4 August 2015



From: Assoc. Prof. James Davidson, Clinical Head, Specialist Chemical Pathology

Subject: New Cortisol Assay

LabPLUS will be changing to a new cortisol assay (Roche cortisol II) for all serum, plasma and salivary samples from 31st August 2015. Urine cortisol utilising a different assays will not be affected.

The new assay will give results about **26% lower** on average than the current assay. The new assay has a lower crossreactivity to cortisol metabolites, and has been restandardised. The results are close to the true cortisol value as measured by mass-spectrometry.

New reference intervals for early morning cortisol and for interpretation of synacthen, ITT and DST tests apply. These were drafted in collaboration with the Endocrinology Department of Auckland Hospital.

Short synacthen test

(30 min. post-synacthen 250ug IV or IM)

cortisol II, nmol/L	Interpretive comment for post-synacthen plasma cortisol
<400	"Post-synacthen cortisol <400 suggests adrenal insufficiency (primary or secondary) or adrenal suppression from exogenous steroids. If the cause is not clear, consider further evaluation and referral to an endocrinologist."
≥400	Males: "Post-synacthen cortisol >400 suggests normal adrenal reserve. A normal result can occur in partial or recent onset ACTH deficiency (e.g. recent pituitary surgery). If clinical concern exists, discuss with an endocrinologist." Females: "Post-synacthen cortisol >400 suggests normal adrenal reserve. A
	normal result can occur in partial or recent onset ACTH deficiency (e.g. recent pituitary surgery). If taking an OCP, a post-synacthen cortisol below 600 nmol/L suggests adrenal insufficiency. If clinical concern exists, discuss with an endocrinologist."

Notes:

- 1. These cutoff values were derived by converting values from a study using the Roche cortisol I assay¹
- 2. The 30-min. time point is recommended. Cortisol levels at 60-min are on average 15% higher than the 30-min values².



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Early morning plasma cortisol

cortisol II	Comment
170-500	New reference interval. Based on Roche data <u>3</u> : 146 healthy subjects, aged 21y+.
	Taken between 6 and 10 am. 5th – 95th centiles.
<170	" An early morning cortisol less than 170 nmol/L is suggestive of adrenal insufficiency."
170-300	" Early morning cortisol between 170 and 300 nmol/L: adrenal insufficiency is unlikely
	but possible. If clinical concern exists, discuss with an endocrinologist."
>300	" A plasma cortisol higher than 300 nmol/L in an unstressed person excludes adrenal
	insufficiency in the vast majority of cases."

Dexamethasone suppression test

cortisol II	Comment
<50	"A post-dexamethasone cortisol <50 nmol/L indicates normal suppression, and excludes Cushing's syndrome"
50-100	" A post-dexamethasone cortisol between 50 and 100 may be normal but is also consistent with early Cushing's syndrome"
>100	" A post -dexamethasone cortisol >100 nmol/L indicates failure of normal suppression: causes include Cushing's syndrome, alcohol, depression, and stress."

Salivary cortisol

New reference interval³ (bedtime samples): <6 nmol/L

References

- 1. El-Farhan N, Pickett A, Ducroq D, Bailey C, Mitchem K, Morgan N, et al. Method-specific serum cortisol responses to the adrenocorticotrophin test: comparison of gas chromatographymass spectrometry and five automated immunoassays. *Clin Endocrinol (Oxf)* 2013;78(5):673-80.
- 2. Chitale A, Musonda P, McGregor AM, Dhatariya KK. Determining the utility of the 60 min cortisol measurement in the short synacthen test. *Clin Endocrinol (Oxf)* 2013;79(1):14-9.
- 3. Roche Cortisol II package insert 2015.



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