

## Human Placental Lactogen (hPL) in Serum

<b>Specimen Type</b>	Serum	
<b>Specimen Volume</b>	1.0 mL	
<b>Collection</b>	Red top tube. Allow blood to clot for 30 minutes. Centrifuge at 3000 rpm for 10 minutes. Separate serum and place in a transfer tube. Freeze immediately at -20°C.	
<b>Minimum Volume</b>	0.5 mL	
<b>Handling</b>	Ship frozen on dry ice.	
<b>Rejection Criteria</b>	<p>Specimens that are hemolyzed, icteric, or lipemic.</p> <p>Specimens received at ambient temperature.</p> <p>Specimens received at refrigerated temperature.</p> <p>Specimens outside of listed stability.</p> <p>Samples submitted without two unique identifiers and date of collection.</p>	
<b>Stability</b>	<p>Frozen for 90 days.</p> <p>Ambient temperature for 4 hours.</p> <p>Refrigerated for 24 hours.</p>	
<b>Methodology</b>	ELISA	
<b>Reference Range</b>	Men and Non-Pregnant Women:	0 - 0.1 mcg/mL
	1 <sup>st</sup> Trimester of Pregnancy:	0.2 - 2.1 mcg/mL
	2 <sup>nd</sup> Trimester of Pregnancy:	0.5 – 6.7 mcg/mL
	3 <sup>rd</sup> Trimester of Pregnancy:	4.5 – 12.8 mcg/mL
	NOTE: Sex and, if pregnant, the gestation period must be included with the requisition.	
<b>Turnaround Time</b>	Up to 7 business days.	
<b>CPT Code</b>	83632	

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<p><b>Clinical Significance</b></p>	<p>Human placental lactogen (hPL; chorionic somatomammotropin) is a 21,000 KD polypeptide produced during pregnancy by placental trophoblastic cells. The level of hPL in maternal serum is directly related to placental function and fetal well-being.</p> <p>hPL is detected at about 6 weeks after conception and its concentration increases gradually to peak levels (without decreases) until about the 34<sup>th</sup> week where it remains stable for the remainder of the pregnancy. Consistently low levels throughout pregnancy or a sudden drop in serial determinations are an indication of fetal distress. After normal delivery, the hPL concentration falls rapidly to an undetectable level.</p> <p>The hPL levels in serum of women with multiple placenta pregnancies generally exceeds that of single placenta pregnancies. This is generally noted from the 2<sup>nd</sup> trimester to delivery.</p>
<p><b>Principle</b></p>	<p>This procedure uses direct ELISA technology. An antibody specifically recognizing human placental lactogen (hPL) and not cross-reactive with other hormones is used to coat a micro titer plate. The hPL standards, controls, and patient sera are applied to the plate along with a second specific antibody that is labeled with HRP (horse radish peroxidase). This results in the hPL from the sample becoming sandwiched between the unlabeled antibody on the support and the labeled antibody in solution.</p> <p>The amount of labeled secondary antibody that becomes bound to the plate is then quantified by addition of the HRP substrate, TMB (3,3',5,5'-tetramethylbenzidine). TMB is oxidized by HRP and a color change from clear to blue occurs. The intensity of the color is directly proportional to the amount of HRP bound to the support. An acidic solution is added to stop the reaction. The resulting yellow color is then read on a standard ELISA plate reader and standard curve is generated to calculate patient results.</p>

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### DOCUMENT REVISION HISTORY

Version #	Revisions Made	Rationale
4.0	Addition of a Document Revision History section	Facilitate document control and tracking of document revisions.
4.0	Updated header document number from CB-001562 to CDX.Form.00003.	EDocs nomenclature has been updated and replaced with CARA nomenclature.
4.0	Updated company Logo in the header to reflect name change.	Cambridge Biomedical Diagnostics has been changed to BioAgilytix Diagnostics.
4.0	Added version number to the header.	Version number added for traceability.
4.0	Updated web address to BioAgilytix Diagnostics in footer of document.	Cambridge Biomedical Diagnostics have been changed to BioAgilytix Diagnostics. The update to the web address has been made for traceability.
5.0	Updated version number.	Required.
5.0	Updated rejection criteria.	Required.
6.0	Updated version number.	Required.
6.0	Updated rejection criteria.	Required.
6.0	Updated fax number and web address.	Required.