

# Legacy Laboratory Services

## Legacy Lab Alert

June 2021

An Important Update from Legacy Laboratory Services

### **UPDATE: Total and Free Testosterone by LCMSMS Brought In-House**

**Effective June 30, 2021, Legacy Laboratory Services (LLS) will be bringing Testosterone by Liquid Chromatography-Tandem Mass Spectrometry (LCMSMS) in-house.** Since LCMSMS technology is more sensitive than chemiluminescent immunoassay (CIA), we recommend ordering Testosterone by LCMSMS for females, children, and anyone who is suspected of hypoandrogenism. If Free Testosterone is ordered, we will also measure Sex-Hormone Binding Globulin (SHBG). The concentration of Free Testosterone is derived from a mathematical expression based on the constants for the binding of Testosterone to albumin and sex hormone binding globulin (SHBG). This calculation assumes that the albumin concentration is a constant (4.3 g/dL).

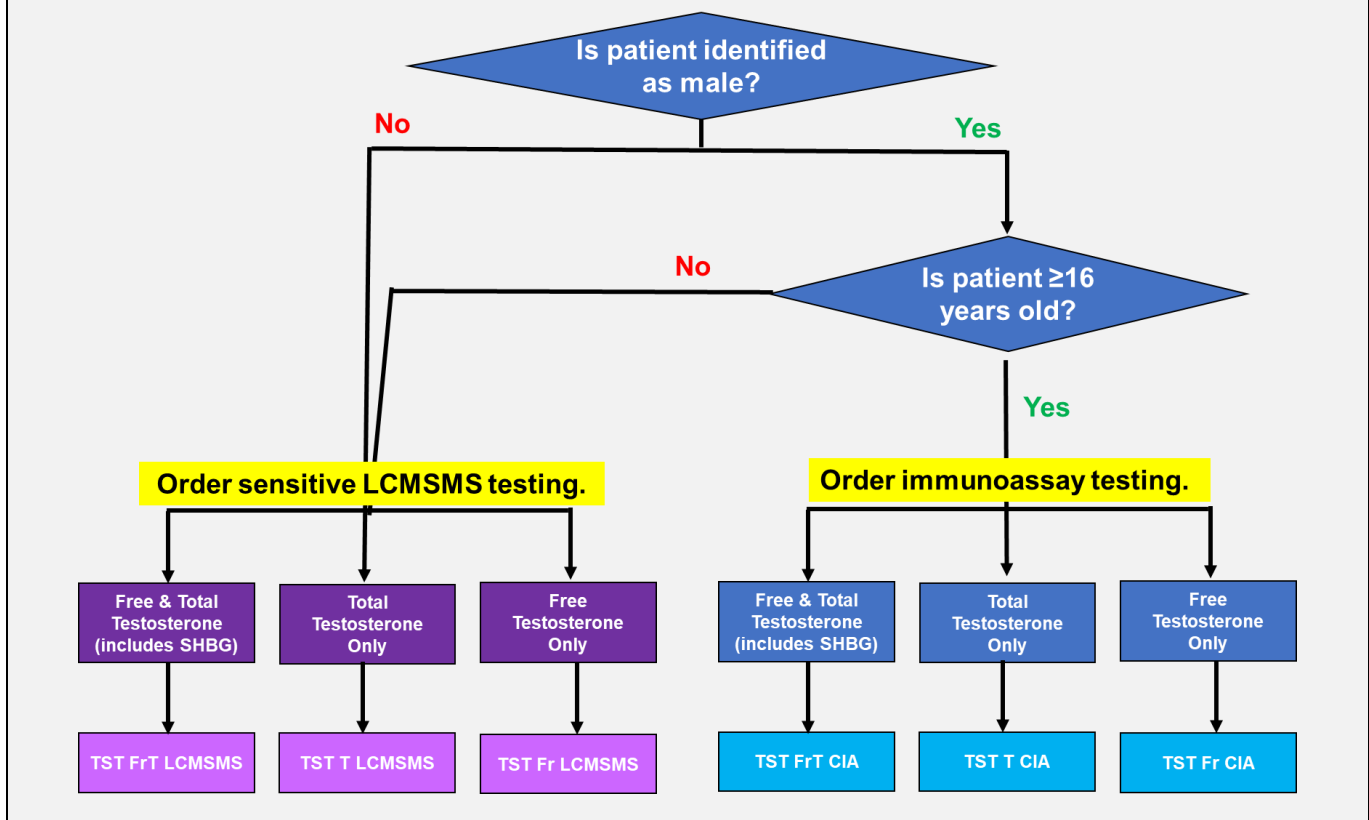
The current Testosterone orderables for patients who identify as adult males will still be available. However, we are taking this opportunity to standardize our naming convention for Testosterone performed by CIA. No other changes to CIA testing will occur. The new ordering mnemonics for LCMSMS testing, as well the changes to mnemonics for our existing testing are listed in Table 1. For additional guidance on which test to order, refer to the Testosterone testing algorithm in Figure 1.

