

Assay information



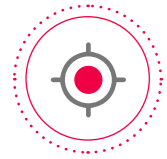
Efficient laboratory workflow

Consolidating the testing of key hormones involved in the regulation of the Hypothalamic-Pituitary-Adrenal axis for Cushing's syndrome and Adrenal Insufficiency (Cortisol, ACTH, Aldosterone* and Direct Renin*) on one fully automated platform from a single plasma sample tube



Traceability

Cortisol: Traceable to the JCTLM-listed LC-MS/MS Candidate Reference Measurement Procedure (cRMP)⁶ for confidence in patient results **ACTH:** Traceable to a commercially available automated ACTH electrochemiluminescence immunoassay



Precise measurements

Excellent functional sensitivity and precision over the clinically relevant range



No biotin interference in the Cortisol, Urinary Cortisol and ACTH II assays

Utilises direct antibody coating immunoassay principle, removing the risk of inaccurate results due to biotin interference

* The Aldosterone and Direct Renin assays are available in the IDS Endocrine Hypertension panel

Kit Reagents

Product Name	Product Code	Sample Type	Sample Volume	Assay Range
IDS Cortisol	IS-4600	Serum or plasma	30 µL	0.59 - 45.00 µg/dL
IDS Salivary Cortisol	IS-4900	Saliva	200 µL	0.02 - 3.0 µg/dL
IDS Urinary Cortisol	IS-5800	Urine	30 µL	0.36 - 52.0 µg/dL
IDS ACTH II	IS-4500NG	Plasma	150 µL	4 - 1000 pg/mL

Calibrator and Control Sets

Product Name	Product Code	Product Format	In-use Stability
IDS Cortisol Calibrator Set	IS-4620	6 levels x 1 vial of 1 mL	28 days
IDS Cortisol Control Set	IS-4630	2 levels x 3 vials of 1 mL	28 days
IDS Salivary Cortisol Control Set	IS-4930	3 levels x 4 vials of 2 mL	27 days
IDS Urinary Cortisol Calibrator Set	IS-5820	6 levels x 1 vial of 1 mL	4 weeks
IDS Urinary Cortisol Control Set	IS-5830	2 levels x 3 vials of 1 mL	4 weeks
IDS ACTH II Calibrator Set	IS-4520NG	5 levels x 2 vials of 1 mL (lyophilised)	2 hours
IDS ACTH II Control Set	IS-4530NG	2 levels x 6 vials of 1 mL (lyophilised)	8 hours

References

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- Bornstein SR, Allolio B, Arlt W, et al. Diagnosis and Treatment of Primary Adrenal Insufficiency: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* 2016 Feb;101(2):364-89.
- Griminger, P. 2016. Cortisol in saliva in the diagnosis of Cushing's syndrome: Diagnostic performance of a new automated chemiluminescence immunoassay and the impact of age, sex and BMI. [Poster]. *ENDO 2016*, 1-4 April, Boston, MA
- Bancos I, Hahner S, Tomlinson J, Arlt W. Diagnosis and management of adrenal insufficiency. *Lancet Diabetes Endocrinol.* 2015 Mar;3(3):216-26.
- Hawley JM, Owen LJ, MacKenzie F, Mussell C, Cowen S, Keevil BG. Candidate Reference Measurement Procedure for the Quantification of Total Serum Cortisol with LC-MS/MS. *Clin Chem.* 2016 Jan;62(1):262-9.

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Adrenal Function



One diagnostic solution for Cushing's syndrome and Adrenal insufficiency

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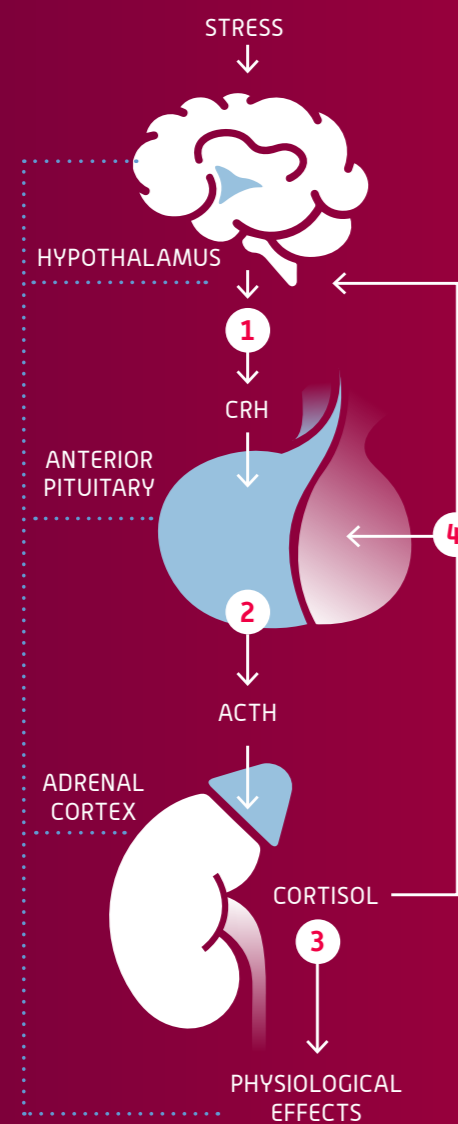
Physiology

