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Weqas New Programme Developments

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New pilot Schemes

- Quantitative FIT
- TEM (thromboelastometry) - Sigma / Delta
- Procalcitonin
- d-Dimer
- Pre-Term Labour & PROM
- Existing Programme Additions

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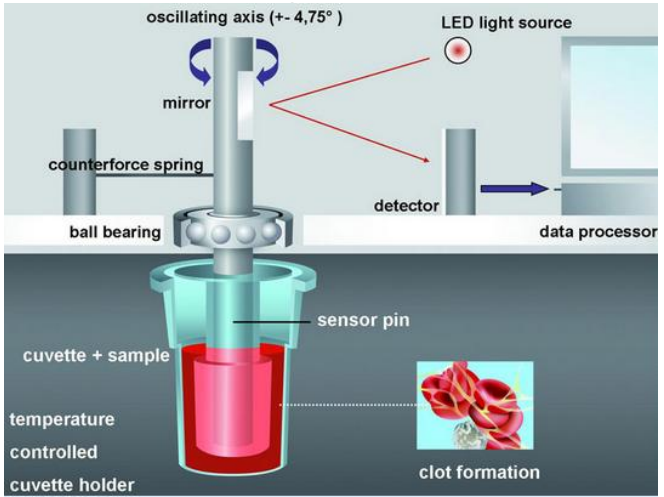
TEM

- TEM (thromboelastometry)
  - Provides information on the whole kinetics of haemostasis: Clotting time, clot formation, clot stability and lysis
- Start date – January 2018
- 4 distributions per year, 2 samples
- Samples provided by ECAT



Procalcitonin

Sample Commutability and Appropriate Clinical (analytical) Range

- Recombinant source of PCT . Samples will be assayed on various instruments including the Radiometer AQT90 and Roche Cobas to ensure sample commutability. The appropriate clinical range will be covered.

Preparation of Programme Samples (for pilot distribution)

- 6 pools to be prepared for distribution in the EQA pilot
- 1st Distribution scheduled for April 2018.
- Range 0 to 100 µg/L

Radiometer AQT 90 Evaluation / Roche Cobas verification

- Doubling dilutions of a high spiked pool with a known negative pool will be prepared to provide a linear series of 6 samples.
- Imprecision : within and between batch
- 6 samples will be assayed in duplicate over 10 events using the Radiometer AQT90 and Roche Cobas. Precision profile calculated for both methods.
- Inaccuracy / Linearity / Recovery: - linear series compared to the spiked target values, percentage dilution to calculate recovery.

Stability

- 3 levels aliquoted and stored at room temp, 4°C , -20°C and assayed in duplicate for short term and long term stability.

