

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D2036085	<b>(X3) Date Survey Completed</b>  02/07/2020
<b>Name of Provider or Supplier</b>  Crescent Derm Surgery	<b>Street Address, City, State</b>  4421 Chastant St, Metairie, LA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Certification survey was performed at Crescent Derm Surgery, CLIA ID 19D2036085 on February 7, 2020. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to establish complete personnel competency policies. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not include how testing personnel competency are assessed. 2. Further review of the laboratory's policy and procedure manual revealed the laboratory did not include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting of test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 3. In interview on February 7, 2020, the Laboratory Director confirmed the laboratory did not include in their policies how competency for his duties as testing personnel are assessed.</p>

<p><b>D5401</b></p>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include the following: a) Corrective action to take if room temperature and/or humidity are not within acceptable range 2. In interview on February 7, 2020 at 11:15 am, the Laboratory Director confirmed the laboratory did not include the identified information in their policies.</p>
<p><b>D5413</b></p>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to document the room temperature and humidity of the laboratory. Findings: 1. Review of the laboratory's temperature logs for 2018, 2019, and January 2020 revealed the laboratory has the following temperature/humidity requirements: a) Room temperature: "Temperature Less Than 87 degrees Check for Yes" b) Humidity: "Relative Humidity Less Than 60 Percent Check for Yes" 2. Further review of the laboratory's temperature logs revealed the laboratory documented check marks, not the temperature and humidity readings. 3. In interview on February 7, 2020 at 11:15 am, the Laboratory Director confirmed the laboratory did not record/document the temperature and humidity readings.</p>
<p><b>D6087</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(3)(iii)</p> <p>The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Refer to D5413.</p>

<p><b>D6103</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.</p> <p>This STANDARD is not met as evidenced by:  Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency. Refer to D5209.</p>
<p><b>D6106</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p> <p>This STANDARD is not met as evidenced by:  Based on record review and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D5401.</p>
<p><b>D6107</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1445(e)(15)</p> <p>The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.</p> <p>This STANDARD is not met as evidenced by:  Based on record review and interview with personnel, the Laboratory Director failed to include written duties and responsibilities of personnel involved in all phases of testing. Findings: 1. Review of the laboratory's policies, procedures, and personnel records revealed job descriptions related to the duties of the Laboratory Director (who also serves as the Technical Supervisor, Clinical Consultant, General Supervisor, and Testing Personnel) were not included. 2. In interview on February 7, 2020 at 11:15 am, the Laboratory Director confirmed a written description of duties and responsibilities of the Laboratory Director position was not included in the laboratory's policies.</p>