A summary of the updates and changes are listed below.

- New orderable test names are available for both the LCMSMS and CIA tests. Refer to Table 1 for how to convert current mnemonics to the new ones. For further guidance on which test to order, refer to Figure 1.
- Since our new Total Testosterone by LCMSMS method compares very well with our referral lab, ARUP (Mean Bias = 0.16%), the reference intervals for Total Testosterone by LCMSMS will remain the same (Table 2).
- Since our Free Testosterone results calculated from SHBG and Total Testosterone by LCMSMS has a bias of 11-14% when compared to ARUP, the reference intervals for Free Testosterone will change. The new reference intervals are listed in Table 3.
- Reference intervals for SHBG included in the orderables for LCMSMS will change from ARUP's to Legacy's current reference intervals (Table 4).
- Plasma samples will no longer be accepted for LCMSMS testing.
- Specimen volumes for LCMSMS testing will increase slightly depending on the orderable. For additional specimen requirements, refer to Table 5 for more information.

TABLE 1: CONVERSION CHART FOR NEW AND CURRENT TESTOSTERONE ORDERABLES				
CURRENT ORDERABLES (PRIOR TO 6/30/21)			NEW ORDERABLES (STARTS 6/30/21)	
TEST NAME	MNEMONIC		TEST NAME	MNEMONIC
<b>LCMSMS – Order for patients NOT identified as males ≥16 years old.</b>				
<b>Additional changes are described in this Lab Alert</b>				
Testosterone, Total, Females or Children	TESTOS MAS	<b>Convert To</b>	Testosterone, Total, LCMSMS	TST T LCMSMS
Testosterone, Free, Females or Children	TESTOS FFC		Testosterone, Free LCMSMS	TST Fr LCMSMS
Testosterone, Free & Total (with SHBG), Females or Children	TESTOS FTF		Testosterone, Free & Total LCMSMS (includes SHBG)	TST FrT LCMSMS
<b>Chemiluminescent Immunoassay – Order for patients identified as males ≥16 years old.</b>				
<b>No other changes are occurring.</b>				
Testosterone, Adult Males	TEST	<b>Convert To</b>	Testosterone, Total, CIA	TST T CIA
Testosterone, Free, Adult Males	TESTOS FM		Testosterone, Free CIA	TST Fr CIA
Testosterone, Free & Total (with SHBG), Adult Males	TESTOS FTM		Testosterone, Free & Total CIA (includes SHBG)	TST FrT CIA

**FIGURE 1: TESTOSTERONE TESTING ALGORITHM** – Order LCMSMS testing for children less than 16 years old OR patients not identified as male. Order the current chemiluminescent immunoassay testing for patients who are identified as male AND greater than or equal to 16 years old.



**TABLE 2: REFERENCE INTERVALS FOR TOTAL TESTOSTERONE BY LCMSMS**

AGE	MALES (ng/dL)		FEMALES (ng/dL)	
	ARUP (BEFORE 6/30/21)	LEGACY (STARTS 6/30/21)	ARUP (BEFORE 6/30/21)	LEGACY (STARTS 6/30/21)
<1 month	75-400	75.0-400.0	20-64	20.0-64.0
1-5 months	14-363	14.0-363.0	<20	0.0-19.9
6-23 months	<37	0.0-36.9	<9	0.0-8.9
2-3 years	<15	0.0-14.9	<20	0.0-19.9
4-5 years	<19	0.0-18.9	<30	0.0-29.9
6-7 years	<13	0.0-12.9	<7	0.0-6.9
8-9 years	2-8	2.0-8.0	1-11	1.0-11.0
10-11 years	2-165	2.0-165.0	3-32	3.0-32.0
12-13 years	3-619	3.0-619.0	6-50	6.0-50.0
14-15 years	31-733	31.0-733.0	6-52	6.0-52.0
16-17 years	<b>Performed by Chemiluminescent Immunoassay (no changes)</b>		9-58	9.0-58.0
18-39 years			9-55	9.0-55.0
40-59 years			9-55	9.0-55.0
≥60 years			5-32	5.0-32.0
Tanner Stage I	2-15	2.0-15.0	2-17	2.0-17.0
Tanner Stage 2	3-303	3.0-303.0	5-40	5.0-40.0
Tanner Stage 3	10-851	10.0-851.0	10-63	10.0-63.0
Tanner Stage 4	162-847	162.0-847.0	11-62	11.0-62.0
Tanner Stage 5	162-847	162.0-847.0	11-62	11.0-62.0

