

Legacy Laboratory Services

Legacy Lab Alert

March 2019

An Important Update from Legacy Laboratory Services

Methods for SHBG, Total Testosterone, and Free Testosterone Results Changing up to 37%

Effective March 19, 2019, Legacy Laboratory Services will be introducing new methods for Sex Hormone Binding Globulin (SHBG), Total Testosterone, and Free Testosterone. The new SHBG and Total Testosterone assays were standardized to international standards by the manufacturer, which also significantly changes the reference ranges. For a complete list of specimen requirements, please refer to Table 3. By switching to the new SHBG and Testosterone methods, the following changes will occur:

- **SHBG results will decrease, on average, by 37%** from the previous Legacy Laboratory Services' method. **Total Testosterone results will demonstrate an average increase of 12%**. Since Free Testosterone is based on a calculation using measurements from SHBG and Total Testosterone, **Free Testosterone results will decrease, on average, by 34%**. Refer to Table 1.
- **Reference ranges will be updated for SHBG and Free Testosterone based on in-house studies. Total Testosterone reference ranges will remain the same.** Refer to Table 2. We were not able to validate Tanner Stages at this time, but additional studies are being performed to bring these ranges back in the future.
- **Lithium heparin plasma will no longer be accepted for Total Testosterone.**
- **Specimen stability will increase to longer storage times.** For more information, refer to Tables 1 and 3.
- **The reportable range for Total and Free Testosterone will be updated.** Refer to Table 1 for more information.

Table 1: Summary of Changes to SHBG and Testosterone Testing – Changes are in **red** font.

Parameter	SHBG		Total Testosterone		Free Testosterone	
	Previous	NEW	Previous	NEW	Previous	NEW
Results	-----	Average = 37% decrease	-----	Average = 12% increase	-----	Average = 34% increase
Reference Ranges	Refer to Table 2		No Change		Refer to Table 2	
Reportable Range	No Change		10-7,500 ng/dL	7-3,000 ng/dL	1-3183 pg/mL (0.5-4.2%)	1-1264 pg/mL (0.3-4.2%)
Specimen Type	Serum	Serum	Serum & Lithium Heparin Plasma	Serum Only	Serum	Serum
Stability	Refrigerated: 5 days	Refrigerated: 6 days	Room Temp: 8 hours	Room Temp: 48 hours	Refrigerated: 5 days	Refrigerated: 6 days
			Refrigerated: 5 days	Refrigerated: 7 days		

Table 2: Comparing Reference Ranges – Changes are in red font.

Age	Legacy Laboratory Services – Previous	Legacy Laboratory Services – NEW
SHBG (Females)		
0–30 days	18 – 66 nmol/L	11 – 180 nmol/L
31–364 days	66 – 226 nmol/L	11 – 180 nmol/L
1–3 Years	66 – 200 nmol/L	11 – 180 nmol/L
4–6 years	61 – 180 nmol/L	11 – 180 nmol/L
7–9 years	40 – 180 nmol/L	11 – 180 nmol/L
10–12 years	22 – 164 nmol/L	11 – 180 nmol/L
13–15 years	15 – 128 nmol/L	11 – 180 nmol/L
16–17 years	24 – 154 nmol/L	11 – 180 nmol/L
18-60 years	35 – 143 nmol/L	11 – 180 nmol/L
≥61 years	35 – 143 nmol/L	24 – 159 nmol/L
SHBG (Males)		
0–30 days	17 – 92 nmol/L	15 – 94 nmol/L
31–364 days	76 – 262 nmol/L	15 – 94 nmol/L
1–3 Years	56 – 190 nmol/L	15 – 94 nmol/L
4–6 years	50 – 185 nmol/L	15 – 94 nmol/L
7–9 years	33 – 200 nmol/L	15 – 94 nmol/L
10–12 years	28 – 169 nmol/L	15 – 94 nmol/L
13–15 years	17 – 149 nmol/L	15 – 94 nmol/L
16–17 years	14 – 66 nmol/L	15 – 94 nmol/L
18-49 years	15 – 87 nmol/L	15 – 94 nmol/L
≥50 years	15 – 87 nmol/L	15 – 113 nmol/L
Total Testosterone (Males)		
0-15 years	not available	not available
16 years	220 - 800 ng/dL	220 - 800 ng/dL
≥17 years	241 - 827 ng/dL	241 - 827 ng/dL
Free Testosterone (Males)		
0-15 years	not available	not available
16-17 years	38 - 173 pg/mL % not available	56 - 286 pg/mL 1.6 - 3.3%
18-49 years	47 - 244 pg/mL 1.6 - 2.9%	47 - 293 pg/mL 1.6 - 3.3%
≥50 years	47 - 244 pg/mL 1.6 - 2.9%	47 - 259 pg/mL 1.1 - 3.1%

Table 3: Legacy Laboratory Services' Specimen Requirements for NEW Testing – Significant differences from previous Legacy Laboratory Services testing are in red font.