The Hypothalamic-Pituitary-Adrenal axis

1 Corticotrophin Releasing Hormone (CRH) is secreted by the hypothalamus in response to stress

2 The peptide adrenocorticotrophic hormone (ACTH) is secreted by the anterior pituitary in response to CRH

ACTH and Cortisol concentrations are evaluated for disorders causing hyper- and hypo-cortisolism



3 Cortisol is a steroid hormone secreted by the adrenal gland that regulates a wide range of processes¹, including:

- Blood sugar levels
- Heart rate
- Blood Pressure
- Immune response
- Metabolism
- Growth

4 Cortisol feeds back to the hypothalamus and pituitary to regulate the secretion of CRH and ACTH

IDS Assays

IDS Cortisol



Use the IDS Cortisol assay (IS-4600) to determine Cortisol levels in serum and plasma.

IDS Salivary Cortisol



Use the IDS Salivary Cortisol assay (IS-4900) to determine Cortisol levels in saliva.

IDS Urinary Cortisol



Use the IDS Urinary Cortisol assay (IS-5800) to determine Cortisol levels in urine.

IDS ACTH II



Use the IDS ACTH II assay (IS-4500NG) to determine ACTH levels in plasma samples.

The key areas of clinical use

for ACTH and Cortisol

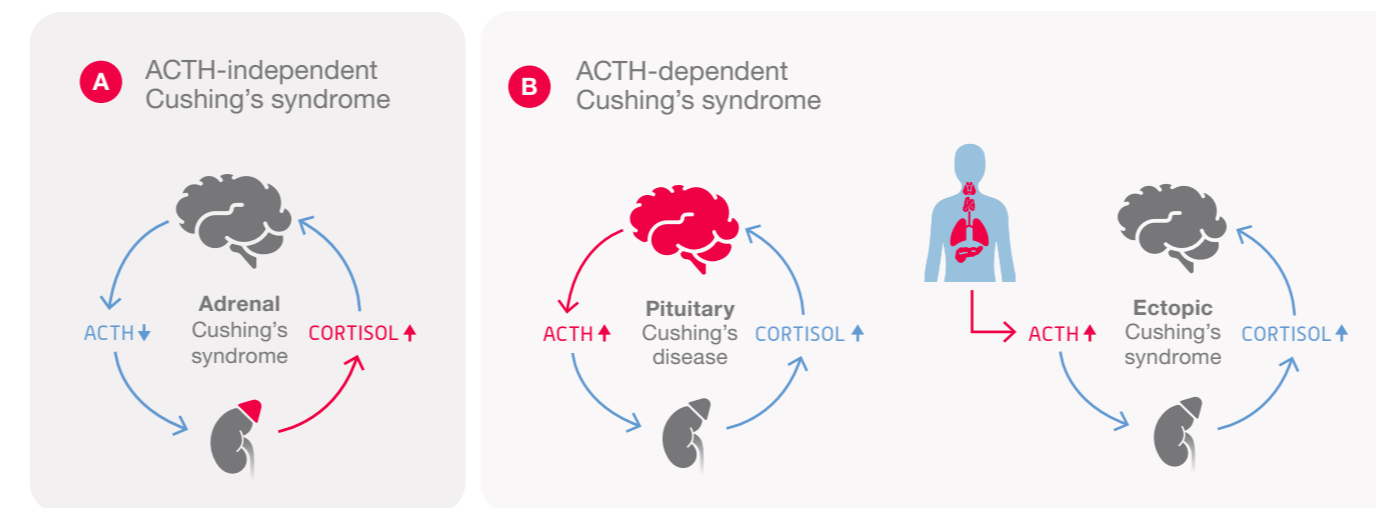
Cushing's syndrome (CS)

is a large group of signs and symptoms due to exposure to hypersecretion of cortisol

Signs and symptoms:



Subtype differentiation:



