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A study to assess analytical interference on routine endocrine immunoassays

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Introduction

The Weqas Endocrine programme has operated for over 20 years and is accredited to ISO 17043. The panel of tests in this programme covers a range of hormones routinely used to assess endocrine diseases such as adrenocortical disorders (cortisol), thyroid disease (FT_4, FT_3, TSH), pituitary function (LH, FSH, prolactin), and gonadal disorders (oestrogen, progesterone, testosterone, and SHBG). Four levels of liquid human serum are distributed monthly, covering a clinically relevant range for steroid, thyroid hormone and fertility profiles. ID-LCMS/MS reference target values are available for cortisol and testosterone. The programme allows for long-term assessment of laboratory and method performance, including trueness, linearity, bias and within/between batch imprecision, with scoring based on Milan Model 3 performance specifications. In addition to routine samples, the programme also regularly provides challenging samples for laboratories, including samples at clinical decision points and samples to assess the effects of endogenous interferents.

Haemolysis, icterus and lipaemia (HIL) are three of the most common endogenous interferents encountered in routine chemistry and immunoassay that can affect patient results. Mechanisms for interference include:

- Spectral interference – changes in light absorption or scatter may affect optical measurements
- Chemical interference – direct interaction with assay reagents or binding sites
- Matrix effects – altered protein binding, partitioning or changes in viscosity altering reaction kinetics

Most routine analysers in Clinical Chemistry laboratories automatically test for HIL indices before assaying patient samples. In addition, most manufacturers include validated HIL limits, however in practice performance may vary. There is an ongoing requirement for independent evaluation of assay performance.

Aim and methods

The aim of this study was to assess the effect of HIL interference on routine Endocrine assays included in the current Weqas Endocrine programme.

Human serum was prepared for distribution for the Endocrine programme following standard Weqas procedures. Selected pools were spiked with either bilirubin (target total bilirubin concentration 180 µmol/L), Intralipid (target triglyceride concentration 10 mmol/L) or lysed red blood cells (target haemoglobin concentration 1.73 g/L). Matched pools were distributed to participants in separate distributions, one containing the base serum and the other the spiked serum. Results were collated and the effect of interference on each analyte assessed for participating assay platforms. Initially, results were compared using box and whisker plots to assess for differences; and where differences were identified, the Wilcoxon Rank Sum test was used to confirm significance.

Results

For most analytes in the study, no significant interference was seen for any of the HIL indices, for example cortisol shown in Figure 1 below.

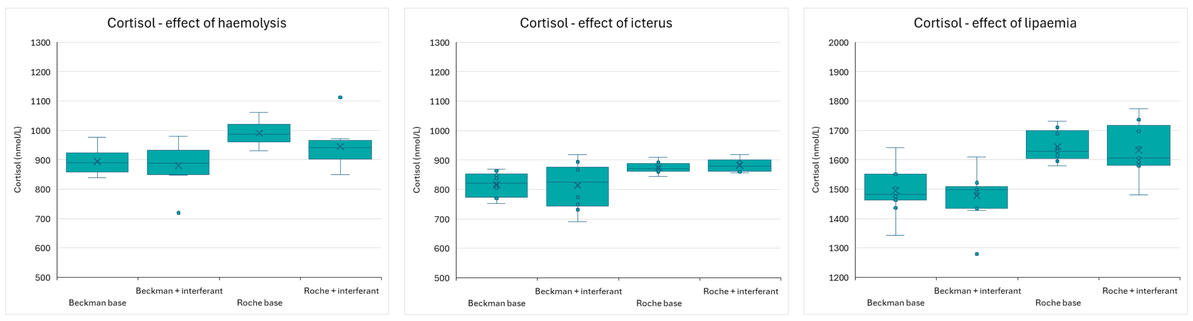

Figure 1: No significant effect on cortisol concentration was noted for either Beckman or Roche platforms following spiking of samples with haemoglobin, Intralipid or bilirubin

Results - continued

Furthermore, no interference caused by haemolysis was noted for any analyte in this study. However, some analytes in the programme were shown to be affected by interference from icterus and lipaemia.

Interference from icterus

Oestradiol results showed a decrease of approximately 15 % when spiked with bilirubin compared to non-spiked samples when measured on Roche instruments. Similarly, free T4 results showed a decrease of approximately 24 % when spiked with bilirubin compared to non-spiked samples when measured on Beckman instruments (Figure 2).

