

EQA serum composition directly impacts performance surveillance; an example for creatinine is shown



Birmingham Quality



We are, and always have been, part of the NHS

Rachel Marrington, Consultant Clinical Scientist

Birmingham Quality *UK NEQAS Birmingham*

UK NEQAS
International Quality Expertise

50 Years as World
Leaders in EQA
1969–2019



Birmingham Quality

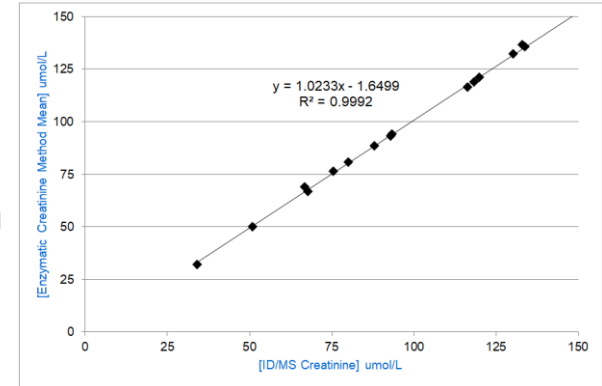
NHS
University Hospitals Birmingham
NHS Foundation Trust

Role of EQA material and data

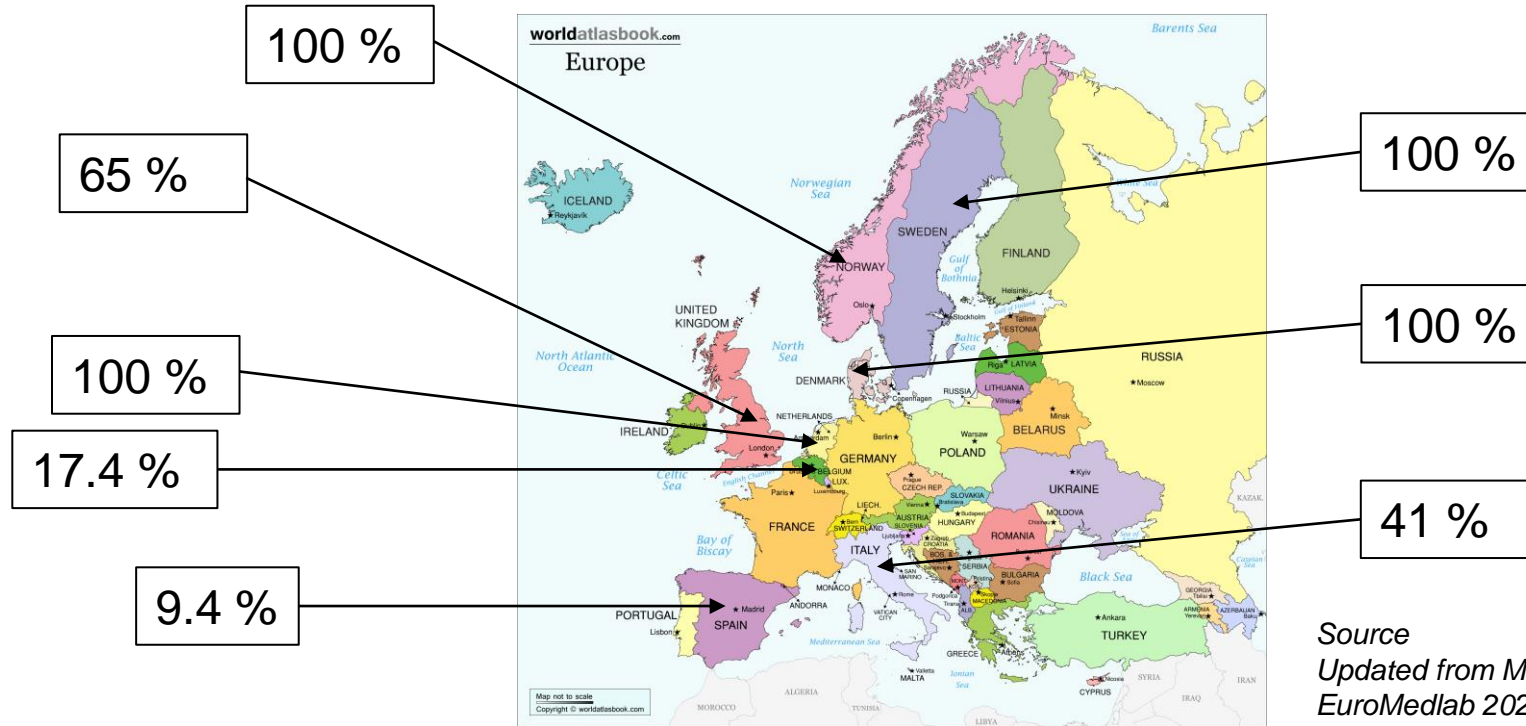
- Part of an individual laboratory's quality assurance process
 - Part of a network or regions quality assurance process
 - Post market surveillance for individual methods
 - Verification of assay systems.
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- Very important that the EQA material resembles clinical material as closely as possible i.e. is commutable
 - However, we need specific assays before we can even consider commutability