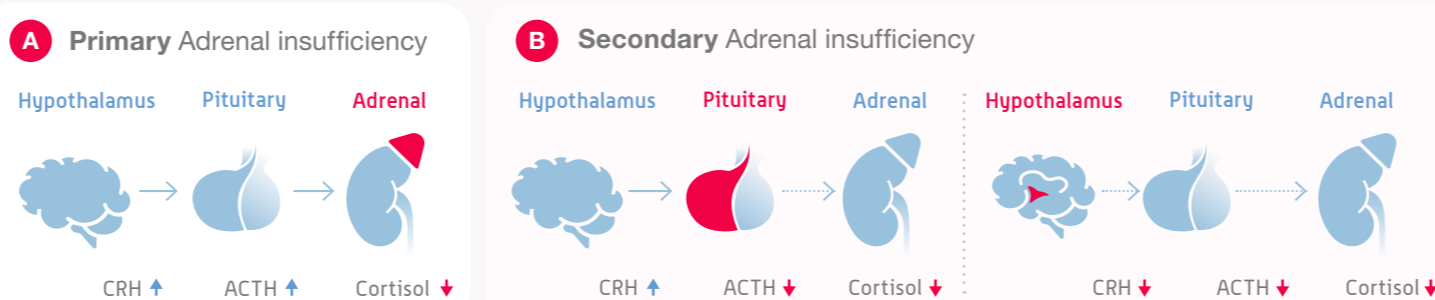
Adrenal insufficiency

A failure of the adrenal to produce cortisol, either due to loss of function of the adrenal gland or the hypothalamic-pituitary-adrenal axis.

Signs and symptoms:



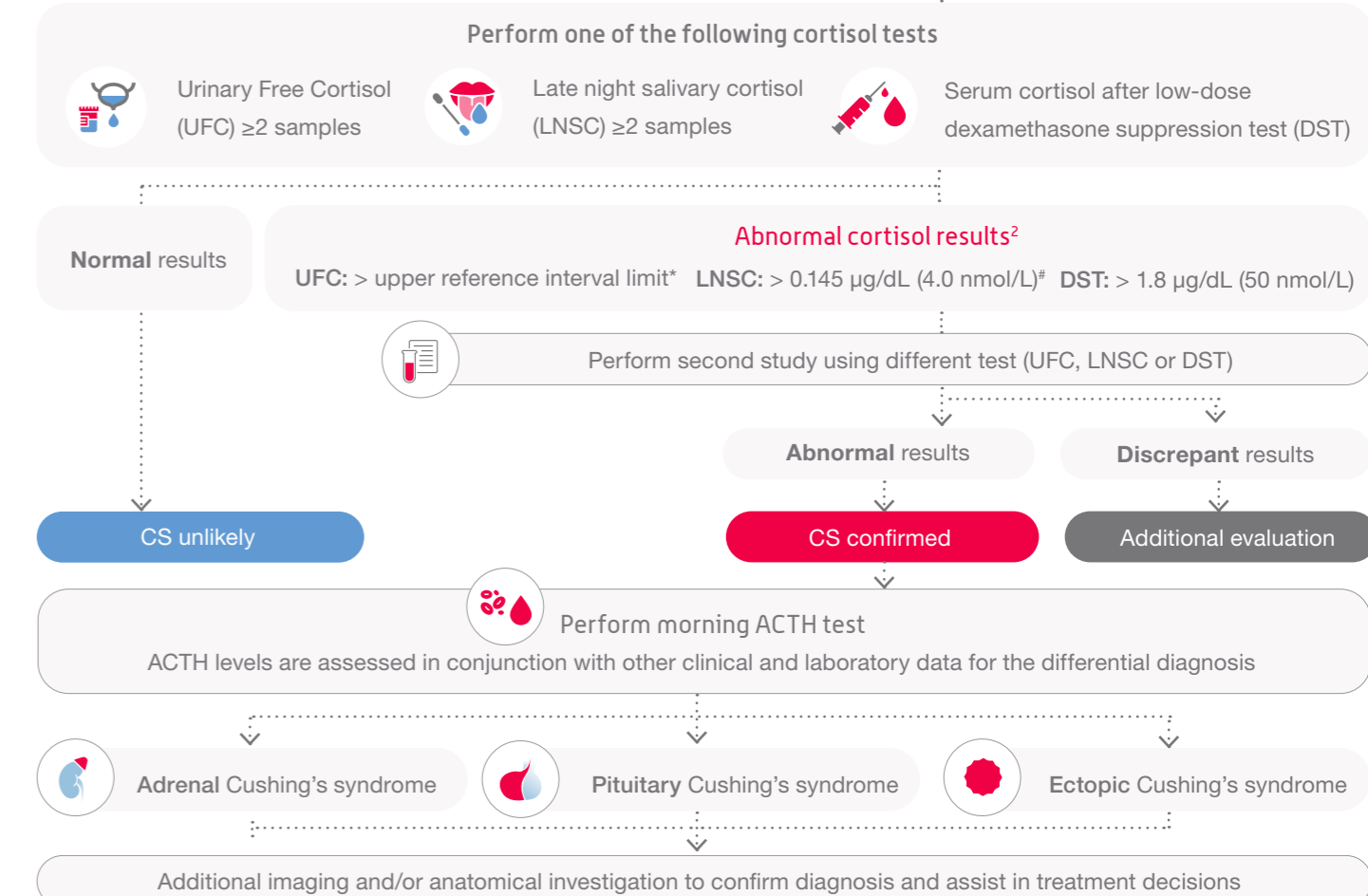
Subtype differentiation:



Testing algorithms

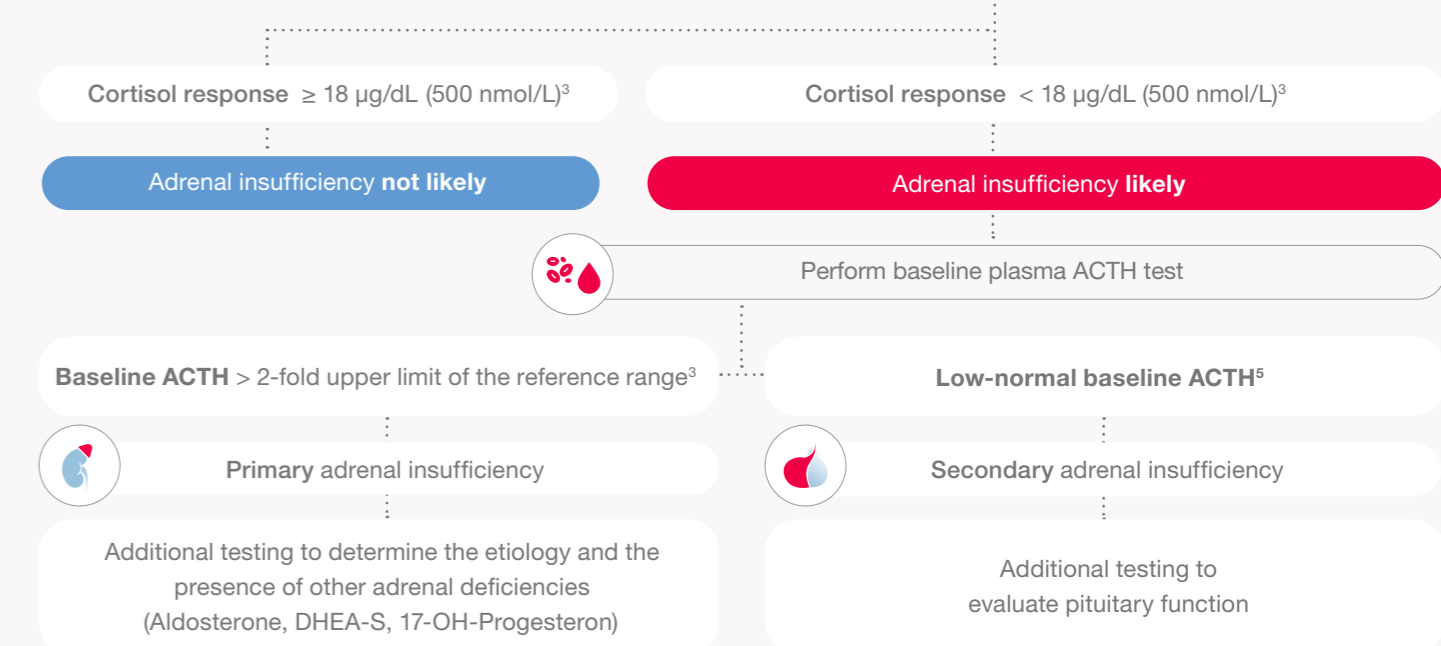
adapted from the Endocrine Society guidelines^{2,3}

Cushing's syndrome suspected



*Consult the IDS Urinary Cortisol (IS-5800) Instructions for Use for the IDS reference interval. †The IDS recommended cut-off is 0.1 µg/dL³. Publication available upon request.

Adrenal insufficiency suspected



Cascade testing algorithms provided for information only. Testing and diagnosis should be determined by a clinician