

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D2016117	<b>(X3) Date Survey Completed</b>  08/17/2020
<b>Name of Provider or Supplier</b>  Crescent City Surgical Centre Diagnostics, Llc	<b>Street Address, City, State</b>  3016 Galleria Drive, 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 PT Desk Review was performed on August 17, 2020. Crescent City Surgical Center, CLIA ID 19D2016117, was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.803 CONDITION: Successful Participation 42 CFR 493.1403 CONDITION: Laboratories Performing Moderate Complexity Testing; Laboratory Director
<b>D2016</b>	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of proficiency testing (PT) results from the CASPER 155D report, the laboratory failed to successfully participate in proficiency testing for Chemistry. Findings: 1. The laboratory failed to attain a score of at least 80% for Albumin and</p>

	<p>Blood Urea Nitrogen (BUN) for two (2) events in 2020. Refer to D2087. 2. The laboratory failed to participate in two (2) events for 2020 resulting in unsatisfactory performance and a score of zero for Albumin. Refer to D2089. 3. The laboratory failed to achieve a score of at least 80% for Albumin in two consecutive events, resulting in an initial unsuccessful performance. Refer to D2096 I. 4. The laboratory failed to achieve a score of at least 80% for Blood Urea Nitrogen (BUN) in two consecutive events, resulting in an initial unsuccessful performance. Refer to D2096 II.</p>
<p><b>D2087</b></p>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the proficiency testing results from the CASPER Report 155D, the laboratory failed to attain a score of at least 80% for Albumin and Blood Urea Nitrogen (BUN) for two (2) events in 2020. Findings: 1. Review of CASPER Report 155D proficiency test results revealed the laboratory did not achieve a score of at least 80% for the specialty of Chemistry for the following two (2) events and analytes: 2020 1st Event Albumin score received 0% 2020 2nd Event Albumin score received 0% 2020 1st Event BUN score received 60% 2020 2nd Event BUN score received 20% .</p>
<p><b>D2089</b></p>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.841(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on review of the proficiency testing results from the CASPER Report 155D, the laboratory failed to participate in two (2) events for 2020 resulting in unsatisfactory performance and a score of zero for Albumin. Findings: 1. Review of CASPER Report 155D proficiency test results for Albumin revealed the laboratory did not participate and achieved a score of zero for the following two (2) test events in 2020: a) 2020 1st Event Albumin score received 0% b) 2020 2nd Event Albumin score received 0%</p>
<p><b>D2096</b></p>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.841(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two</p>

consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

I. Based on review of proficiency testing results from the CASPER 155D report, the laboratory failed to achieve a score of at least 80% for Albumin in two consecutive events, resulting in an initial unsuccessful performance. Findings: 1. Review of CASPER Report 155D proficiency test results for Albumin revealed the laboratory received the following scores resulting in an initial unsuccessful performance: a) 2020 1st Event Albumin score received 0% b) 2020 2nd Event Albumin score received 0%  
II. Based on review of proficiency testing results from the CASPER 155D report, the laboratory failed to achieve a score of at least 80% for Blood Urea Nitrogen (BUN) in two consecutive events, resulting in an initial unsuccessful performance. Findings: 1. Review of CASPER Report 155D proficiency test results for BUN revealed the laboratory received the following scores resulting in an initial unsuccessful performance: a) 2020 1st Event BUN score received 60% b) 2020 2nd Event BUN score received 20%

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on record review, the Laboratory Director failed to provide overall management and direction for the laboratory. Refer to D6016.

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on record review, the Laboratory Director failed to ensure that proficiency testing results are satisfactory as required. Findings: 1. The laboratory failed to attain a score of at least 80% for Albumin and Blood Urea Nitrogen (BUN) for two (2) events in 2020. Refer to D2087. 2. The laboratory failed to participate in two (2) events for 2020 resulting in unsatisfactory performance and a score of zero for Albumin. Refer to D2089. 3. The laboratory failed to achieve a score of at least 80% for Albumin in two consecutive events, resulting in an initial unsuccessful performance. Refer to D2096 I. 4. The laboratory failed to achieve a score of at least 80% for Blood Urea Nitrogen (BUN) in two consecutive events, resulting in an initial unsuccessful performance. Refer to D2096 II.