Creatinine

- UK NEQAS for Acute and Chronic Kidney Disease Scheme
- Data from March 2022 to March 2023
- Approximately 500 participants, primarily UK
- 16 different serum matrices using off-the-clot human serum distributed as 36 specimens
 - Individual donations
 - Pooled donations
 - Pooled donations with added creatinine
- Target Value – enzymatic creatinine method mean
- Relative method biases

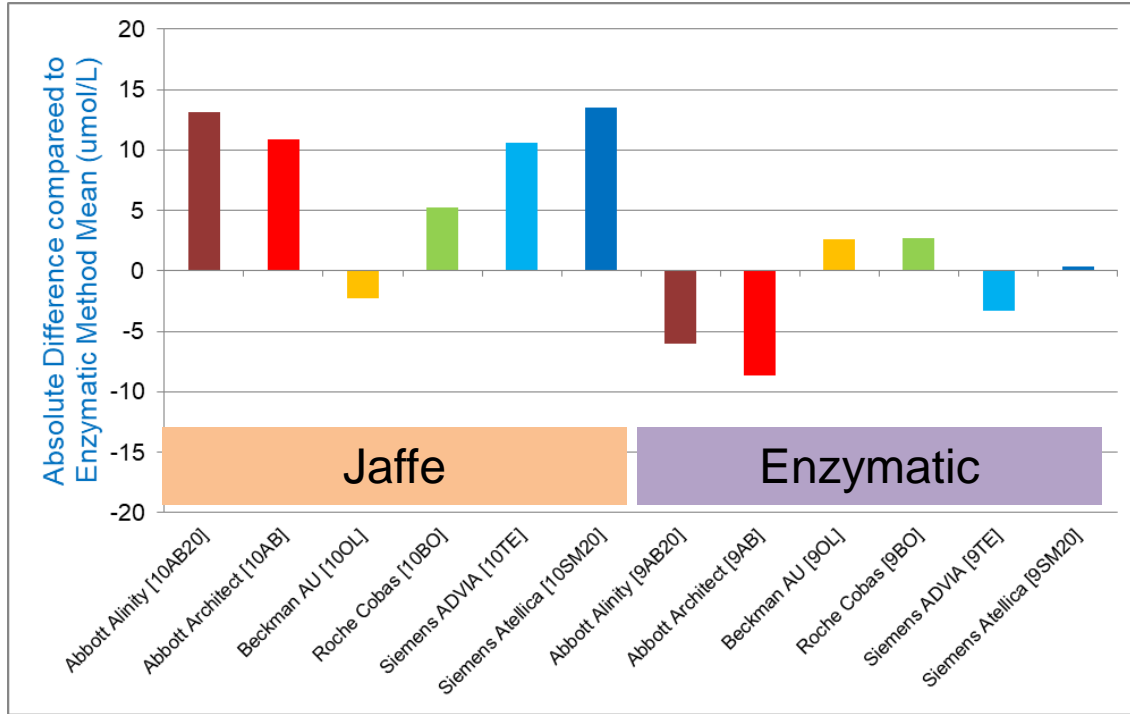


Enzymatic split across Europe



Source
Updated from M Panteghini,
EuroMedlab 2023

Relative Method Biases



Single donation Male

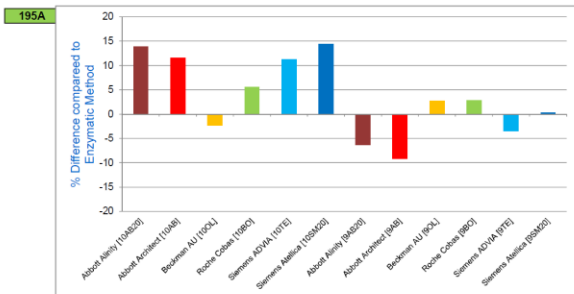
Enzymatic Mean – 94.2 umol/L

Ref Method – 93.4 umol/L

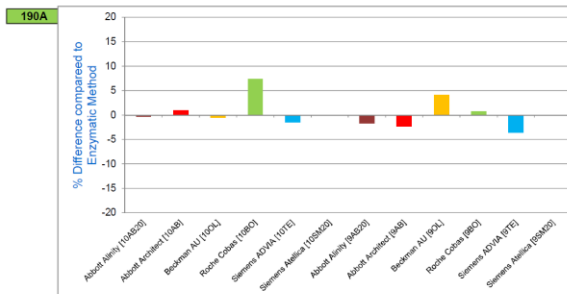
Acceptable bias based on biological variation is 5.6%

Creatinine Fingerprint bias plots, colour coded by method - 3 Distributions, 9 Specimens

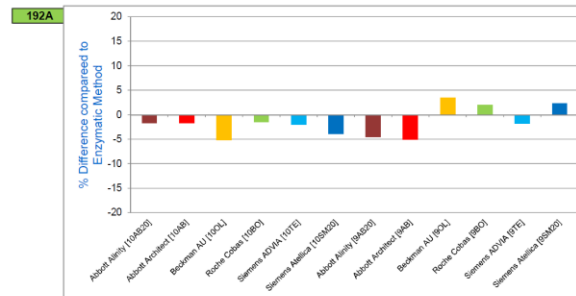
% Bias



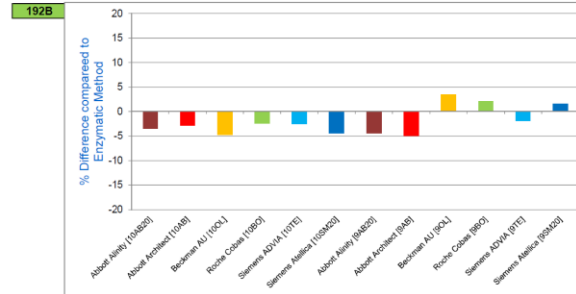
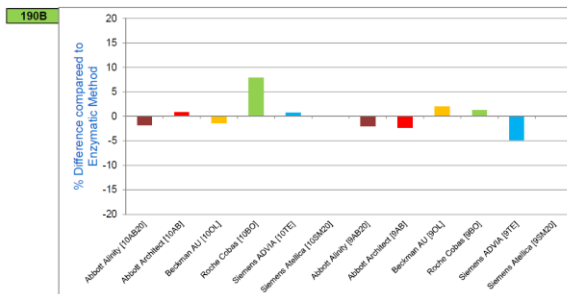
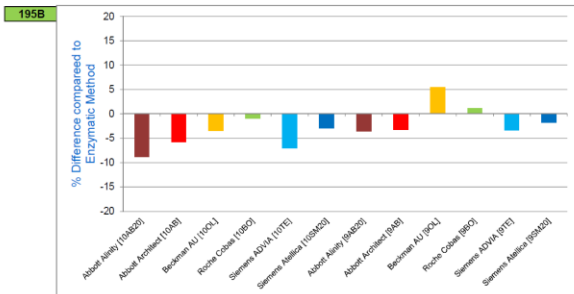
% Bias