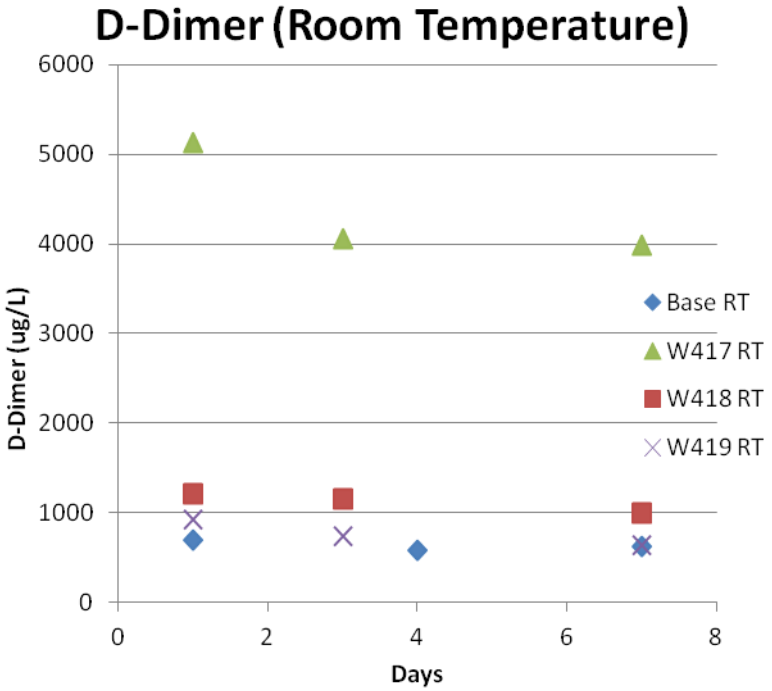
d-Dimer

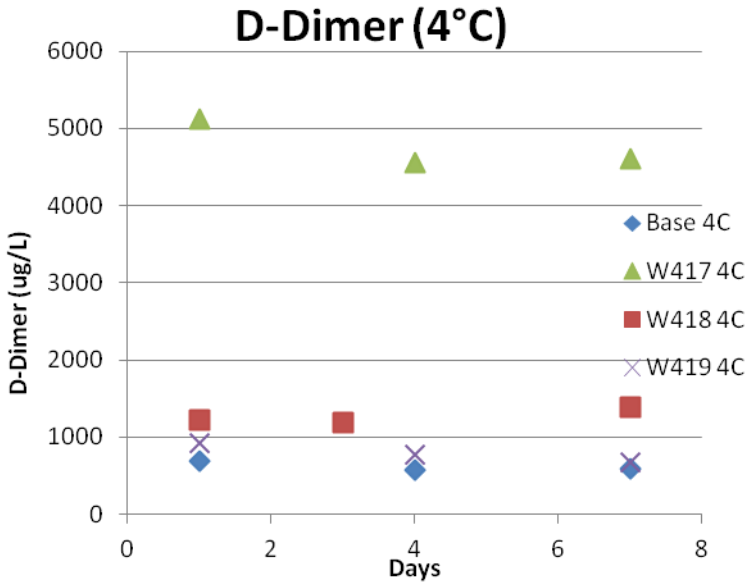
Sample preparation and Appropriate Clinical (analytical) Range

- Source of extracted d-Dimer added to EDTA plasma
- Endogenous patient samples.
- Samples assayed on Roche Cobas C6000, Roche Cobas h232 and Werfen ACL Top.
- 6 pools prepared for distribution in the EQA pilot – 1st Distribution April 2018.
- Range 450 to 5,000 ug/L

Stability

- 3 levels aliquoted and stored at room temp and 4°C and assayed in duplicate for short term and long term stability.





Biomarker testing for premature rupture of membrane (PROM)

PAMG -1

- Placental alpha microglobulin-1 (PAMG-1) has been the subject of over 20 clinical investigations, the majority of which have focused on the antigen's ability to detect premature rupture of the fetal membranes (PROM) in non-labouring pregnant women presenting with unexplainable vaginal leakage. (AmniSure PROM test)

IGFBP-1 (PROM)

- Insulin-like growth factor binding protein-1 (IGFBP-1). Amniotic fluid is normally not found in the vagina, but when fetal membranes rupture, amniotic fluid leaks into the vagina and the IGFBP-1 concentration quickly rises and remains high until delivery. 'Actim PROM' detects IGFBP-1 in vaginal swab samples and helps to identify membrane ruptures.
- Samples already prepared. Call for Pilot sites.