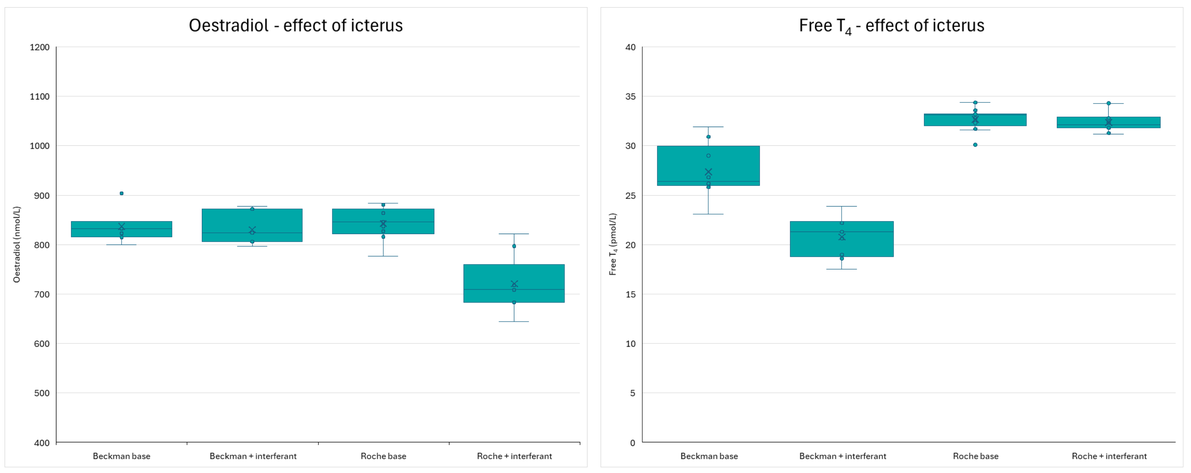

Figure 2: Spiking samples with bilirubin (180 µmol/L) resulted in an approximately 14 % decrease in oestradiol when measured on Roche platforms, compared to matched non-spiked samples. Spiking samples with bilirubin (180 µmol/L) resulted in 24 % decrease in free T4 when measured on Beckman platforms, compared to matched non-spiked samples.

Interference from lipaemia

Progesterone results showed a decrease of approximately 14 % when spiked with intralipid compared to non-spiked samples when measured on Beckman instruments; and approximately 19 % when measured on Roche instruments (Figure 3). In addition, an increase in variation was noted for the Roche platform when measuring spiked samples, although sample size was relatively small.

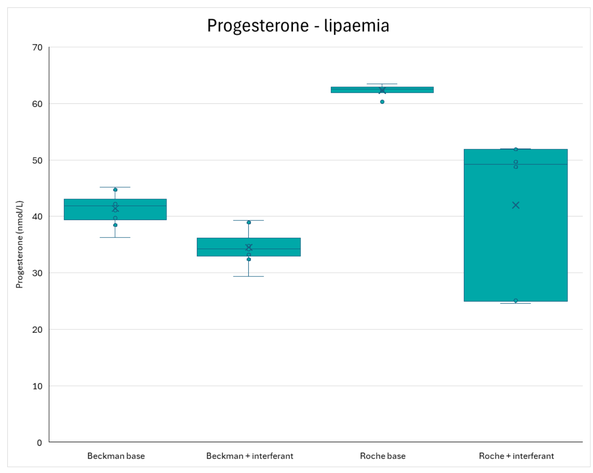

Figure 3: Spiking samples with Intralipid (triglycerides 10 mmol/L) resulted in an approximately 14 % decrease in progesterone when measured on Beckman platforms, and 19 % decrease in progesterone when measured on Roche platforms when compared to matched non-spiked samples.

Discussion and conclusions

This study has shown that there is no evidence of interference from haemolysis, icterus or lipaemia in most assays included in the Weqas Endocrine programme, including cortisol, testosterone, prolactin and TSH. However, for three assays (oestradiol, free T4 and progesterone) interference was identified for either or both assay platforms included in the study for lipaemic or icteric samples. Assuming patient samples behave in a similar manner to these manipulated samples, this could result in falsely low results for these analytes, potentially risking misdiagnosis or inappropriate treatment. Further studies would focus on confirming the magnitude of interference on larger sample sizes and assessing the effect of different levels of spiking.

This study has highlighted potential interferences from icterus and lipaemia in commercial endocrine assays. It is important that laboratories are aware of potential interferences in their assays, are aware of which analytes could be affected, can detect the potential interferences and have systems in place to ensure the accuracy of results when these interferences are present.