# Urinary Cortisol

The IDS Urinary Cortisol assay is a fully automated CLIA assay for the quantitative determination of cortisol in human urine samples. Results are to be used in conjunction with other clinical and laboratory data to assist clinicians in the diagnosis and monitoring of disorders of the adrenal gland.

Cortisol is a steroid hormone synthesized in the adrenal gland regulating a variety of physiological processes[1,2,3].

Urinary Cortisol results are used in conjunction with a complete clinical evaluation to assist in the diagnosis and monitoring of disorders such hypercortisolism, commonly known as 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 society[5].

Cortisol present in the urine represents free serum cortisol levels which are not bound to the cortisol-binding-globulin (CBG) and are filtered into urine. Approximately 1% of unbound cortisol is excreted in the urine[6]. Urinary Cortisol has the advantage of not being affected by conditions that alter CBG levels such as oral contraceptives.

The Endocrine Society recommends the measurement of 24hr urinary cortisol as one of the screening tests for diagnosing Cushing's syndrome[5], with a cut-off point for a normal response considered the upper limit of normal (ULN) range as established for each respective assay[7].

## Features and benefits

- Direct urine measurement, no extraction procedure required, for streamlined workflow
- No risk of biotin interference by employing direct antibody-solid phase coating principle
- Excellent functional sensitivity and precision over the clinically relevant range
- Validated reference intervals in 24-hour urine collections from healthy subjects
- Demonstrated clinical concordance in routine clinical samples

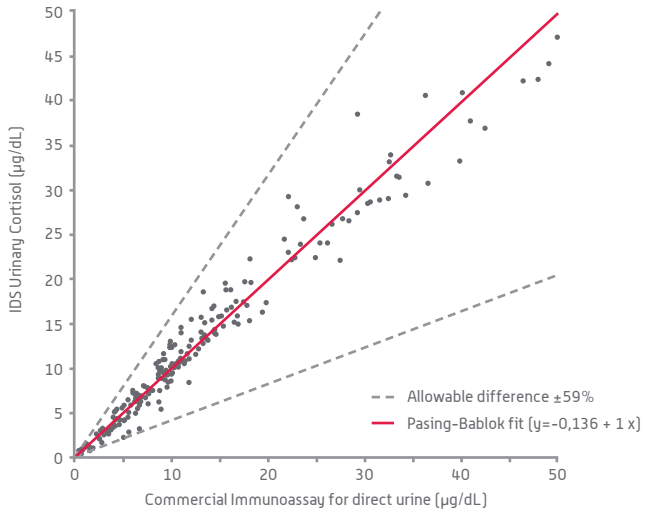
## Specifications

| Parameter | Description |
|---|---|
| **Limit of Quantitation (LOQ)** | 0.36 µg/dL |
| **Assay Measuring Range** | 0.36 – 52.0 µg/dL |
| **Assay Reportable Range** | 0.36 – 120.0 µg/dL, via optional dilution procedure |
| **Expected Reference Range (µg/24hr)** | 50.8 to 324.2 (2.5th - 97.5 percentile), n=147 |
| **Sample Volume** | 30 µL urine plus dead volume |
| **Sample type** | Urine samples (no preservative, or with addition of boric acid) |
| **Time to first result** | 28 minutes |
| **Calibration frequency** | 14 days |
| **Reagent Stability**<br>On-board system:<br>2 - 8°C: | <br>14 days<br>28 days |

## Traceability

The IDS Urinary Cortisol is an established non-standardized assay. In the JCTLM list, no reference measurement procedure or material are included for cortisol in human urine. The Beckman Coulter Access Cortisol (Ref 33600) was selected to guarantee the trueness and therefore the metrology and traceability of the assay.

| N | Slope | 95% CI | Intercept ( g/dL) | 95% CI | Correlation Coefficient ($R^2$) |
|---|---|---|---|---|---|
| 205 | 1.00 | 0.96 to 1.04 | -0.14 | -0.46 to -0.22 | 0.96 |




## Method comparison: IDS Urinary Cortisol vs. Commercially available immunoassay

205 specimens (range 0.35 – 47.12 µg/dL), including clinical routine samples were assessed in parallel with the IDS Urinary Cortisol and another commercially available automated immunoassay for measurement in direct urine samples.

**The following results were obtained:**

| IDS Urinary Cortisol = 1.00x - 0.14 g/dL | |
|---|---|
| Slope (95 % CI) | 0.96 to 1.04 |
| Intercept (95 % CI) | -0.46 to -0.22 µg/dL |
| Correlation Coeff. $R^2$ | 0.96 |

## Ordering information

| Product name | Code | Description |
|---|---|---|
| IDS Urinary Cortisol | IS-5800 | Reagent pack: 100 tests |
| IDS Urinary Cortisol Calibrator Set | IS-5820 | Calibrator set: 6 levels |
| IDS Urinary Cortisol Control Set | IS-5830 | Control set: 2 levels |

## Relevant assays

| Product | Code | Description | Portfolio |
|---|---|---|---|
| IDS Cortisol | IS-4600 | Reagent pack: 100 tests | Adrenal Function |
| IDS Salivary Cortisol | IS-4900 | Reagent pack: 100 tests | Adrenal Function |
| IDS ACTH | IS-4500N | Reagent pack: 100 tests | Adrenal Function |
| IDS Aldosterone | IS-3300 | Reagent pack: 100 tests | Endocrine Hypertension |
| IDS Direct Renin | IS-3400 | Reagent pack: 100 tests | Endocrine Hypertension |


**References**

1. Ramamoorthy, S. & Cidlowski, J. A. Corticosteroids: Mechanisms of Action in Health and Disease. Rheumatic diseases clinics of North America 42, 15-31, (2016).
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. Best practice & research. Clinical endocrinology & metabolism 29, 545-556, (2015).
4. Findling, J. W. & Raff, H. Cushing's Syndrome: important issues in diagnosis and management. The Journal of clinical endocrinology and metabolism 91, 3746-3753, (2006).
5. Nieman, L. K. et al. The diagnosis of Cushing's syndrome: an Endocrine Society Clinical Practice Guideline. The Journal of clinical endocrinology and metabolism 93, 1526-1540, (2008).
6. Raff, H. et al. Urine free cortisol in the diagnosis of Cushing's syndrome: Is it worth doing and, if so, how? The Journal of clinical endocrinology and metabolism 100(2), 395-397, (2015).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