

Full evaluation study of a quantitative, whole-blood POC method for TSH analysis

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INTRODUCTION

Vivacta have developed a novel point of care immunoassay system for the measurement of analytes in **whole-blood**, without separation of the cells and with no wash step. The system comprises a low-cost instrument in combination with a disposable cartridge. Signal is generated when illumination of sample results in micro-heating effects on carbon particles bound to piezofilm sensor.



The system has been designed to be CLIA waived and comprises a reader and disposable cartridge. Initial proof of concept work has involved the successful in house evaluation of the system using thyroid stimulating hormone (TSH). Here we present the results of the in-house evaluation study.

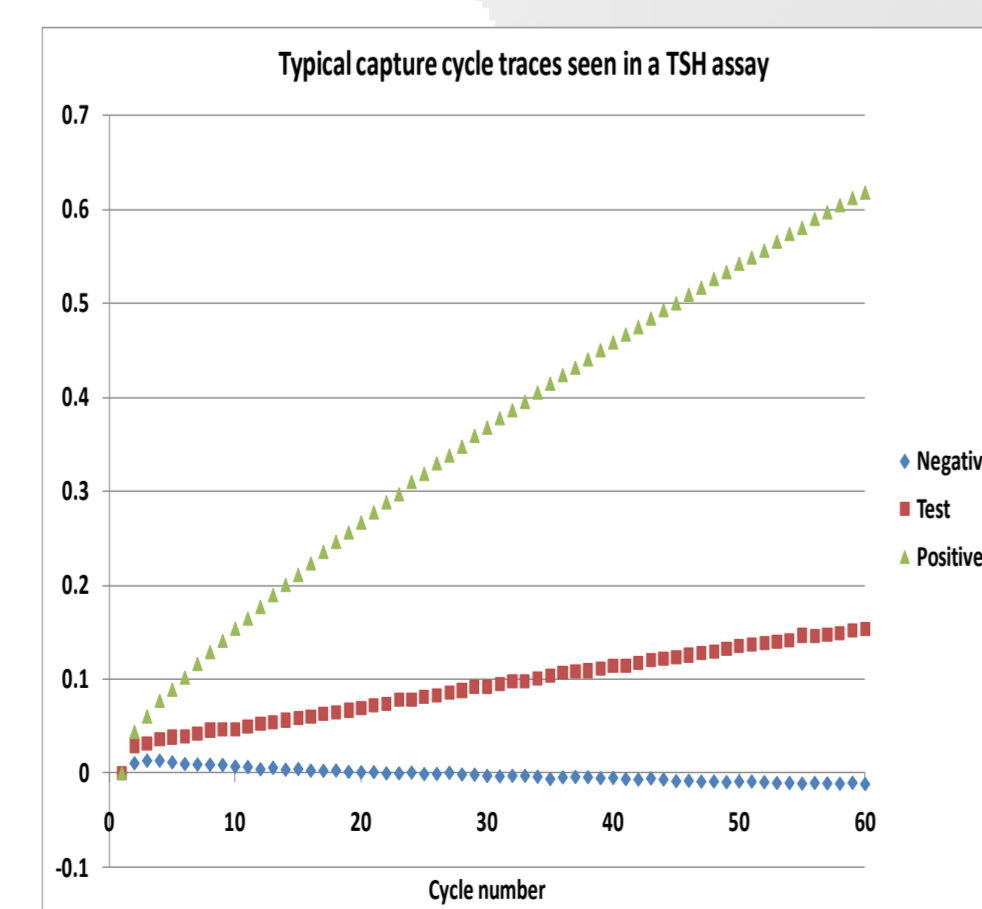
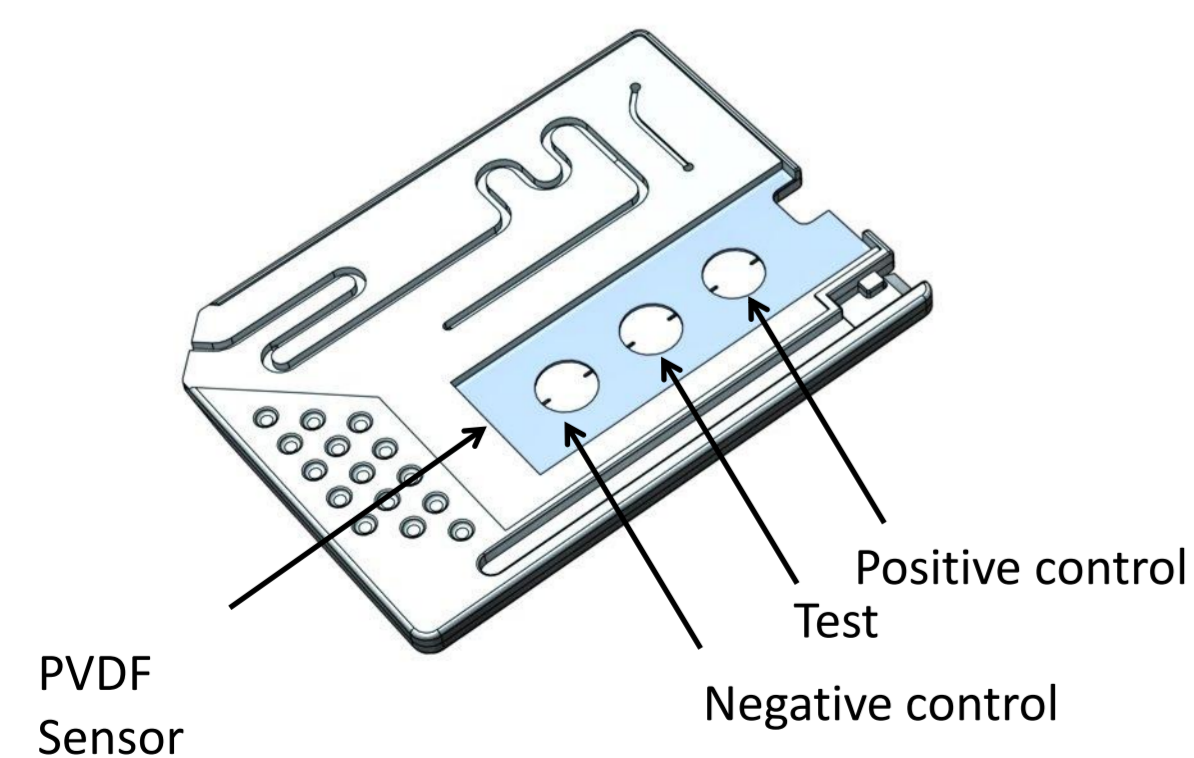
SYSTEM DESIGN

