From:	labclientservice
To:	GME PC; Ortolf, Barbara; Sullivan, Kathleen; Salvatore, Alicia; Regional Physician Group Physicians; Regional Physician Group Practice Managers; Regional Physicians Group Directors of Operations; CPUP DOO's; CPUP Business Administrators; CPUP Managers; Allen, Kathleen; Grier, Kathy; Theurkauf, Linda; Viola, Kathy; Redmond, Cassandra I; Khemraj, Darci; Major, Katherine
Cc:	Fogt, Franz; Atweh, Mahmoud (Michael); Brooks, John; Hunt, William; Gualtieri, Roseann; Murphy, Alice M; Herman, Daniel; Lussier, Beth; Mayer, Nancy; Tojino, Amy; Milano, Joe; Nachamkin, Irving; Mincarelli, Deborah; Bulley, Margaret; Danoski, Daniel; McLaughlin, Cara; Leonard, Sarah; Vespasiani, Lynn; Long, Jeff; Acker, David; Agront, Sarita; Bahar, Wael Y; Mcaleer, Diane S; Macchione, Gerald; Kim, Sharon; Metheny, Robert
Subject:	PENN MEDICINE - Changes to HUP progesterone and growth hormone testing
Date:	Tuesday, October 8, 2019 11:00:35 AM
Attachments:	image002.png PROG_GH.memo.v1.0.docx

Penn Medicine
University of Pennsylvania Health System

Subject: Changes to HUP progesterone and growth hormone testing

Dear colleagues,

The HUP Endocrinology laboratory will be changing the performance of our progesterone and growth hormone testing on 10/8/2019. The performance of these immunoassays will be moved from a Siemen's Immulite to Roche Cobas. The progesterone results are now higher and the reference ranges have been adjusted slightly. See details below.

Please continue to request each of these tests using the same order code. Note, that because of differences in the new Progesterone method's results, it will be referred to in PennChart as Progesterone (ECLIA).

Please contact the HUP Clinical Chemistry resident on-call or me directly with any questions or concerns.

Sincerely,

Daniel Herman MD, PhD
Director, Endocrinology Laboratory
Hospital of the University of Pennsylvania
daniel.herman2@pennmedicine.upenn.edu

DETAILS

Progesterone

The new progesterone assay is the Roche Progesterone III immunoassay performed on a Roche Cobas 601 instrument. It is able to accurately quantify lower analyte concentrations (as low as 0.2 ng/mL) compared to the previous method (lower limit of 0.8 ng/mL). This assay's results appear to be on average 50% higher than that of the previous method. The reference ranges have generally increased slightly, per manufacturer's studies. We have also adjusted naming in PennChart Result

Review to “Progesterone (ECLIA)” so that this test’s results are clearly separated from those of other assays. The “ECLIA” stands for electrochemiluminescence, which refers to the assay methodology. Note, biotin supplements can lead to falsely elevated results.

Progesterone reference ranges (ng/mL)

Male		< 0.2
Female	*Follicular Phase*	< 0.2 – 0.9
	Ovulatory Peak	< 0.2 – 12
	Luteal Phase	1.8 – 24
	Post-menopausal	< 0.2
Female, pregnancy	*1st trimester*	11 – 44
	2nd trimester	25 – 83
	3rd trimester	59 - 214

Growth Hormone

The new growth hormone assay is the Roche human Growth hormone (hGH) immunoassay performed on a Roche Cobas 601 instrument. In a study of 54 samples, the majority of patient results showed very similar results using the new compared to old assay (NEW_GH = 1.08 x OLD_GH + 0.03 ng/mL). GH concentrations near 1 ng/mL run ~10% higher for the new assay. The new assay reports concentrations as low as 0.05 ng/mL.

Growth hormone reference ranges (ng/mL)

[90th percentile central range]

Male	< 0.05 – 2.47
Female	0.13 – 9.9

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Interpretive comment for Progesterone: (6 months)

** NOTE: Progesterone testing is performed using Roche Progesterone III assay. The progesterone testing method and reference ranges changed effective XXXXX. Current results are approximately 50% higher than that of the previous method.

Interpretive comment for Growth Hormone: (6 months)

** NOTE: Growth hormone testing is performed using the Roche human Growth hormone assay. The low results for this assay (approximately 1 ng/mL) are approximately 10% higher than those of the previous method. The growth hormone testing method and reference ranges changed effective XXXXX.