**TABLE 3: REFERENCE INTERVALS FOR FREE TESTOSTERONE BY LCMSMS**

AGE	MALES (pg/mL)		FEMALES (pg/mL)	
	ARUP (BEFORE 6/30/21)	LEGACY (STARTS 6/30/21)	ARUP (BEFORE 6/30/21)	LEGACY (STARTS 6/30/21)
1-6 years	0.0-0.5	<b>0.0-0.9</b>	0.0-0.5	<b>0.0-0.9</b>
7-9 years	0.1-0.9	<b>0.0-0.9</b>	0.6-1.8	<b>0.0-2.0</b>
10-11 years	0.1-6.3	<b>0.0-7.1</b>	0.1-3.5	<b>0.0-3.9</b>
12-13 years	0.5-98.0	<b>0.0-110.8</b>	0.9-6.8	<b>0.0-7.6</b>
14-15 years	3.0-138.0	<b>3.3-156.0</b>	1.2-7.5	<b>1.3-8.4</b>
16-17 years	<b>Performed by Chemiluminescent Immunoassay (no changes)</b>		1.2-9.9	<b>1.3-11.1</b>
18-30 years			0.8-7.4	<b>1.0-8.3</b>
31-40 years			1.3-9.2	<b>1.4-10.3</b>
41-51 years			1.1-5.8	<b>1.2-6.5</b>
≥52 years			0.6-3.8	<b>0.0-4.2</b>
Tanner Stage I	0.0-3.7	<b>0.0-4.1</b>	0.0-2.1	<b>0.0-2.3</b>
Tanner Stage 2	0.3-21.0	<b>0.0-23.7</b>	0.4-4.5	<b>0.0-5.0</b>
Tanner Stage 3	1.0-98.0	<b>1.1-110.8</b>	1.3-7.5	<b>1.4-8.4</b>
Tanner Stage 4	35.0-169.0	<b>39.5-191.1</b>	1.1-15.5	<b>1.2-17.5</b>
Tanner Stage 5	41.0-239.0	na*	0.8-9.2	<b>1.0-10.3</b>

\*Tanner stages for Stage 5 are not yet available on the CIA method and we do not perform testing for these individuals on LCMSMS.

**TABLE 4: REFERENCE INTERVALS FOR SHBG IN LCMSMS ORDERABLES\***

AGE	MALES (nmol/L)		FEMALES (nmol/L)	
	ARUP (BEFORE 6/30/21)	LEGACY (STARTS 6/30/21)	ARUP (BEFORE 6/30/21)	LEGACY (STARTS 6/30/21)
<1 month	13-85	15.0-94.0	14-60	11.0-180.0
1-11 months	70-250	15.0-94.0	60-215	11.0-180.0
1-3 years	50-180	15.0-94.0	60-190	11.0-180.0
4-6 years	45-175	15.0-94.0	55-170	11.0-180.0
7-9 years	28-190	15.0-94.0	35-170	11.0-180.0
10-12 years	23-160	15.0-94.0	17-155	11.0-180.0
13-15 years	13-140	15.0-94.0	11-120	11.0-180.0
16-17 years	10-60	15.0-94.0	19-145	11.0-180.0
18-49 years	11-80	15.0-94.0	30-135	11.0-180.0
50-60 years	11-80	15.0-113.0	30-135	11.0-180.0
≥61 years	11-80	15.0-113.0	30-135	24.0-159.0

\*NOTE: Legacy does not offer Tanner SHBG.