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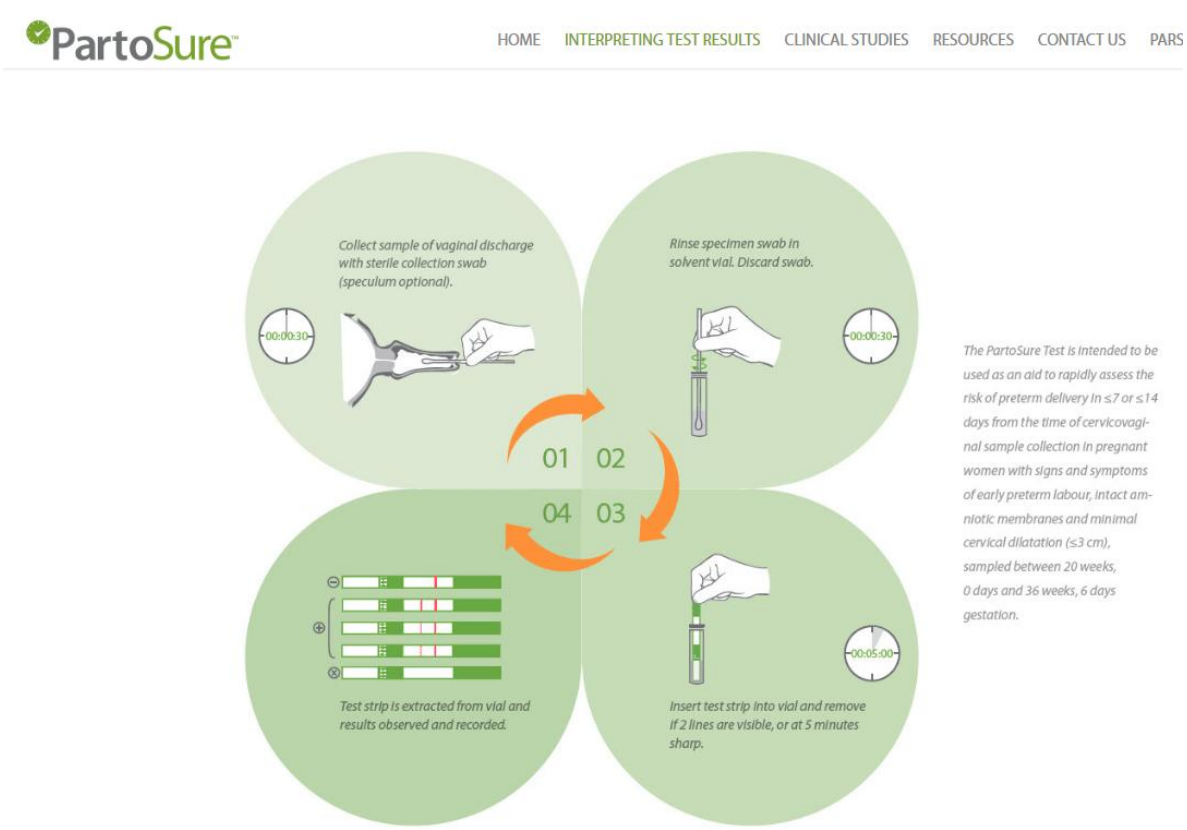
Biomarker testing for Pre-Term Labour

PAMG-1 - Preterm labour biomarker

Placental alpha microglobulin-1

PartoSure (PAMG -1) - predictor of imminent spontaneous delivery within 7 days.



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Additions to existing Programmes

ED-Tox

Analytes to be added: Paraquat, Ethylene glycol, Methanol

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Development of a linear series of stable material for Ethylene Glycol performance monitoring

Introduction

In response to the 'NHS Services, Seven Day Working' from NHS England, the Association for Clinical Biochemistry and Laboratory Medicine published guidance on the clinical biochemistry tests that may be required to allow for the optimal clinical management of 'Critical' and 'Urgent' patients. They recommended that Ethanol, Methanol and Ethylene Glycol be included as 'Urgent' tests and should be available within 4 hours. They did however acknowledge that for some tests such as Ethylene Glycol which may require onward transfer to a specialist referral laboratory for analysis, the availability of results within the time frames indicated below may not be achievable at present by all laboratories.

Aims

To evaluate a commercially available enzymatic method for the measurement of ethylene glycol that could be applied in a routine laboratory.
To develop a stable linear series of Quality Control material that could be used for method validation according to ISO 15189:2012.
To establish performance criteria for Ethylene Glycol for use in EQA.

Method

Catachem enzymatic reagents, were adapted "in house" for the Siemens Advia 1200 analyser. The Ethylene Glycol kinetic method uses Glycerol Dehydrogenase to catalyze the oxidation of Ethylene glycol in the presence of NAD. The rate of increase in absorbance of NADH at 340nm is monitored.