Reader –

- Designed for CLIA waiver
- Whole blood measurement
- 30µl sample volume
- No wash step
- Time to result < 10min

Cartridge –

- Blood collected directly
- No liquid reagents
- Reagent mixing occurs within cartridge
- Contains 3 measurement spots



Instrument output from each spot

METHODS

An in-house evaluation of the TSH system was carried out according to FDA guidelines. All cartridges manufactured by the Vivacta Pilot facility.

Serum/Plasma	Within-run/between-run precision Minimum detection limit Limit of blank, Limit of detection, Limit of quantitation Functional sensitivity 20% between-run CV at lowest concentration Lowest reportable limit Recovery Specificity Linearity Dynamic range
Serum/Plasma v Whole Blood	Correlation with predicate reference method Vivacta in whole blood v predicate in serum/plasma Equivalence between blood and serum/plasma Vivacta in whole blood v Vivacta in serum/plasma

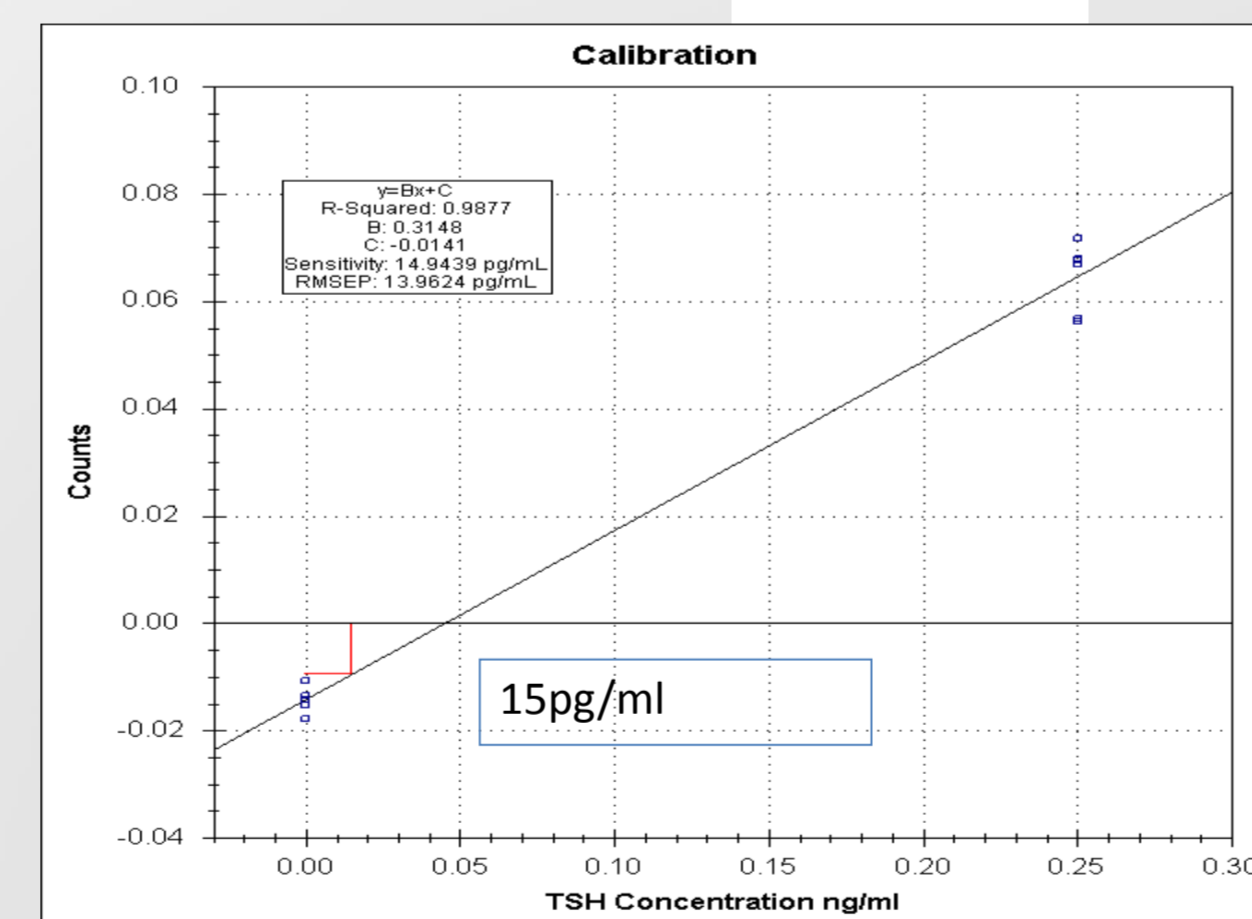
RESULTS

Precision

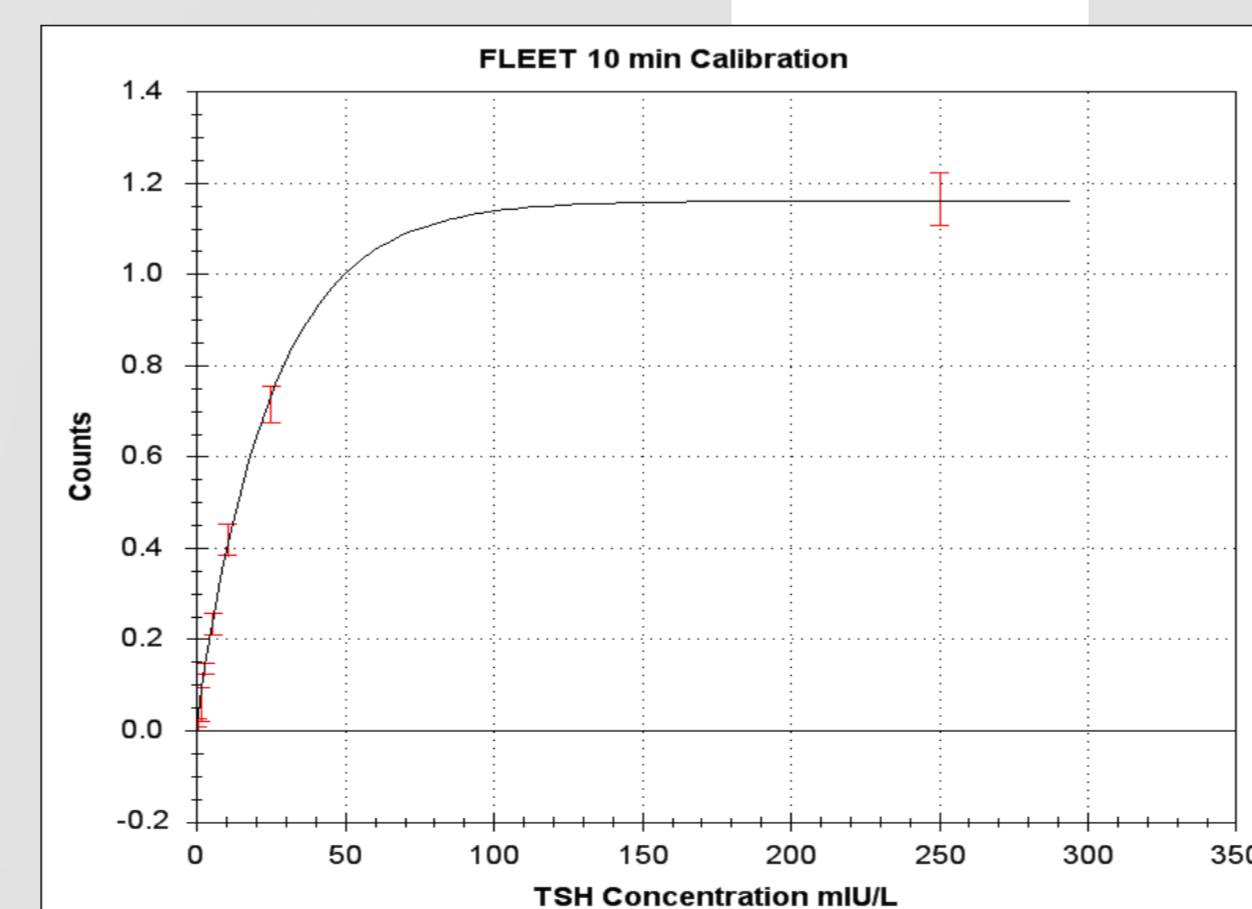
- Repeated over 20 days (morning and afternoon)
- Multiple readers
- Multiple operators
- **CV = 8%**

Limit of detection (LOD)

