Weqas
Unit 6, Parc Tŷ Glas
Llanishen, Cardiff, UK
CF14 5DU

Tel: +44 (0) 2920 314750
E-mail: contact@weqas.com
Web: www.weqas.com

UKAS PROFICIENCY TESTING 4301

Post-analytical EQA – Weqas Interpretive Programmes

Author Names: G Davies, S Jones, G Pritchard, A Fowler, MA Thomas

Introduction

External Quality Assessment (EQA) is an essential part of assuring the quality of laboratory diagnostic services, and should where possible include assessment of both pre and post analytical phases of the diagnostic cycle. Weqas programmes assess both laboratory and method performance, including bias and within batch imprecision. The programmes also assess the laboratory's pre and post analytical phases through the distribution of challenging samples and post analytical interpretation.

Method

Samples covering clinically relevant ranges were distributed for the Weqas Fetal Fibronectin (fFN), Pre-eclampsia (PE), and POCT D-dimer programmes and participants were asked to provide both their quantitative results and the qualitative interpretation.

The correct interpretation was set by Weqas and participants were scored based on the comparison of their interpretation to the 'correct' result. The scores broadly reflect clinical importance and quantitative concentration. A correct result (in agreement with Weqas interpretation) was given a score of 0. A sliding scale score of between 1 and 5 was assigned for incorrectly identified results, where 5 represents a gross misclassification of the result.

Fetal Fibronectin (fFN)

Fetal Fibronectin is an adhesive glycoprotein that holds the membranes of the uterus to the fetal membranes. After 35 weeks of pregnancy, it begins to break down naturally, and is detectable in vaginal secretions. A positive fFN test result indicates an increased risk of pre-term labour and is useful in aiding patient management. The negative predictive value (NPV) of the test at 10 ng/mL is quoted as 100%, with a NPV at 50 ng/mL of 99.2%. The manufacturers quote a cut-off of >50 ng/mL as a positive result; indicating the likelihood of a preterm birth within the following 14 days.

During 2022, 24 samples were distributed with fFN concentration ranging from approx. 3 – 400 ng/mL. 4 samples below the cut-off were distributed with % Positive rates of < 5%. For all samples except 1, with concentration >100 ng/mL, the % Positive rate was >90%. For the sample with only 89% Positive, (mean 330 ng/mL), 50% of incorrect results were pre-analytical errors (transcription / transposition errors).

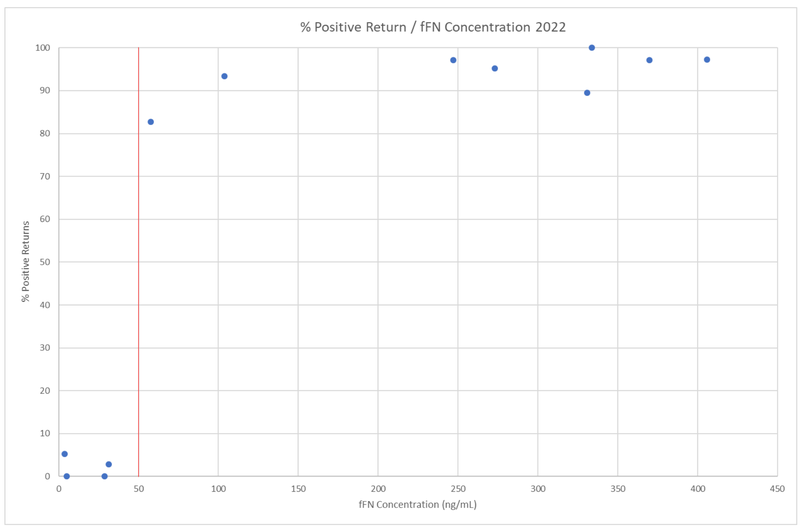
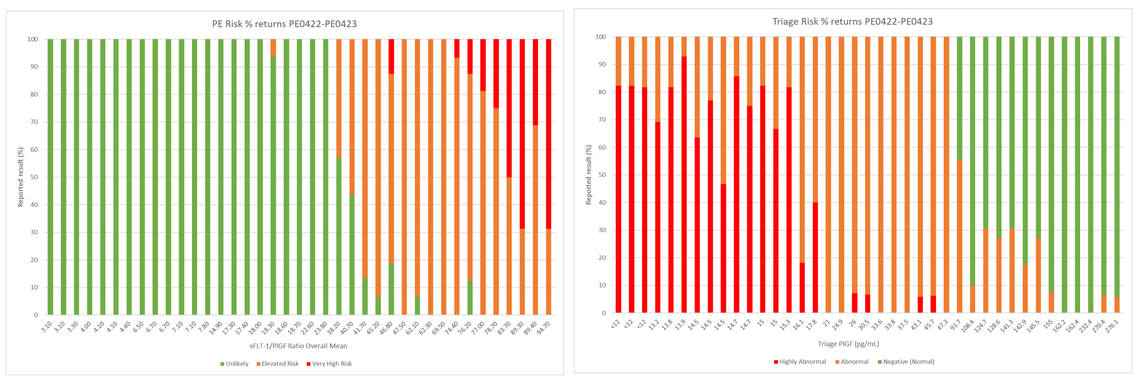


Figure 1. Positive return rate for qualitative fFN against fFN concentration (Overall Mean) for samples distributed in 2022. The red line indicates the cut-off of 50 ng/mL.

