

# Salivary cortisol determination using the Roche generation II assay

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## Background

The Endocrine Society guidelines recommend initial testing for Cushing's syndrome (CS) can be based on non-invasive late-night salivary cortisol measurement. In the BHSCT nocturnal (11pm) salivary cortisol (NSC), measured using the IBL ELISA kit has been found to be highly discriminative in identifying patients with CS. However, it is a labour intensive test and the need for analysing samples in batches delays turnaround time, therefore limiting its use in the routine work up for CS. Roche provide an automated assay for salivary cortisol which employs competitive electrochemiluminescence immunoassay standardised against IRMM/ IFCC-451panel using ID-GCMS.

## Aim

The aim of this project was to evaluate the Roche automated assay for NSC.

## Method

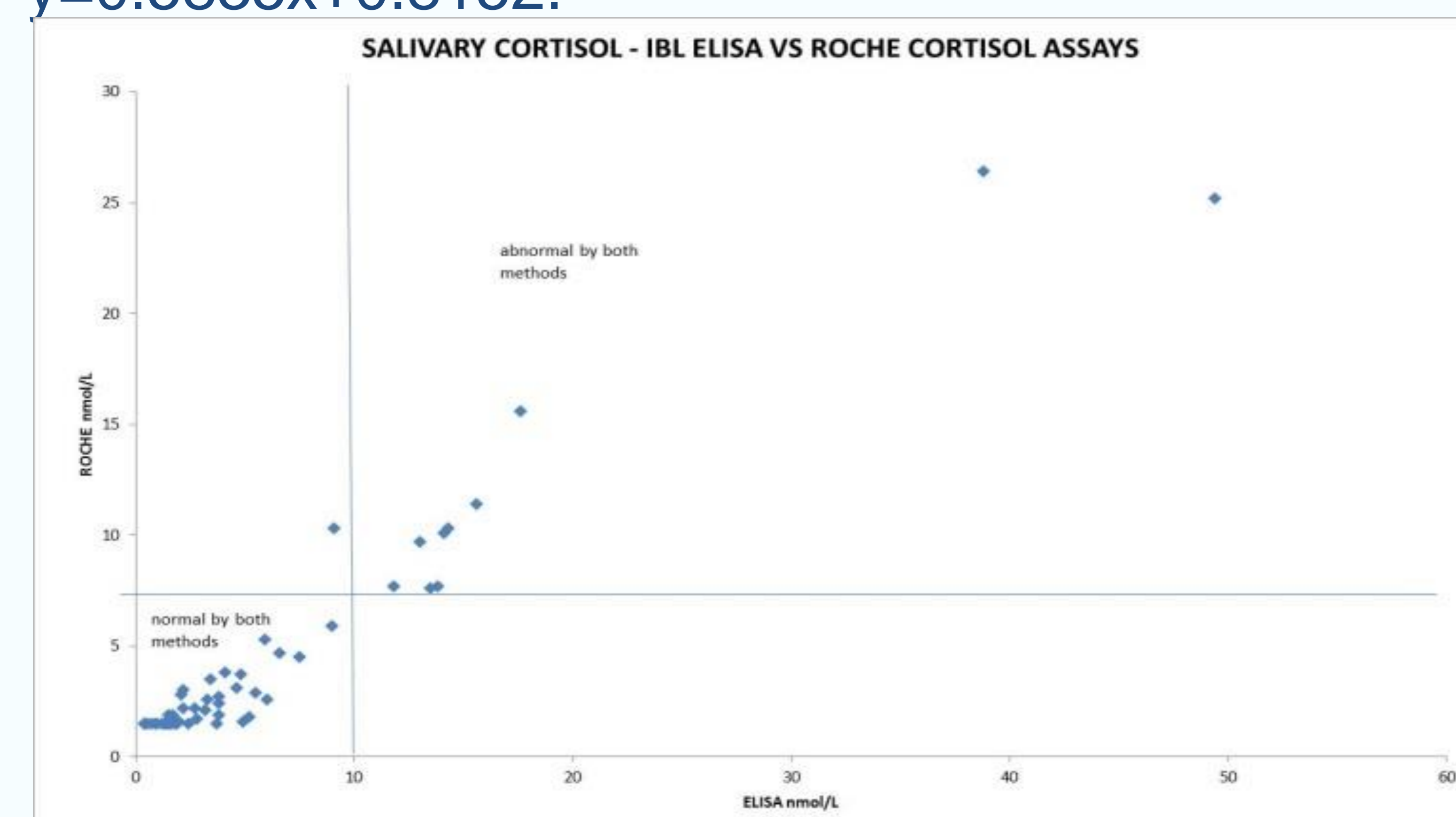
NSC samples were obtained from 52 patients (8 CS+, 44 CS-). Cortisol was measured in each sample using the ELISA and Roche assays and results correlated. An optimal cut-off for the Roche assay was determined.

## Assay characteristics

Between batch imprecision of the Roche automated assay was 8.7% for a level of 11.5 and 5% for 29.2 nmol/L. Within batch imprecision of the Roche automated assay was <1.95% at 8.0 and 26.7 nmol/L. The assay was shown to be linear to approx. 2 nmol/L.