- 0 and 1ng/ml samples (n=50)
- Multiple readers

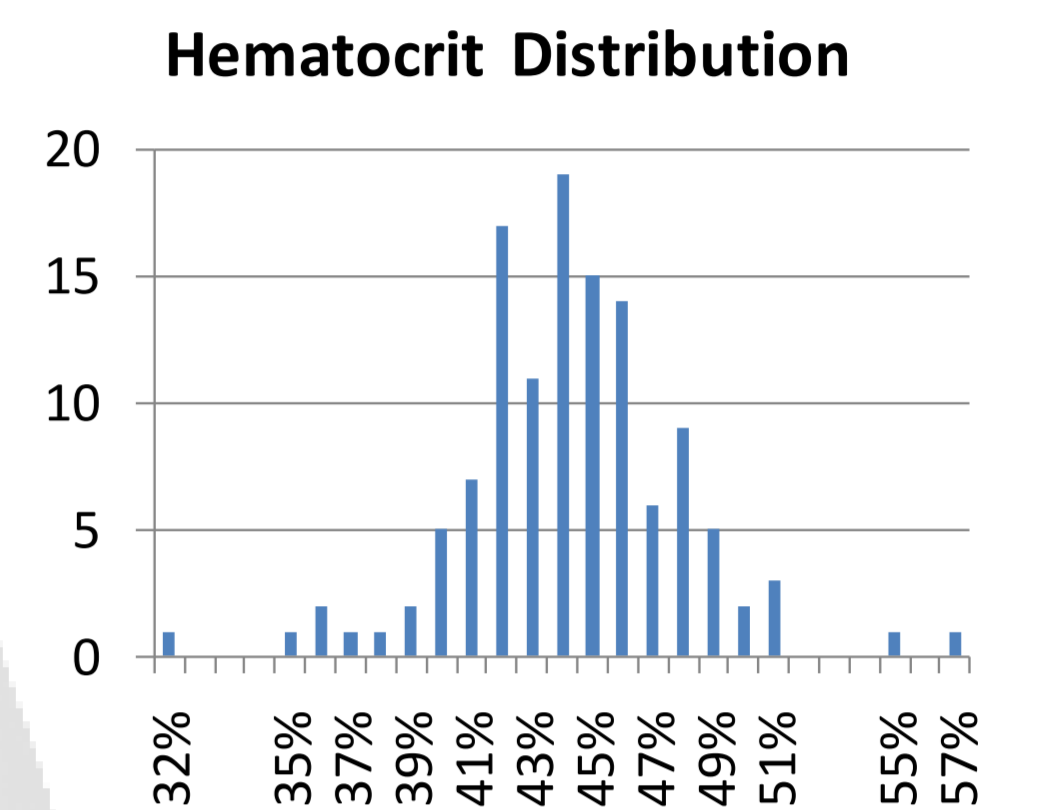
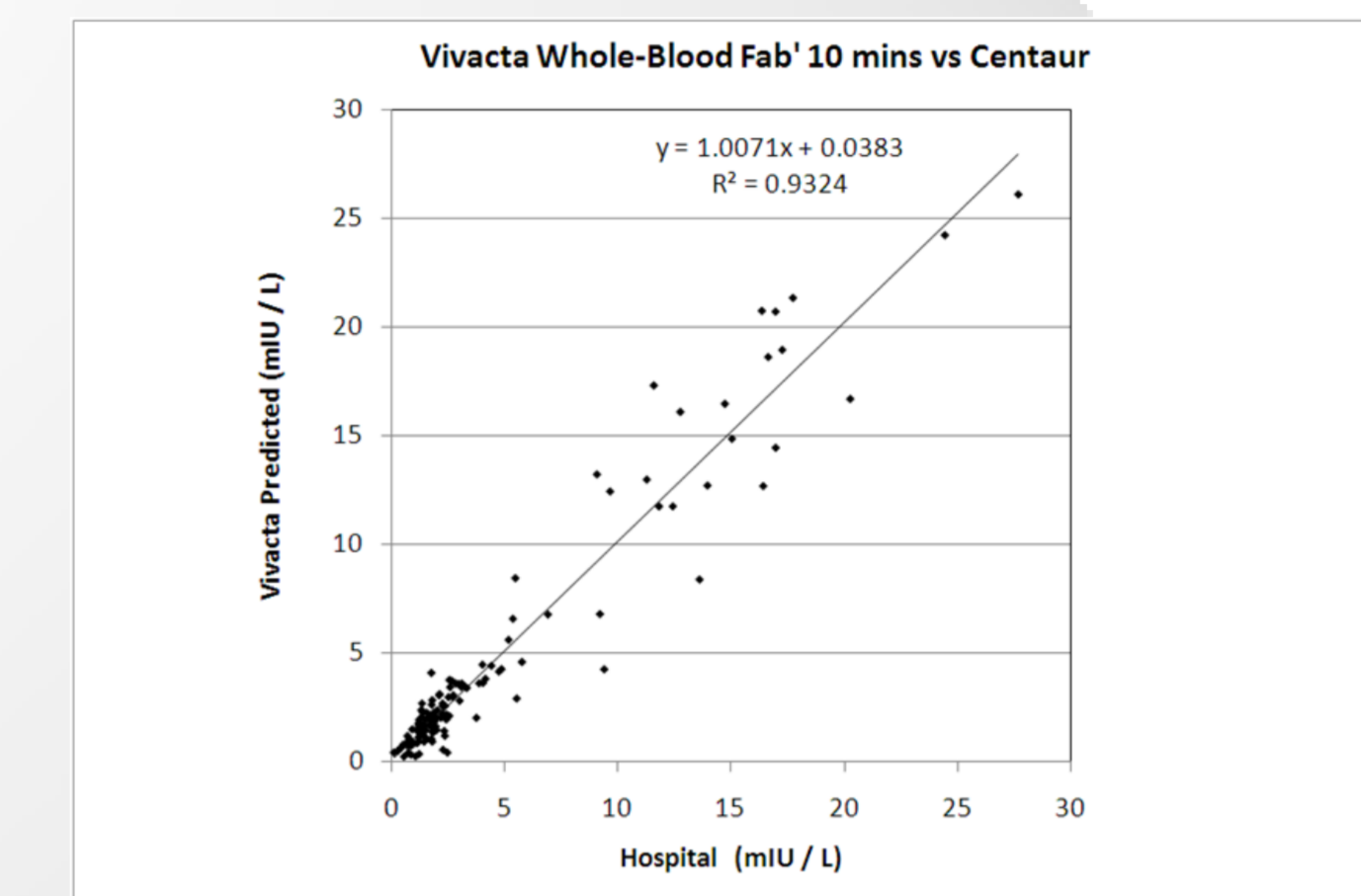


