Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 19D2016117	**(X3) Date Survey Completed** 08/01/2023
Name of Provider or Supplier Crescent City Surgical Centre Diagnostics, Llc	**Street Address, City, State** 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.		

(X4) ID Prefix Tag	**Summary Statement of Deficiencies**
D0000	An offsite PT Desk Review was performed on August 1, 2023 at Crescent City Surgical Centre, 19D2016117, was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.803 CONDITION: Successful Participation 42 CFR 493.1403 CONDITION: Laboratory Director, Moderate Complexity
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: Based on review of laboratory's College of American Pathologist proficiency testing records, CASPER 153D & 155D report the laboratory failed to successfully participate in two of three consecutive proficency testing events in 2022-2023.

	Findings: 1. The laboratory failed to achieve satisfactory score of human chorionic gonadotropin (hCG) in two of three consecutive events, resulting in initial unsuccessful performance. Refer to D2107. 2. The laboratory failed to achieve satisfactory overall score in Endocrinology for two of three consecutive events, resulting in initial unsuccessful performance. Refer to D2108
D2107	ENDOCRINOLOGY CFR(s): 493.843(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a review of the CASPER 153D & 155D Report and College of American Pathologists (CAP) proficiency testing results, the laboratory failed to achieve satisfactory score of human chorionic gonadotropin (hCG) in two of three consecutive events, resulting in initial unsuccessful performance. Findings: 1. Review of CASPER 153D & 155D report and proficiency testing results from (CAP) revealed the laboratory received scores of less than 80% for the following events for human chorionic gonadotropin (hCG): a. Event 1 of 2023 received a score of 0% b. Event 3 of 2022 received a score of 100% c. Event 2 of 2022 received a score of 0%
D2108	ENDOCRINOLOGY CFR(s): 493.843(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a review of the CASPER 153D & 155D Report and College of American Pathologists (CAP) proficiency testing results, the laboratory failed to achieve satisfactory overall score in Endocrinology for two of three consecutive events, resulting in initial unsuccessful performance. Findings: 1. Review of CASPER 153D & 155D report and proficiency testing results from (CAP) revealed the laboratory received an overall score of less than 80% for the following events for Endocrinology: a. Event 1 of 2023 received a score of 75% b. Event 3 of 2022 received a score of 100% c. Event 2 of 2022 received a score of 75%
D2121	HEMATOLOGY CFR(s): 493.851(a) 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. This STANDARD is not met as evidenced by: Based on review of the CASPER 0155D Report and College of American Pathologists (CAP), the laboratory failed to attain a score of at least 80% for Partial Prothromboplastin Time (PTT) in 2023. Findings: 1. Review of the CMS 155D and

	CAP proficiency testing records revealed the laboratory achieved a score of 40% for PTT in the second event in 2023 for the specialty of Hematology.
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 review of the laboratory's proficiency testing records, CASPER 155D report, and interview with personnel, the Laboratory Director failed to provide overall management and direction. 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 and interview with personnel, the Laboratory Director failed to ensure proficiency samples are tested as required. Findings: 1. The laboratory failed to achieve satisfactory score of human chorionic gonadotropin (hCG) in two of three consecutive events, resulting in initial unsuccessful performance. Refer to D2107. 2. The laboratory failed to achieve satisfactory overall score in Endocrinology for two of three consecutive events, resulting in initial unsuccessful performance. Refer to D2108 3. The laboratory failed to attain a score of at least 80% for Partial Prothromboplastin Time (PTT) in 2023. Refer to D2121