

**Subject: Changes to HUP testing for tumor markers AFP and hCG**


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Dear colleagues,

The HUP Endocrinology laboratory will be changing the performance of our alpha-fetoprotein (AFP) and human chorionic gonadotropin (hCG) tumor marker testing on Wednesday, December 23, 2020. The performance of these immunoassays will be moved from a Siemen's Immulite to Beckman Dxl for AFP and Roche Cobas for hCG. The AFP results are expected to be approximately 15% higher. The hCG results for some patients appear lower by as much as 50%. Reference ranges and units have been adjusted. See details below.

For patient's being monitored with these tests, we recommend reassessment of each patient's baseline concentration for the new assays. To facilitate re-baselining, we will be performing and reporting both assays for all orders over the next 3 months (until March 19, 2021).

To improve clarity, the test orders in PennChart have been renamed:

	<b>OLD</b>	<b>NEW</b>
AFP	'ALPHA FETOPROTEIN TUMOR MARKER (AFNP)' (C3501865)	'AFP, TUMOR MARKER' (CAFPOTM)
hCG	'BETA-HCG/QUANT/TUMOR MARKER' (C3501105)	'HCG, TUMOR MARKER' (CHCGOECL)
AFP & hCG	'AFP/HCG TUMOR MARKER' (C3500008)	'AFP/HCG TUMOR MARKER OP' (O340721)

Because of the change in methods, the new assays' results will be reported with new names:

	<b>OLD</b>	<b>NEW</b>
AFP	ALPHA-1-FETOPROTEINS	AFP, Tumor Marker
hCG	BETA-HCG, QUANTITATIVE	hCG, Tumor Marker, ECLIA

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

Sincerely,

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## DETAILS

### Alpha-fetoprotein (AFP)

The new AFP assay is the Beckman Access AFP immunoassay performed on a Beckman Dxl 600 instrument in the HUP Endocrinology Laboratory. The old assay was reported in IU/mL and the new assay will be reported in ng/mL. In comparison to the previous method, we observed 15% higher concentrations for results < 300 ng/mL (slope = 1.14; intercept = 1.2 ng/mL;  $R^2=0.99$ ) and 8% higher concentrations for results > 300 ng/mL (slope = 1.08). The upper reference limit for the new assay is higher at 9 ng/mL, which represents the 99th percentile of an apparently healthy reference population per manufacturer's studies.

We have also adjusted naming in PennChart so that this test's results are clearly separated from those of other assays. The new AFP test can be ordered using 'AFP, TUMOR MARKER' (CAFPOTM) and results will be reported as "AFP, Tumor Marker" (as opposed to the previous "ALPHA-1-FETOPROTEINS" results).

### Human chorionic gonadotropin (hCG)

The new hCG assay is the Roche Elecsys HCG+beta (hCG) immunoassay is performed on a Roche Cobas 601 instrument in the HUP Endocrinology lab. This assay appears to report similar results for many patients, but some patients with hCG less than 100 mIU/mL show up to 50% lower concentrations. This assay detects several forms of hCG, including the full protein (alpha and beta chains), 'nicked' forms', free beta chain, and the beta-core fragment.

We have also adjusted naming in PennChart so that this test's results are clearly separated from those of other assays. The new hCG test can be ordered using 'hCG, Tumor Marker' and results will be reported as "hCG, Tumor Marker, ECLIA" (as opposed to the previous "BETA-HCG, QUANTITATIVE" results). The "ECLIA" stands for electrochemiluminescence, which refers to the assay method. Note, biotin supplements can lead to falsely low results.

hCG reference ranges (mIU/mL)

<b>Male</b>		<b><math>\leq 1</math></b>
<b>Female</b>	<b>Non-pregnant, Premenopausal</b>	<b><math>\leq 1</math></b>
	<b>Postmenopausal</b>	<b><math>\leq 7</math></b>