High dose hook



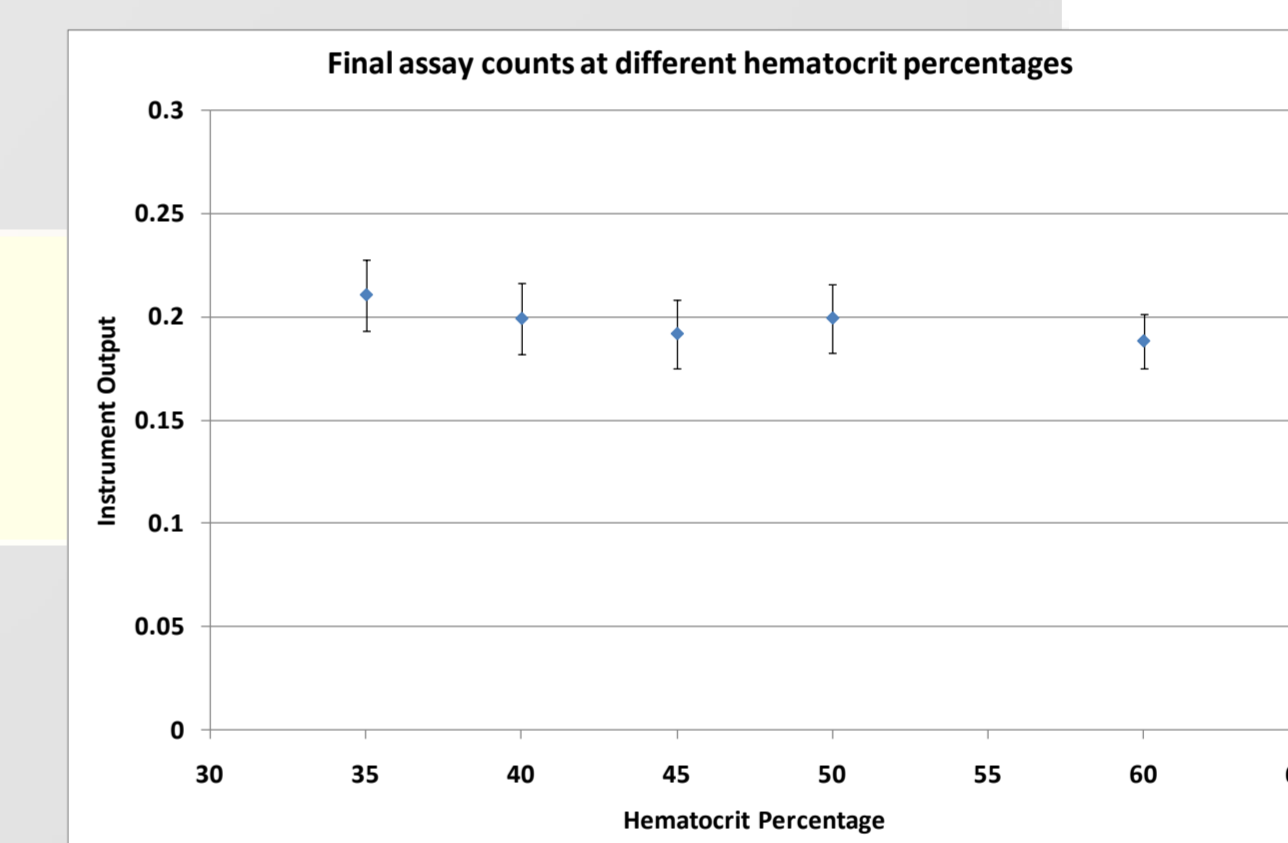
Method Comparison

- Blood v Plasma
- 144 donors
- Blood assays on Vivacta system vs plasma assays on ADVIA Centaur (Medway Maritime Hospital)