**TABLE 5: LEGACY LABORATORY SERVICES' SPECIMEN REQUIREMENTS FOR LCMSMS TESTING – Significant differences from previous testing are in red font.**

NAME	TOTAL TESTOSTERONE BY LCMSMS	FREE TESTOSTERONE BY LCMSMS	FREE & TOTAL TESTOSTERONE BY LCMSMS (INCLUDES SHBG)
<b>Mnemonic</b>	TST T LCMSMS	TST Fr LCMSMS	TST FrT LCMSMS
<b>Includes</b>	Total Testosterone	Free Testosterone	Total Testosterone Free Testosterone SHBG
<b>Guidelines</b>	Recommended for children <16 years old OR patients not identified as male  For patients identified as male <u>AND</u> are ≥16 years old, order <i>Total Testosterone by CIA (TST T CIA)</i> .	Recommended for children <16 years old OR patients not identified as male  For patients identified as male <u>AND</u> are ≥16 years old, order <i>Free Testosterone by CIA (TST Fr CIA)</i> .	Recommended for children <16 years old OR patients not identified as male  For patients identified as male <u>AND</u> are ≥16 years old, order <i>Free &amp; Total Testosterone by CIA (TST FrT CIA)</i> .
<b>Patient Preparation</b>	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.
<b>Collect</b>	<b>Serum, one 5.0 mL gold (SST) or 7 mL red top tube</b>	<b>Serum, one 5.0 mL gold (SST) or 7 mL red top tube</b>	<b>Serum, one 5.0 mL gold (SST) or 7 mL red top tube</b>
<b>Handling</b>	Allow serum to clot completely at room temperature (minimum – SST: 30 minutes; red top tube: 60 minutes). Centrifuge and separate serum from cells within 8 hours of collection.	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.
<b>Preferred Volume</b>	1.0 mL Serum	<b>2.0 mL Serum</b>	<b>2.0 mL Serum</b>
<b>Minimum Volume</b>	<b>0.5 mL Serum</b> (1.5 mL minimum whole blood draw)	<b>1.0 mL Serum</b> (2.5 mL minimum whole blood draw)	<b>1.0 mL Serum</b> (2.5 mL minimum whole blood draw)
<b>Transport</b>	Refrigerated (2-8 °C)	Refrigerated (2-8 °C)	Refrigerated (2-8 °C)
<b>Rejection Criteria</b>	<ul style="list-style-type: none"> <li>Plasma</li> <li>Specimens that have been frozen and thawed more than 1 time.</li> </ul>	<ul style="list-style-type: none"> <li>Plasma</li> <li>Specimens that have been frozen and thawed more than 1 time.</li> </ul>	<ul style="list-style-type: none"> <li>Plasma</li> <li>Specimens that have been frozen and thawed more than 1 time.</li> </ul>

**TABLE 5: LEGACY LABORATORY SERVICES' SPECIMEN REQUIREMENTS FOR LCMSMS TESTING – Significant differences from previous testing are in red font.**

NAME		TOTAL TESTOSTERONE BY LCMSMS	FREE TESTOSTERONE BY LCMSMS	FREE & TOTAL TESTOSTERONE BY LCMSMS (INCLUDES SHBG)
Stability	Room Temp. (18-26°C)	48 hours	4 hours	4 hours
	Refrigerated (2-8°C)	9 days	6 days	6 days
	Frozen (< -20°C)	28 days	28 days	28 days
Performed		Mon and Thurs	Mon and Thurs	Mon and Thurs
Reported		2-8 days	2-8 days	2-8 days
Method		LCMSMS	<ul style="list-style-type: none"> <li>Total Testosterone and SHBG are measured to calculate Free Testosterone, but not reported.</li> <li>The concentration of Free Testosterone is derived from a mathematical expression based on the constants for the binding of testosterone to albumin and SHBG. This calculation assumes that the albumin concentration is a constant (4.3 g/dL).</li> </ul>	<ul style="list-style-type: none"> <li>Total Testosterone: LCMSMS</li> <li>SHBG: Chemiluminescent Immunoassay</li> <li>The concentration of Free Testosterone is derived from a mathematical expression based on the constants for the binding of testosterone to albumin and SHBG. This calculation assumes that the albumin concentration is a constant (4.3 g/dL).</li> </ul>
CPT Codes		<ul style="list-style-type: none"> <li>Total Testosterone: 84403</li> </ul>	<ul style="list-style-type: none"> <li>Free Testosterone: 84402</li> </ul>	<ul style="list-style-type: none"> <li>Total Testosterone: 84403</li> <li>SHBG: 84270</li> </ul>

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](http://www.legacyhealth.org/labservices)