Name	SHBG	Testosterone, Total, Adult Males	Testosterone, Free, Adult Males	Testosterone, Free & Total (with SHBG), Adult Males
Mnemonic	SHBG	TEST	TESTOS FM	TESTOS FTM
Includes	SHBG	Total Testosterone	Free Testosterone	Total Testosterone Free Testosterone %Free Testosterone SHBG
Guidelines	na	Perform on males ≥ 16 years only. For females and male children <16 years old, order <i>Testosterone, Total, Females or Children.</i>	Perform on males ≥ 16 years only. For females and male children <16 years old, order <i>Testosterone, Free, Females or Children.</i>	Perform on males ≥ 16 years only. For females and male children <16 years old, order <i>Testosterone, Free & Total, Females or Children.</i>
Patient Preparation	None	Morning specimen collected between 6-10 AM is preferred.	Morning specimen collected between 6-10 AM is preferred.	Morning specimen collected between 6-10 AM is preferred.
Collect	Serum, one 5.0 mL gold (SST) or red top tube	Serum, one 5.0 mL gold (SST) or red top tube	Serum, one 5.0 mL gold (SST) or red top tube	Serum, one 5.0 mL gold (SST) or red top tube
Handling	Allow serum to clot completely at room temperature (minimum – SST: 30 minutes; red top tube: 60 minutes). Centrifuge and separate serum from cells ASAP.	Allow serum to clot completely at room temperature (minimum – SST: 30 minutes; red top tube: 60 minutes). Centrifuge and separate serum from cells ASAP.	Allow serum to clot completely at room temperature (minimum – SST: 30 minutes; red top tube: 60 minutes). Centrifuge and separate serum from cells ASAP.	Allow serum to clot completely at room temperature (minimum – SST: 30 minutes; red top tube: 60 minutes). Centrifuge and separate serum from cells ASAP.
Preferred Volume	1.0 mL Serum	1.0 mL Serum	2.0 mL Serum	2.0 mL Serum
Minimum Volume	0.3 mL Serum (0.8 mL <i>minimum whole blood draw</i>)	0.3 mL Serum (0.8 mL <i>minimum whole blood draw</i>)	0.75 mL Serum (1.2 mL <i>minimum whole blood draw</i>)	0.75 mL Serum (1.2 mL <i>minimum whole blood draw</i>)
Transport	Refrigerated (2-8 °C)	Refrigerated (2-8 °C)	Refrigerated (2-8 °C)	Refrigerated (2-8 °C)
Rejection Criteria	<ul style="list-style-type: none"> Gross hemolysis Plasma Specimens that have been frozen and thawed more than 5 times. 	<ul style="list-style-type: none"> Gross hemolysis Plasma Specimens that have been frozen and thawed more than 5 times. 	<ul style="list-style-type: none"> Gross hemolysis Plasma Specimens that have been frozen and thawed more than 5 times. 	<ul style="list-style-type: none"> Gross hemolysis Plasma Specimens that have been frozen and thawed more than 5 times.
Stability	Room Temp. (18-26°C)	4 hours	48 hours	4 hours
	Refrigerated (2-8°C)	6 days	7 days	6 days
	Frozen (< -20°C)	1 month	2 months	1 month
Performed	Mon - Sat	7 days/week	Mon - Sat	Mon - Sat
Reported	24-72 hours	24 hours	24-72 hours	24-72 hours
Method	<ul style="list-style-type: none"> Chemiluminescent Immunoassay 	<ul style="list-style-type: none"> Chemiluminescent Immunoassay 	<ul style="list-style-type: none"> Chemiluminescent Immunoassay Total Testosterone and SHBG are measured in serum. The concentration of Free Testosterone is derived from a mathematical expression based on constants for the binding of testosterone to albumin and SHBG. 	
CPT Codes	<ul style="list-style-type: none"> SHBG: 84270 	<ul style="list-style-type: none"> Total Testosterone: 84403 	<ul style="list-style-type: none"> Free Testosterone: 84402 	<ul style="list-style-type: none"> Total Testosterone: 84403 SHBG: 84270

For additional information, please contact your account representative, client services or consult our website: Legacy Laboratory Client Services: 503-413-1234, 877-270-5566, www.legacyhealth.org/labservices