



UW Medicine
Department of Laboratory Medicine

New Assays for Aldosterone, Renin and Parathyroid Hormone

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We have completed evaluation of an automated chemiluminescent immunoassay instrument for measuring Direct Renin, Aldosterone, whole molecule (1-84) bioactive Parathyroid Hormone and Insulin-Like Growth Factor (IGF1) assays. The Direct Renin assay measures the number of immunoreactive renin molecules and will replace the current Plasma Renin Activity assay, which measures the enzymatic assay of renin. The bioactive PTH assay measures only the full 1-84 amino acid PTH molecule and will replace the current PTH assay, which shows cross-reactivity with the 7-84 PTH fragments as well as the full 1-84 molecules. The current radioimmunoassay for serum aldosterone will be replaced by a new chemiluminescent immunoassay. Because the chemiluminescent assay is approved only for serum, urine aldosterone testing will be sent out to the ARUP reference lab for analysis by radioimmunoassay.

1. The Direct Renin assay measures the renin protein molecule per se, rather than the activity of renin in converting Angiotensinogen to Angiotensin I. The units and reference ranges are quite different. The conversion factor is about 11.2; i.e., the plasma renin activity in ng/mL-hr times 11.2 is equivalent to the direct renin measured in mcU/mL. The correlation is not perfect ($r = 0.862$) however. Also, the conversion factor increases to greater than 11.2 as the PRA activity increases above 7.5 ng/mL-hr. The reference range for the Direct Renin assay has been verified at 3.3-41 mcU/mL. An advantage of the new assay is that it directly measures the renin molecule and it is more precise than traditional plasma renin activity assays. It is also not affected by variations in the angiotensinogen levels in the patient specimens.
2. The Aldosterone assay will be a less significant change from our current method. The results will be about 0.9 times those with our current method. Accordingly, the reference ranges will be slightly lower: For upright adults, the range will be ≤ 34.0 ng/dL for specimens drawn from 8-10 am; for supine adults, the range will be ≤ 19 ng/dL for 8-10 am. The 4-6 pm upright values will be ≤ 23 ng/dL. **Serum will be the only acceptable sample type.** We will no longer be able to use EDTA plasma samples from the renin assay.
3. Aldosterone/Direct Renin ratios will be calculated dividing the Serum Aldosterone in ng/dL by the Direct Renin result in mcU/mL. Ratios > 3.0 and serum aldosterone concentrations of >15.0 ng/dL are considered suggestive of hyperaldosteronism. Because we cannot accurately measure serum aldosterone less than 3.0 ng/dL and plasma direct renin less than 2.75 mcU/mL, aldosterone/renin ratios will be calculated using 3.0 as the numerator for serum aldosterone < 3.0 mg/dL. For direct renin concentrations < 2.75 mcU/mL, 2.75 will be used as the denominator for calculating ratios.

4. We will replace our current PTH assay, which has some crossreactivity with the 7-84 amino acid fragments that may accumulate to high levels in renal patients, with a bioactive PTH (1-84) whole molecule assay which does not cross react with the degradation product. The new bioactive PTH results are about half the values seen with our current PTH assay. The reference range will consequently be lower, at 8-50 pg/mL.

We will not replace our current intraoperative parathyroid hormone (PTH) assay at UWMC and at Harborview Medical center.

5. We will begin testing for IGF1 on the new instrument. We are currently sending testing out to ARUP laboratories, where the assays are being done using the same instrument with identical reference ranges:

Adults:

16-24 years: 182-780 ng/mL
25-39 years: 114-492 ng/mL
40-54 years: 90-360 ng/mL
55+ years: 71-290 ng/mL

Children:

2 mo. - 5 years	(male/female):	17-248 ng/mL
6-8 years	(male/female):	88-474 ng/mL
9-11 years	(female):	117-771 ng/mL
	(male):	110-565 ng/mL
12-15 years	(female):	261-1096 ng/mL
	(male):	202-957 ng/mL

If you would like to respond by phone to this memo, please contact Diane Yamaguchi or Debbie Lee (206-598-6226), or Hossein Sadrzadeh at (206- 341-4530).