Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0464416	(X3) Date Survey Completed 12/10/2019
Name of Provider or Supplier Northeast Louisiana Health Center	**Street Address, City, State** 256 Hwy 3048, Rayville, 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	A PT Desk Review was performed on December 09, 2019. Northeast Louisiana Health Center - 19D0464416 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
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 proficiency testing results from the CMS-153, CMS-155D and American Association of Bioanalysts (AAB), the laboratory failed to successfully participate in proficiency testing as evidence by: 1. The laboratory failed to achieve a

	score of at least 80% for Hematology analytes in two consecutive events, resulting in initial unsuccessful performance. Refer to D2130. 2. The laboratory failed to acieve an overall score of at least 80% for two consecutive events in the specialty of Hematology. Refer to D2131
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of proficiency testing results from the CMS-155D and American Association of Bioanalysts (AAB), the laboratory failed to achieve a score of at least 80% for Hematology analytes in two consecutive events, resulting in initial unsuccessful performance. Findings: 1. Review of proficiency testing records and the CMS 155D Report revealed the laboratory received a score of 0% for the following analytes resulting in initial unsuccessful performance: a. 2019 Event 3: Score of 0% for Cell ID or WBC Diff b. 2019 Event 2: Score of 0% for Cell ID or WBC Diff c. 2019 Event 3: Score of 0% for Red Blood Cell (RBC) d. 2019 Event 2: Score of 0% for Red Blood Cell (RBC) e. 2019 Event 3: Score of 0% for Hematocrit f. 2019 Event 2: Score of 0% for Hematocrit g. 2019 Event 3: Score of 0% for Hemoglobin e. 2019 Event 2: Score of 0% for Hemoglobin h. 2019 Event 3: Score of 0% for White Blood Cell (WBC) i. 2019 Event 2: Score of 0% for White Blood Cell (WBC) j. 2019 Event 3: Score of 0% for Platelets k. 2019 Event 2: Score of 0% for Platelets
D2131	HEMATOLOGY CFR(s): 493.851(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 review of proficiency testing records and CMS Report 0155D, the laboratory failed to acieve an overall score of at least 80% for two consecutive events in the specialty of Hematology. Findings: 1. Review of proficiency testing records and Casper Report 0155D revealed the laboratory received an overall score of 0% for the following two consecutive events in Hematolgy: a. 2019 Event 2: Score of 0% for Hematology b. 2019 Event 3: Score of 0% for 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 record review and interview with personnel, 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: The laboratory director failed to ensure that proficiency testing samples are satisfactory as required. Findings: 1. The laboratory failed to achieve a score of at least 80% for Hematology analytes in two consecutive events, resulting in initial unsuccessful performance. Refer to D2130. 2. The laboratory failed to acieve an overall score of at least 80% for two consecutive events in the specialty of Hematology. Refer to D2131