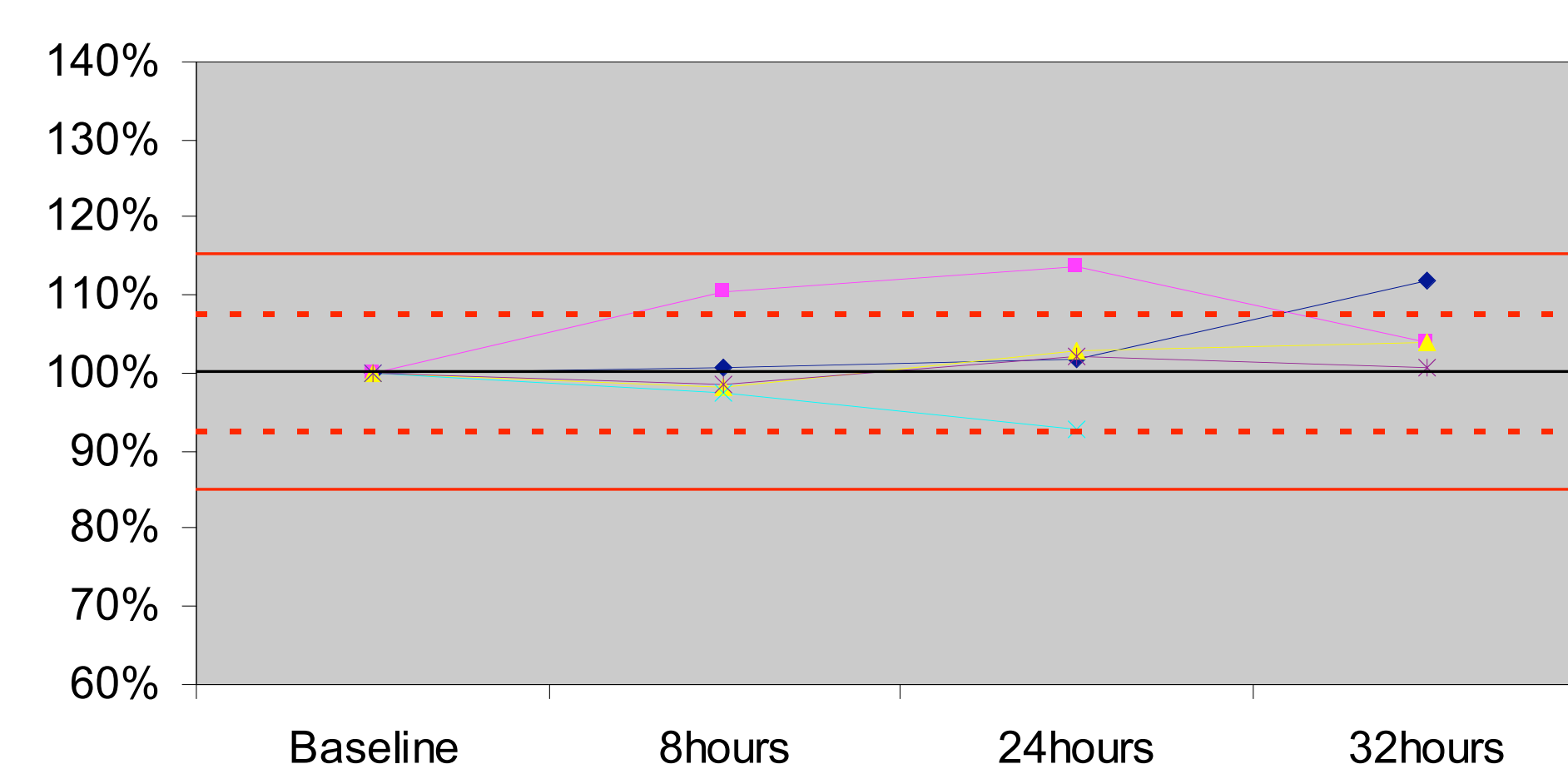


Figure 2. Analyte stability for Cortisol in SST at room temperature. Results from individual subjects are shown with comparison to CVwi. Solid red line: +/- 2 CVwi. Dashed red line: +/- 1 CVwi.

## Results: Summary

- ❖ On the basis of the data in this study revise recommendations for sample type and storage stability were derived for routine use (see table).
- ❖ All sample types are acceptable except for cortisol where serum is required.
- ❖ All analytes are considered stable for 24 hours at room temperature and for 7 days at 4°C.

	Bayer			SydPath		
Analyte	Tubes	Stability		Tubes	Stability	
		R/T	4°C		R/T	4°C
Cortisol	S	8 hrs	2days	S	24hrs	7d
Prolactin	S	8 hrs	2days	S, H, E	24hrs	7d
LH	S	8 hrs	2days	S, H, E	24hrs	7d
FSH	S	8 hrs	2days	S, H, E	24hrs	7d
Ferritin	S,H,E	8 hrs	2days	S, H, E	24hrs	7d
FT3	S	8 hrs	2days	S, H, E	24hrs	7d
FT4	S	8 hrs	2days	S, H, E	24hrs	7d

Table. Bayer and Study recommendations for sample types and stability. S - Serum, H – Heparin, E – EDTA.

## Discussion

- ❖ The data presented here indicates that the Manufacturer's data for sample type and analyte stability is overly conservative.
- ❖ By using the data obtained in this study we have validated the use of a wider range of sample types and longer storage times, which should reduce the number of re-collections required.
- ❖ As recollections are inconvenient for the patient, waste pathology resources and markedly increase turn-around time, any reduction in recollections is valuable.
- ❖ As this study is limited to the Bayer centaur and BD tubes, the data may not be transferable to other analytical systems and other collection tubes.

## Conclusions

- ❖ The manufacturer's claims for sample type and storage stability are conservative and may lead to unnecessary recollections.
- ❖ The data generated (see table) will be used to allow measurement of these analytes on samples which would otherwise be rejected.
- ❖ Manufacturers are encouraged to provide comprehensive information of sample type acceptability and maximum allowable storage times.

## Acknowledgement

We thank the volunteers for donating the blood samples used for these experiments.