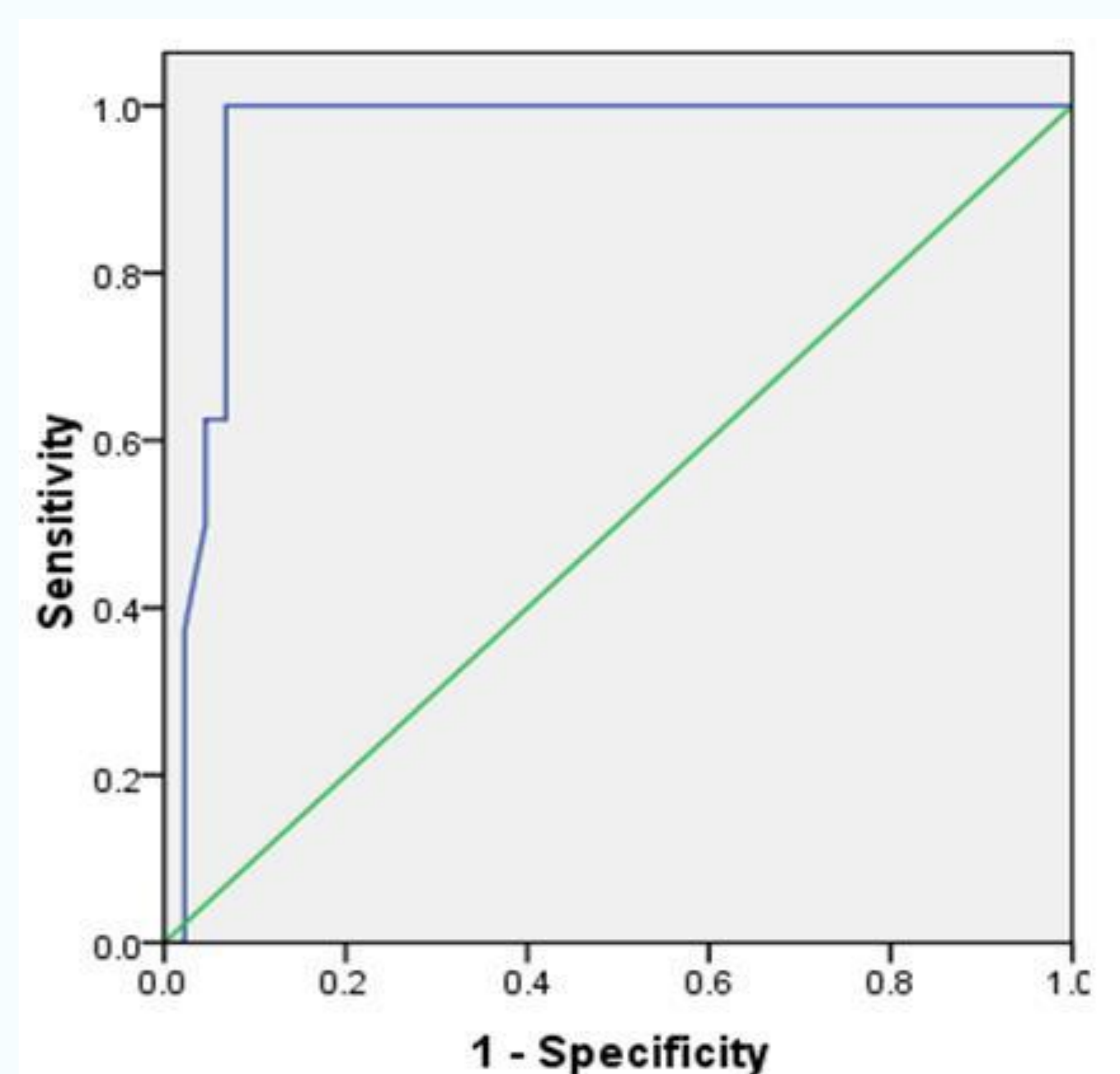
Measurement of Uncertainty (MU) was determined at a level of 11.46 nmol/L to be 1.99 nmol/L (9.48-13.45 nmol/L) and for a level of 29.17 nmol/L the MU was 2.97nmol/L (26.21-32.14 nmol/L).

Correlation between IBL ELISA and Roche assays was demonstrated with  $r^2=0.933$  and  $y=0.5835x+0.8152$ .



Correlation between IBL ELISA and Roche cortisol assay

ROC curve analysis (Roche) showed area under curve 0.956 ( $p < 0.001$ ) with an optimal cut-off 7nmol/L to identify CS (sensitivity 100%, specificity 93.2%). This correlates well with the cut-off provided by Roche of <7.56nmol/L and <11.3nmol/L, 95<sup>th</sup> and 97.5<sup>th</sup> percentiles respectively.



ROC curve for Roche cortisol

## Conclusion

In conclusion the Roche automated cortisol generation II assay meets performance requirements and will be introduced into clinical practice. Further evaluation of the diagnostic usefulness of the assay as a routine test is planned.

## Reference

The Diagnosis of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. JCEM 2008; 93 (5) 1526-1540