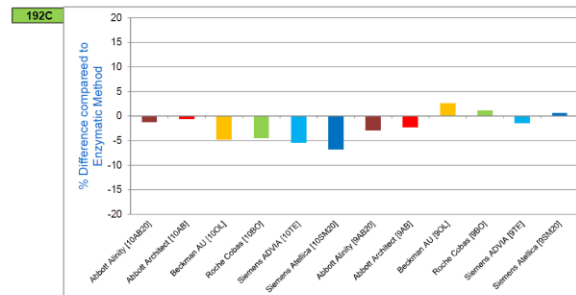
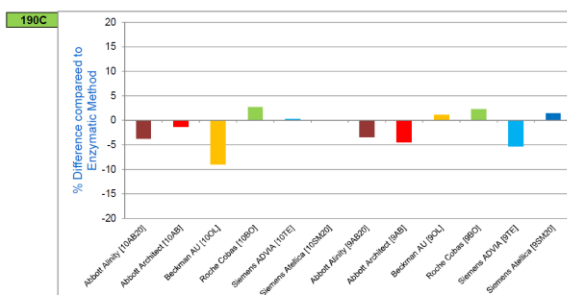
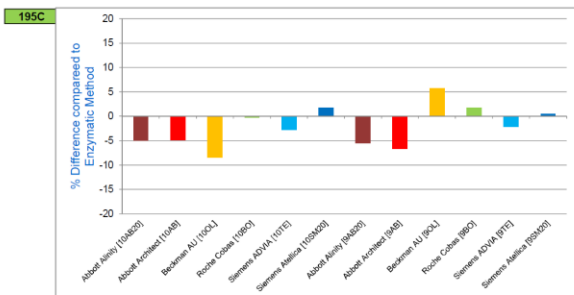
% Bias