Ethylene Glycol + NAD ----------> NADH + Glycoaldehyde + H^+

The method was optimised for the Advia 1200 analyser (sample volume, reaction time, detection points) and validated for accuracy, linearity and imprecision.

To assess recovery, Ethylene Glycol was added gravimetrically to serum from a healthy donor to produce a range of samples with ethylene glycol concentration ranging from 250 to 3000 mg/L. Recovery was calculated as a percentage of the observed / gravimetric value (Table 1). Accuracy was further assessed by comparison to the GCMS method (Fig 1).
Imprecision was assessed using the manufacturers IQC material and two pools of the serum based material assayed daily over a two week period.
Linearity was assessed by preparing doubling dilutions of the High Pool to produce a linear series of 5 pools. The enzymatic results were compared with the % mix of the High pool (Fig2). Stability of the material was assessed over 8 days at storage temperatures of -70°C, -20°C, +4°C, and +20°C (Fig3).

Results

The within lot Coefficient of Variation (CV%) was 1.3% and 0.7% at a mean of 280 and 1060 mg/L respectively for the serum based material (n=58). CV = 1.1% and 0.7% at a mean of 643 mg/L and 2284 mg/L respectively for the manufacturer's IQC material (n= 8).

The method was found to be linear to 2500 mg/L and agreed well with the gravimetric and GCMS value (Fig 1 and 2).

Table 1 -Recovery

Pool number	1	2	3	4	5	Units
Gravimetric value	250	500	1000	2000	3000	mg/L
Result	270	520	990	1820	2650	mg/L
Recovery	108	104	99	91	88	%

Fig 1 – Comparison of Ethylene Glycol enzymatic and GCMS methods to gravimetric.

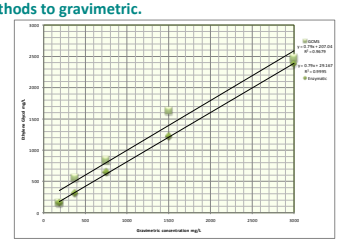


Fig 2- Linearity of Ethylene Glycol enzymatic method.

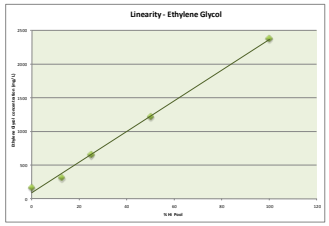
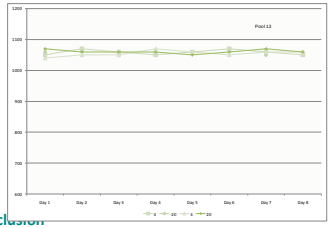


Fig 3- Stability of Linear Panel



Conclusion

The data suggest that the material is suitable for use as a linearity verification panel for laboratories introducing these methods into routine practice. Excellent stability was observed for the material at room temperature over the time period studied. As a result of this study, Ethylene glycol and methanol have been included as part of the WEQAS ED Toxicology Scheme. As these methods are introduced, the lot to lot variation and interlaboratory performance will be further monitored through participation in this Programme.

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Additions to existing Programmes

- Endocrine – SHBG added April 2017
- Gases – iCa^{++} (filter line from CRRT patients 0.2 – 0.5 mmol/l)
- TDM – Everolimus / Mycophenolate

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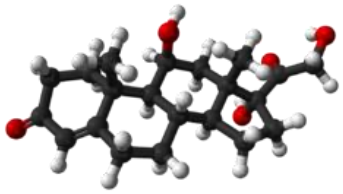
Endocrine Programme Update

Method development progressing on the newly acquired Waters Xevo TQ-XS Tandem LC-MSMS

- **Cortisol** Reference Measurement values now available for all endocrine distributions
- **Testosterone** to be available on all distributions by the end of quarter one 2018
- **Progesterone** and **Oestradiol** to follow shortly for all distributions



Targeted Cortisol calibrators now available for use in Tandem MS methods. These complement the testosterone calibrators already available