



IDS Cortisol assay is a fully automated CLIA assay for the quantitative determination of cortisol in human serum and plasma samples. Cortisol is a steroid hormone synthesized in the adrenal gland regulating a variety of physiological processes^{1,2,3}.

The IDS Cortisol results are to be used in conjunction with other clinical and laboratory data to assist clinicians in the diagnosis and treatment of disorders of the adrenal gland, such as hypo- and hyper-cortisolism, most commonly referred to as Addison's disease and Cushing's syndrome^{3,4}. Many common signs of Cushing's such as obesity, high blood pressure, and increased blood glucose are frequently observed in today's society⁵.

The Endocrine Society recommends the overnight dexamethasone suppression test as one of the screening tests for diagnosing Cushing's syndrome⁶, with a cut-off of <1.8 μ g/dL as indication of suppressed serum levels. A peak cortisol <18 μ g/dL following a standard-dose corticotropin stimulation test is indicative of adrenal insufficiency⁴.

Features and benefits

- Traceable to the Joint Committee for Traceability in Laboratory Medicine (JCTLM)-listed LC-MS/MS Candidate Reference Measurement Procedure (cRMP)⁷ for confidence in patient results
- Utilises direct antibody coating immunoassay principle, removing the risk of inaccurate results due to biotin interference
- · Excellent functional sensitivity and precision over the clinically relevant range
- Efficient laboratory workflow, consolidating the testing of ACTH, Aldosterone and Direct Renin on one fully automated platform from one plasma sample tube

Specifications

| Assay range | 0.59 (LOQ) – 45.00 µg/dL | Calibration frequency | 14 days |
|-------------------|---|------------------------|---|
| Sample volume | 30 µL plus dead volume | Time to first result | 28 minutes |
| Sample type | Serum and plasma samples | Precision (Within-Run) | <2 µg/dL SD ≤0.08 ≥2 µg/dL %CV ≤2.3% |
| Reagent stability | On-board system 14 days 28 days at 2 – 8°C | Precision (Total) | <2 µg/dL SD ≤0.18 ≥2 µg/dL %CV ≤5.0% |

Traceability

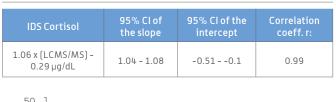
The IDS Cortisol assay is traceable to the LC-MS/MS Candidate Reference Measurement Procedure (cRMP) Total Serum Cortisol. Through analysis of a Joint Committee for Traceability in Laboratory Medicine (JCTLM)-listed panel of higher-order Candidate Reference Materials (CRM), ERM-DA451/IFCC panel, the IDS Cortisol demonstrates traceable results.

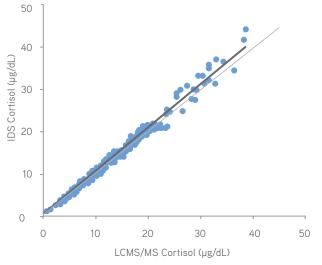
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|----------------------------|-------|----------------|----------------------|-----------------|-----------------------------|
| Ν | Slope | 95% CI | Intercept (µg/dL) | 95% Cl | Correlation coefficient (r) |
| 34 | 1.005 | 0.965 to 1.069 | 0.135 | -0.256 to 0.560 | 0.993 |

Method comparison

IDS Cortisol vs LCMS/MS

190 specimens (range $0.9 - 44.7 \mu g/dL$), including clinical routine samples and the ERM-DA451/IFCC panel (n=34), were assessed in parallel with the IDS Cortisol and LCMS/MS method of the University Hospital of South Manchester (UK).

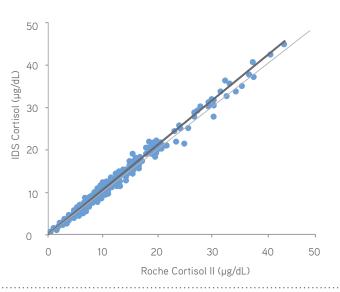




IDS Cortisol vs Immunoassay

194 specimens (range 0.6 – 44.7 μ g/dL), including clinical routine samples and the ERM-DA451/IFCC panel (n=34), were evaluated in parallel with the IDS Cortisol and the Roche Cortisol II (Ref 06687733 190).

| IDS Cortisol | 95% Cl of | 95% Cl of the | Correlation |
|--------------------------------|-------------|---------------|-------------|
| | the slope | intercept | coeff. r: |
| 1.06 x (Roche) - 0.10 µg/dL | 1.04 - 1.07 | -0.39 - 0.04 | 0.99 |



Other assays in the hypertension portfolio

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Product name

IDS-iSYS Aldosterone

IDS-iSYS Direct Renin

IDS-iSYS ACTH

IDS-iSYS Salivary Cortisol

Ordering Information

| ✓ Product name | Description | Code |
|-----------------------------|----------------------------|---------|
| IDS Cortisol | Reagent pack: 100 tests | IS-4600 |
| IDS Cortisol Calibrator Set | 6 levels | IS-4620 |
| IDS Cortisol Control Set | 3 levels | IS-4630 |

Visit www.idsplc.com for an extended range of IDS products

References

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2. Wild, D. The immunoassay handbook. (Elsevier, 2005).

3. Cain, D. W. & Cidlowski, J. A. Specificity and sensitivity of glucocorticoid signalling in health and disease.

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Code

IS-3300

IS-3400

IS-4900

IS-4500N