124.052 u

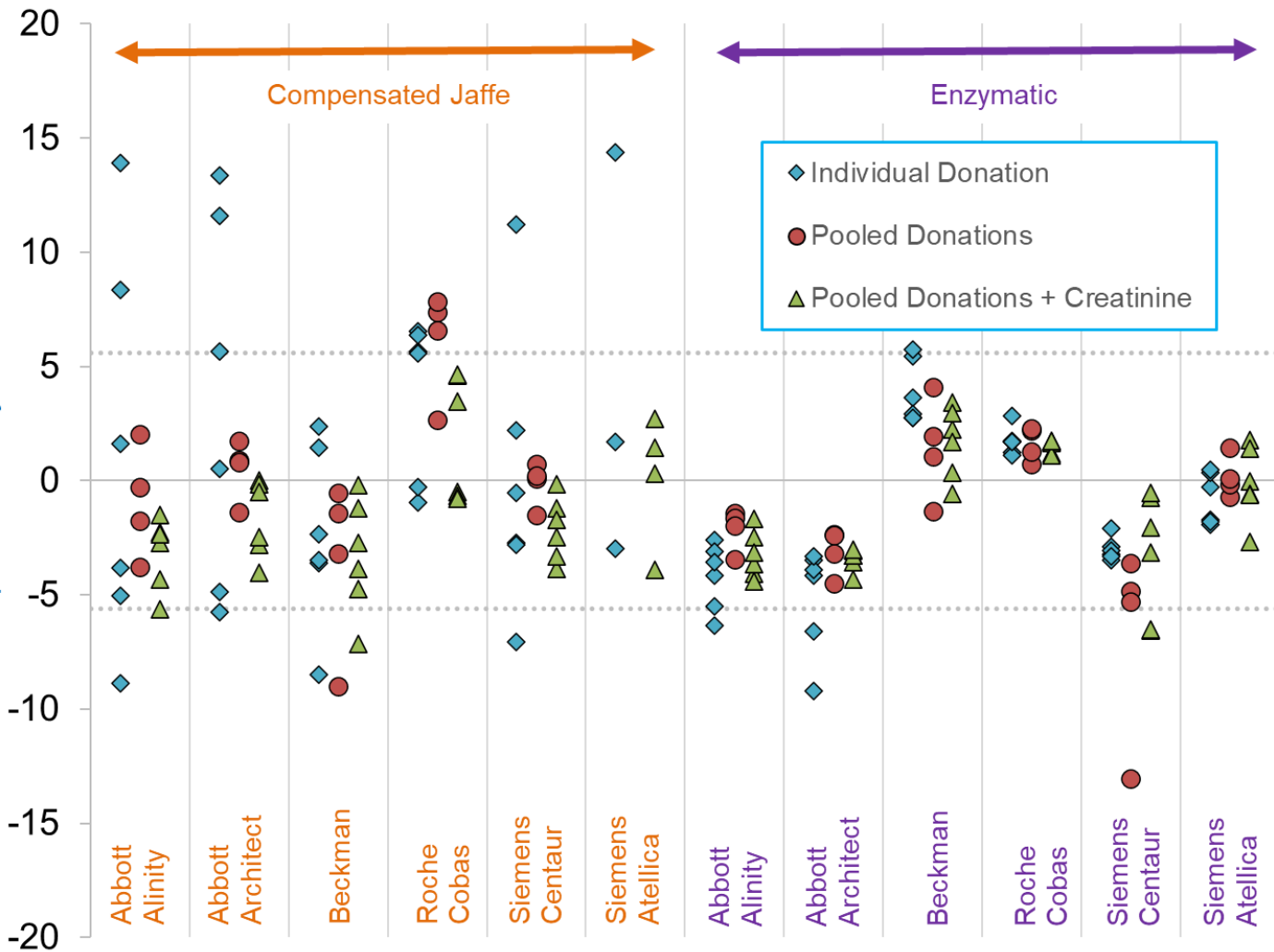


134.367 u



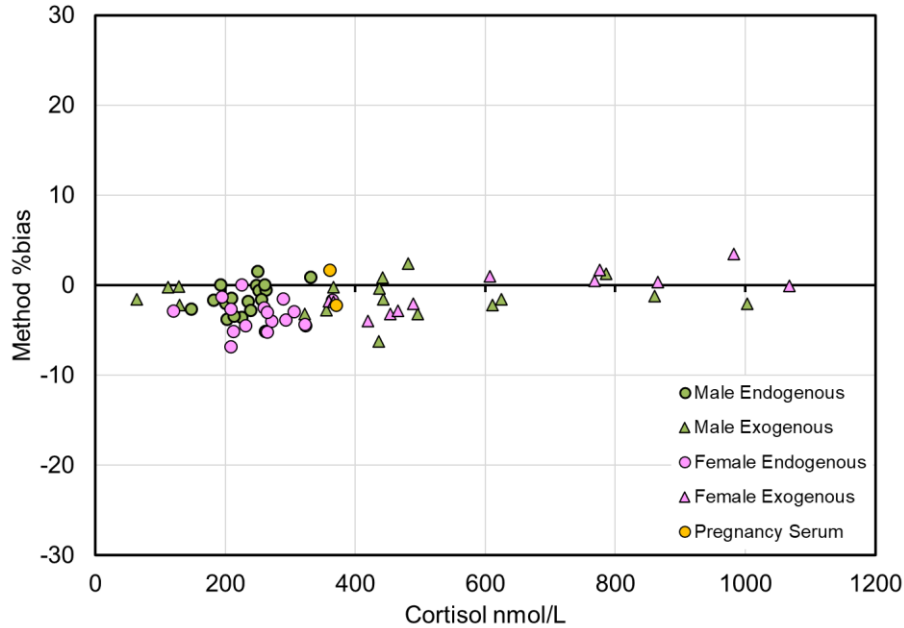
289.576 u

% Difference compared to Enzymatic Method Mean

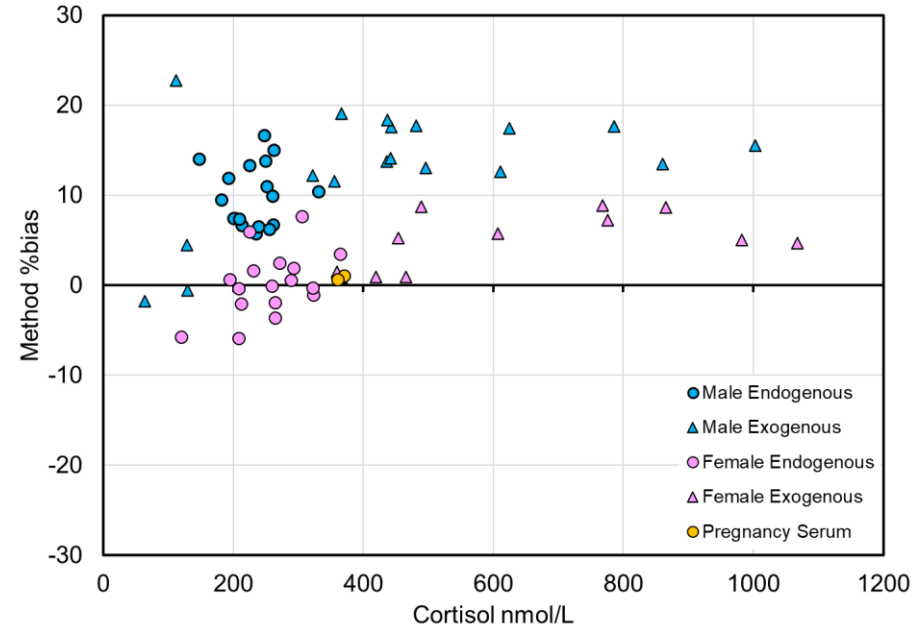


Cortisol

Roche Cobas

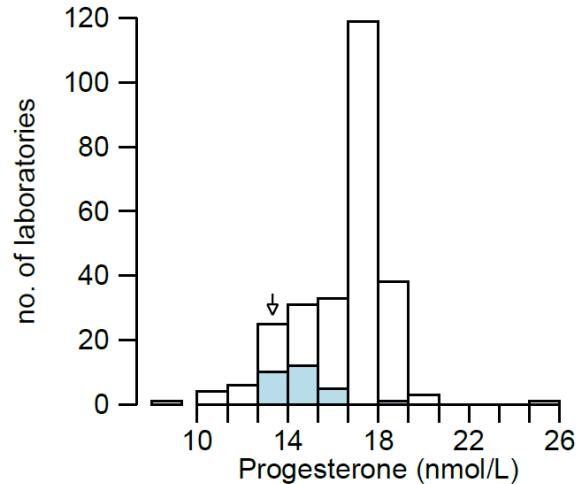


Siemens Centaur

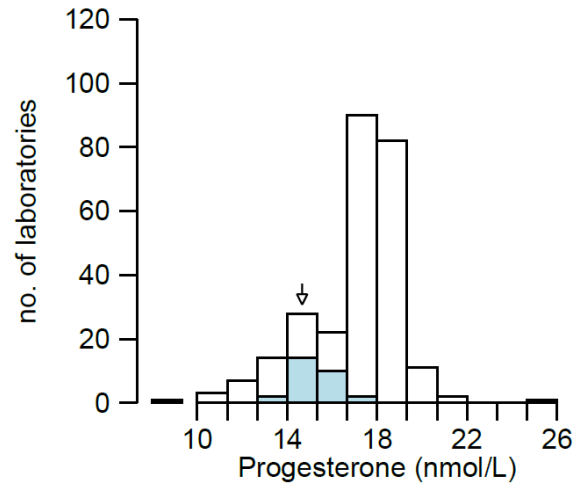


Progesterone

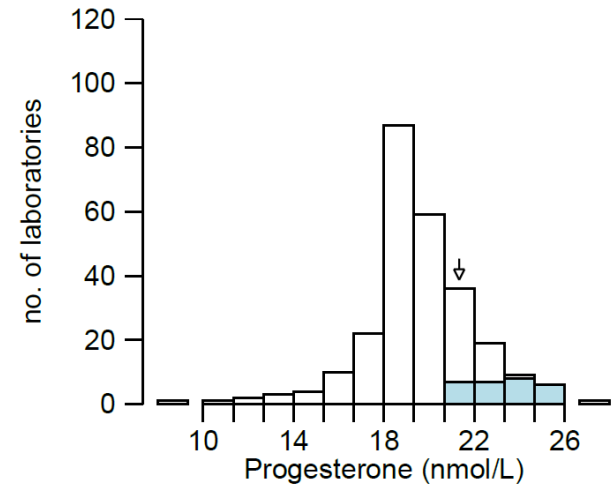
Pooled human serum



Pooled human serum + Progesterone



Pregnancy serum



Conclusion

- When large numbers of individual donations are combined, variable amounts of non-specific chromagens are mixed and any single 'interferent' will be diluted by the increase in volume.
 - Therefore, if EQA material is of this nature it will be very difficult to determine an accurate assessment of an assay's true bias and imprecision from EQA.
- Laboratories invest a lot of time and money in quality management, therefore they need to know the limitations of their assays.
 - No need to investigating problems from EQA/IQC which are purely down to a non-specific, imprecise assay
- Manufacturers' may be falsely reassured of the performance of their assays through poor design of EQA Schemes, thus compromising IVDR and post market surveillance