

Birmingham Quality

Does your EQA falsely reassure you?

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UK NEQAS
International Quality Expertise

50 Years as World Leaders in EQA 1969–2019

Introduction

External Quality Assessment (EQA) has two very important roles:

- (i) a retrospective assessment of an individual laboratory's quality and (ii) post market surveillance of all assays that are currently in use.

There are surprisingly many major differences in Scheme design between EQA providers. ISO/IEC 17043:2010 accreditation does not stipulate how an EQA Scheme is designed e.g. material distributed, frequency of distribution etc. Laboratories should not assume all EQA Schemes are the same.

Likewise, the laboratory should not assume that just because an assay is commercially available that it is fit for the purpose that they are using it for.

An example is shown here for Cortisol within the UK NEQAS for Steroid Hormones; however, the same principles apply to the majority of analytes.

Method

The UK NEQAS for Steroid Hormones Scheme distributes individual specimens, monthly, to ~480 participants in the UK and worldwide. Specimens are predominantly non-manipulated patient serum; however, in some cases exogenous steroid is added to increase concentration or exogenous material is added for interference studies / more challenging specimens.

Data from all major methods for Cortisol from 2021–2022 has been reviewed. The Target Value is the Mass Spectrometry field method mean which is validated by a reference method.

Results

Figure 1 shows data and histograms for two different specimens, of similar concentration, for the same laboratory. Both specimens are pooled human serum with no added analytes.

- The %CV for all methods is similar for both specimens, as is also the case for each individual method.
- For the Siemens Advia Centaur user shown, the scoring is very different – a positive bias of ~+17% for 499B and ~+4% for 500A, one month later. This could lead to investigation into a possible laboratory or EQA issue when in fact the difference is due to the analytical method.
- The serum used for Specimen 499B was from male donors and the serum for Specimen 500A was from female donors.