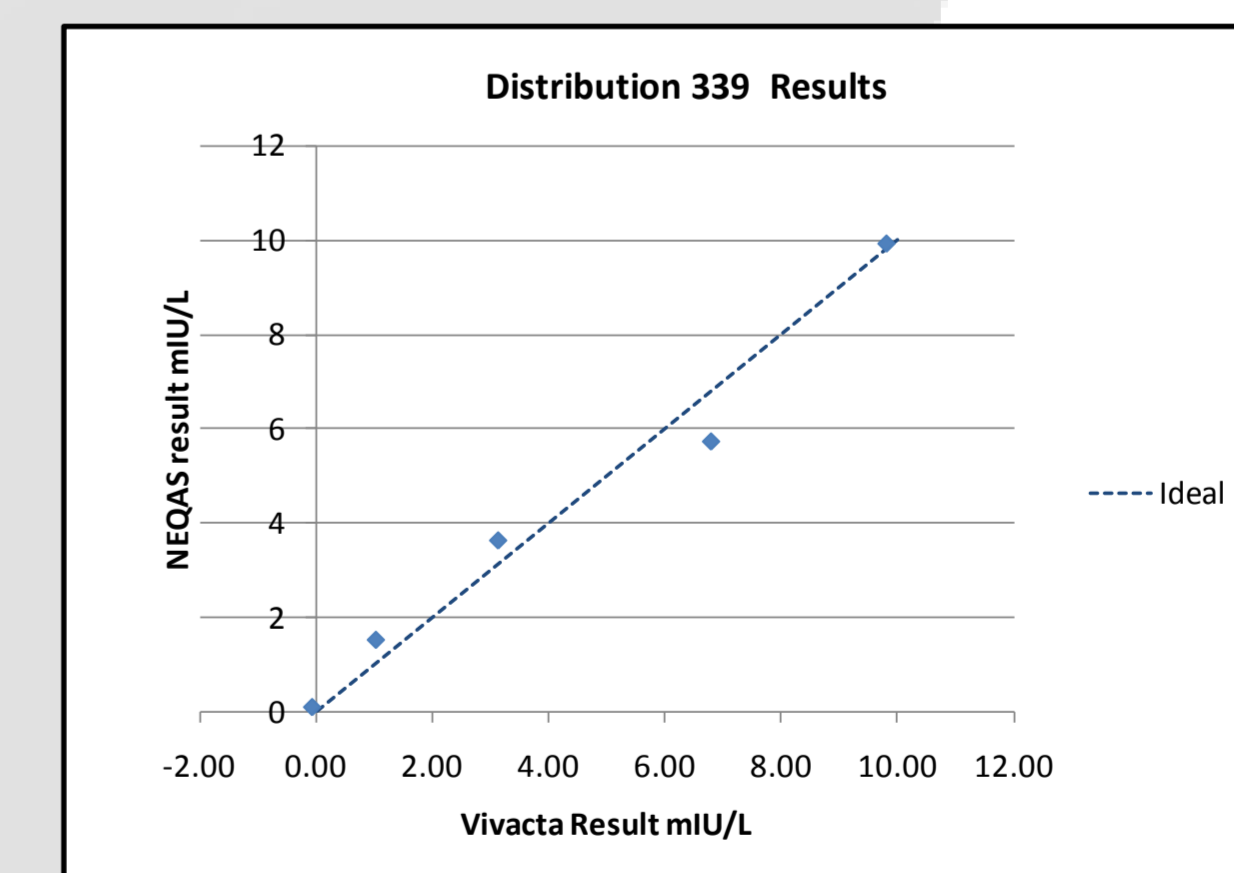
Hematocrit

A donor blood sample was spun down and plasma and red blood cells recombined at different ratios.



NEQAS Results

The Vivacta TSH assay system is also routinely tested against 400 other clinical analysers in the UK.



CONCLUSIONS

- Precision CV = 8%
- LOD = 15pg/ml
- No high dose hook
- Good blood vs plasma comparison
- No hematocrit effect in normal range