Pre-eclampsia (PE)

The NICE guideline on hypertension in pregnancy defines pre eclampsia as new hypertension with significant proteinuria after 20 weeks gestation. Biochemical Markers for pre-eclampsia include Placental Growth Factor, (PlGF) used on its own, or as a ratio to Soluble fms-like tyrosine kinase-1 (sFlt-1 or sVEGFR-1) i.e. sFlt-1/PlGF ratio.

Participants using the Roche Cobas report a pre-eclampsia risk based on the sFlt-1/PlGF Ratio. Risk categories are 'Unlikely' (ratio ≤38), 'Elevated Risk' (ratio >38 to ≤85) and 'Very High Risk' (ratio >85). For samples with ratio <30 there was generally 100% reporting Unlikely, at ratios around the cut-off of 38, there was approx. 50% Unlikely, 50% Elevated Risk.



Figures 2a and 2b. 2a: % returns for Roche: 'Unlikely' (ratio ≤38), 'Elevated Risk' (ratio >38 to ≤85) and 'Very High Risk' (ratio >85) against concentration. 2b: % returns for Triage Meter: 'Highly Abnormal' (<12), 'Abnormal' (≥12 to <100) and 'Normal' (≥100) against concentration.

Participants using the Quidel Triage Meter report a classification of 'Highly Abnormal' at PlGF concentrations < 12 pg/mL, 'Abnormal' at ≥12 to <100 pg/mL and 'Normal' at PlGF ≥100 pg/mL. At concentrations <12 around 80% of participants correctly reported Highly Abnormal. At concentration 91.7 pg/mL there was approx. 50% reporting Abnormal and Normal, at concentration 108.4 pg/mL, 90% correctly reported Normal.

POCT D-dimer

D-dimer is a Fibrin Degradation Product (FDP) used to determine whether clot formation has occurred or not. Its clinical application is as part of the diagnosis pathway for venous thromboembolic diseases: Deep Vein Thrombosis (DVT) and Pulmonary Embolism.

POCT D-dimer samples with concentrations between 460 and 5200 µg/L FEU were distributed over a 12 month period. For the sample just below the cut-off (overall mean 460.8 µg/L FEU), 30% of participants reported Positive, however, 93% Radiometer AQT90 participants correctly reported Negative. For samples above the cut-off, positive return rates ranged from 85 – 100%.

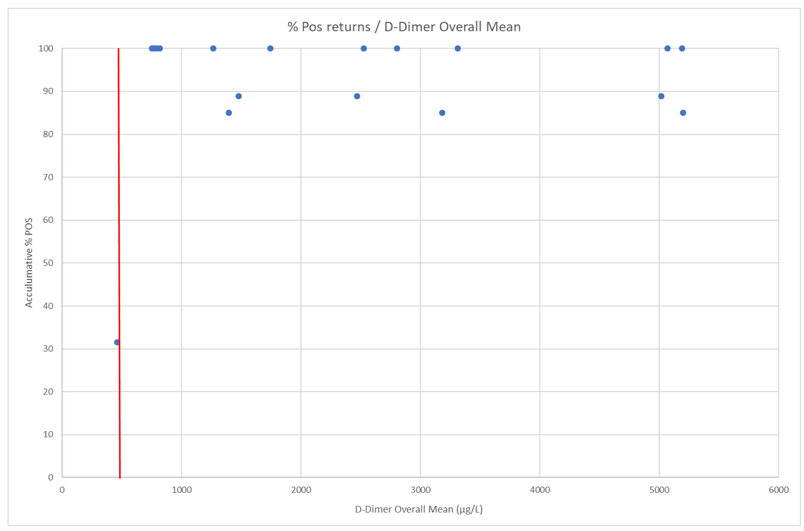


Figure 1. Positive return rate for D-dimer against concentration (Overall Mean) for samples distributed in 2022-23. The red line indicates the cut-off of 500 µg/L FEU

Conclusions

The "additional value" of interpretation is a major contributor in the delivery of improved clinical effectiveness and laboratorians have a professional responsibility to provide this service [1]. However, these Weqas programmes have highlighted the variability of expertise in reporting results and demonstrates the importance of assessing the post-analytical phase. Laboratories should consider whether post analytical assessment is considered when selecting their EQA provider.

[1] Beastall GH, Adding value to laboratory medicine: a professional responsibility. Clin Chem Lab Med. 2013 Jan;51(1):221-7.