Bias Plots

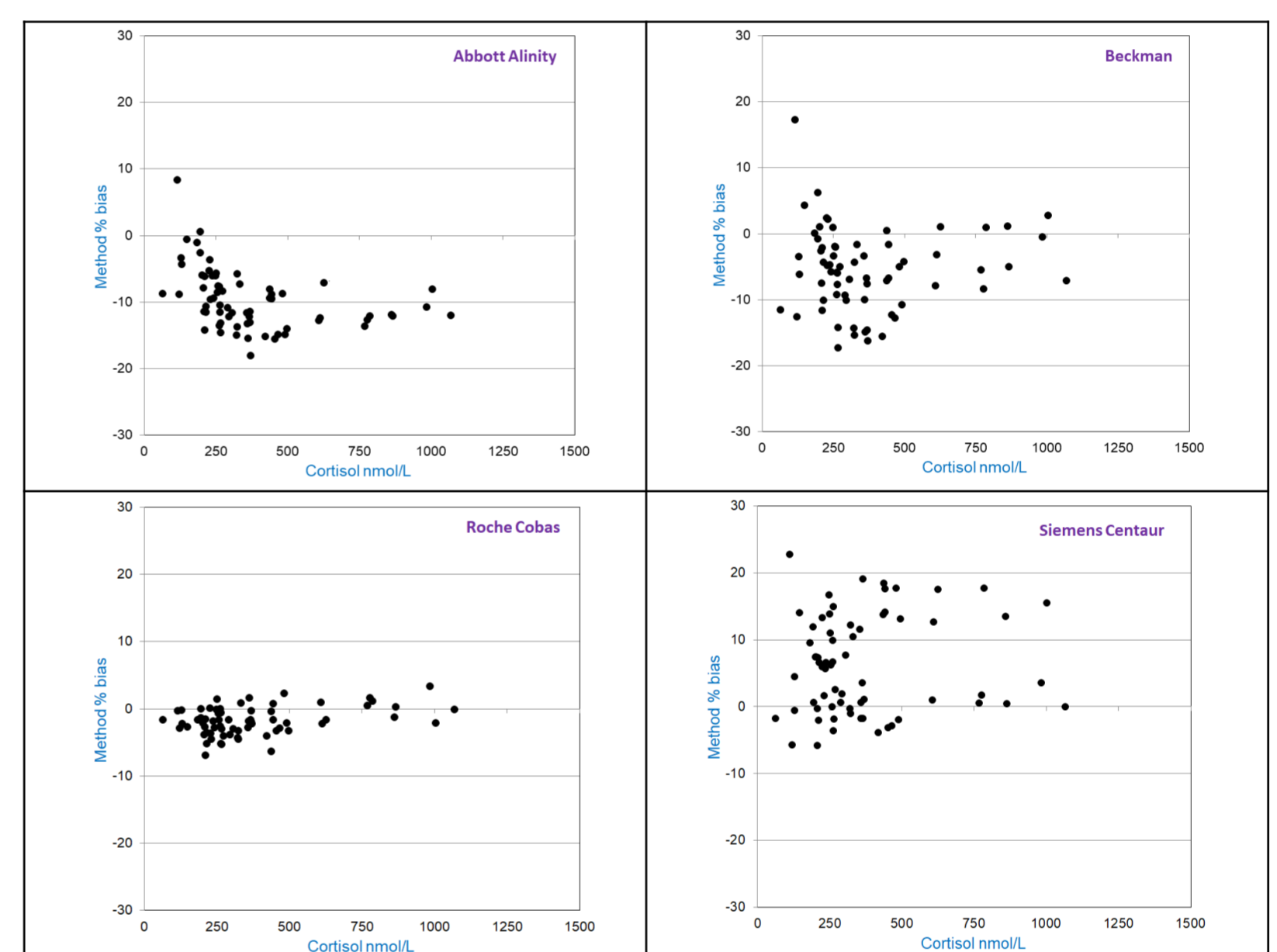


Figure 2. Bias plots for Cortisol by Manufacturer: Data for all specimens shown

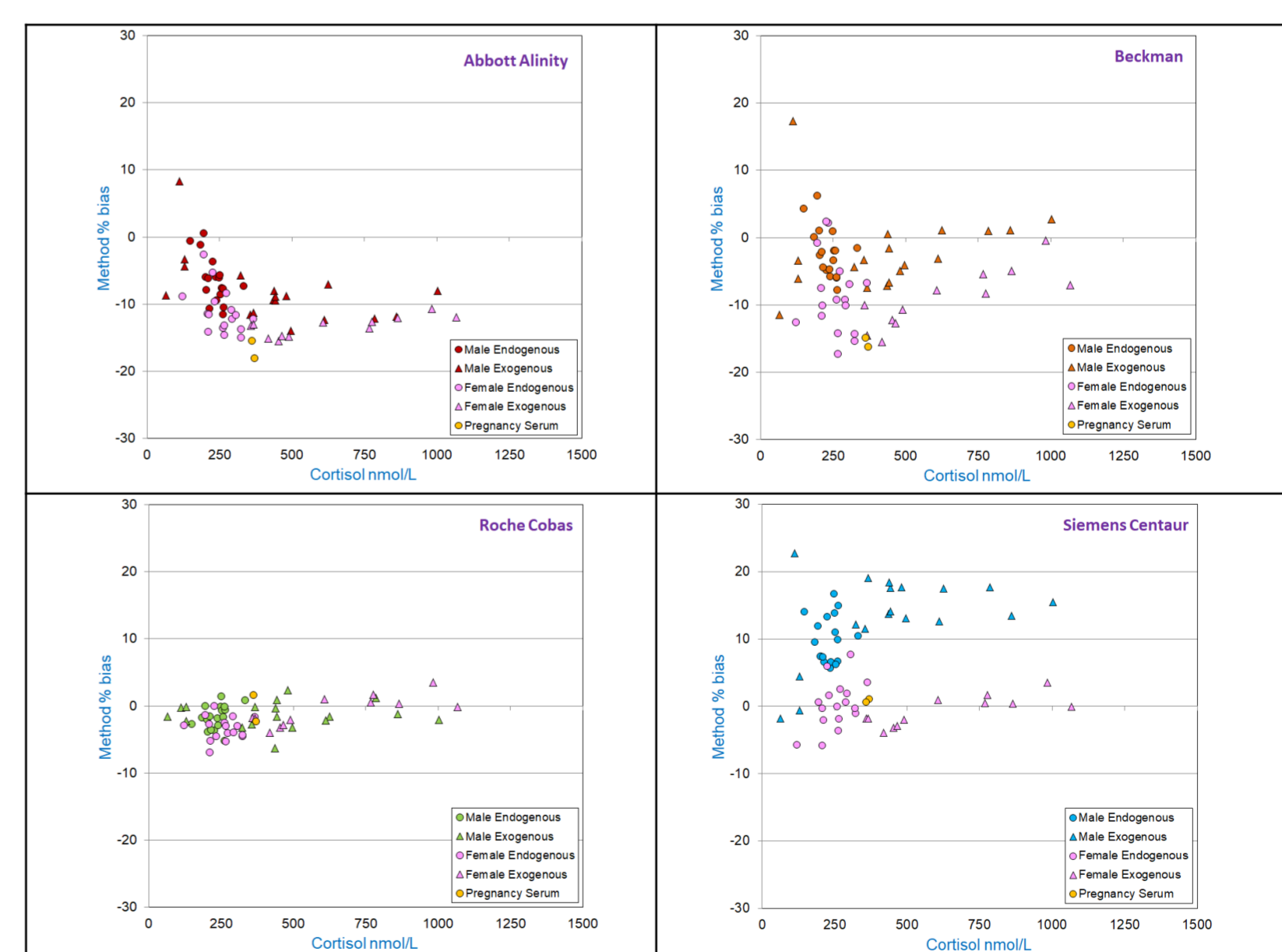


Figure 3. Bias plots for Cortisol by Manufacturer: Data shown by sex of serum and whether endogenous serum or serum with exogenous material added

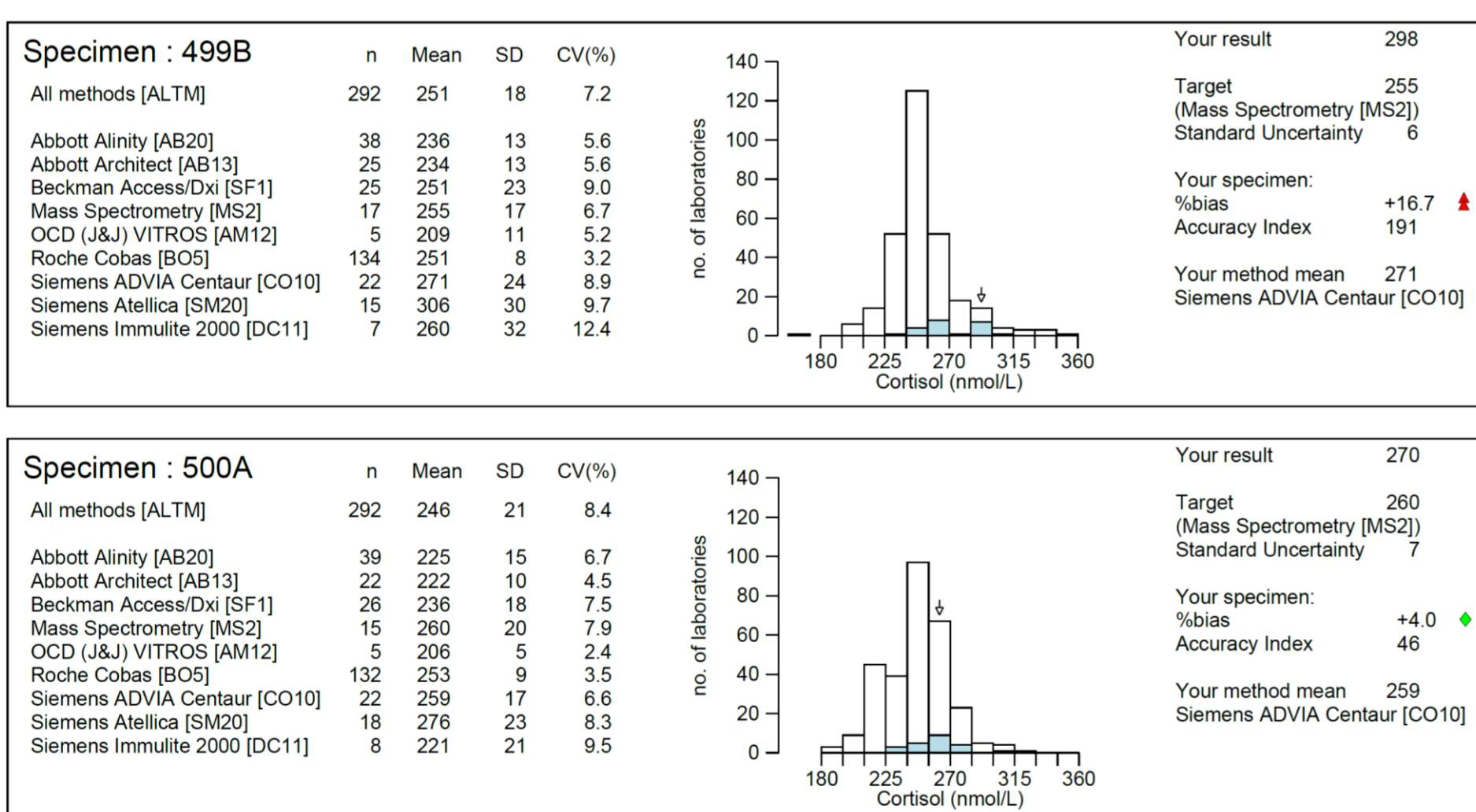


Figure 1. Histograms of reported Cortisol results on Specimens 499B and 500A for the same user using a Siemens Advia Centaur: Pooled human serum with no added analyte

- Figure 2 shows bias plots by method during 2021–2022. Variation is observed both within and between manufacturers.
- When data is split by sex of serum, as shown in Figure 3, it is clear to see that there are sex differences in the Cortisol method for Beckman and Siemens Advia Centaur assays and a concentration dependent bias for Abbott Alinity. The Roche Cobas Cortisol assay shows negligible bias and no sex differences.

Conclusion

Using individual specimens with minimal or no manipulation has shown that there are significant assay and sex specific differences for a defined analyte such as Cortisol. These differences not only impact interpretation of clinical results, but also EQA data. Laboratories may have taken these differences into account in their reference ranges and risk assessment of service provision, but they need to be aware of the shortcomings of all assays and the need to probe with challenging EQA, not just easy to pass, bland, superficial EQA.