Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D1044303	03/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Mcleod Dr Lindaberry At Carolina Forest	108 Finnegan Court, Myrtle Beach, SC	

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
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: During an onsite recertification survey on 03/10/2022, based on review of CASPER report 155D and graded reports from American Proficiency Institute (API) it was determined that the laboratory failed to successfully participate in proficiency testing for the overall specialty of hematology, the analyte WBC Diff, white blood cell count (WBC), platelets (Plt), red blood cell (RBC), hematocrit (Hct), and hemoglobin (Hgb) for two out of three consecutive proficiency testing events reviewed (2021, Events 1 and 3). See D2121 and D2130.
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: During an onsite recertification survey performed on 03/10/2022, based on review of the CASPER report 155D and laboratory proficiency testing records (graded report from API), it was determined that the laboratory failed to attain a score of at least 80 percent in proficiency testing for the overall specialty of hematology, the analyte WBC Diff, white blood cell count (WBC), platelets (Plt), red blood cell (RBC), hematocrit (Hct), and hemoglobin (Hgb) for two out of three consecutive proficiency testing events reviewed (2021, Events 1 and 3). The findings include: 1. Review of CASPER report 155D revealed the following proficiency scores for your laboratory: a. 2021, Event 1:overall specialty of hematology: 0% WBC Diff: 0%,WBC: 0%, Plt: 0%, RBC: 0% , Hct:0%, Hgb: 0% b. 2021, Event 3:overall specialty of hematology: 0% WBC Diff: 0%,WBC: 0%, Plt: 0%, RBC: 0% , Hct:0%, Hgb: 0% 2. The scores were confirmed upon review of the graded API reports. Scores less than 80% for these analytes indicate failure or unsatisfactory performance. A failure of the analytes for two consecutive or two out of three testing events is scored as unsuccessful. A failure of the analyte for three consecutive or three out of four/five events is scored as a repeat unsuccessful.
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: During the onsite recertification performed on 03/10/2022, based on review of CASPER report 155D and graded API results, it was determined that the laboratory failed to successfully participate in proficiency testing for the overall specialty of hematology, the analyte WBC Diff, white blood cell count (WBC), platelets (Plt), red blood cell (RBC), hematocrit (Hct), and hemoglobin (Hgb) for two out of three consecutive proficiency testing events reviewed (2021, Events 1 and 3), resulting in unsuccessful proficiency testing performance. See D2121.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by:

	Based on review of the Sysmex hematology operators guide, lack of documentation and staff interview, it was determined that the laboratory failed to monitor and document acceptable room temperature and humidity recordings for eight of eight months reviewed (August 2021 through March 2022). Findings include: 1. Review of the Sysmex hematology operators guide revealed that the test kit must be stored at 2 to 30 degrees Celsius. 2. During an onsite recertification survey on 03/10/2020, there was no documented room temperatures or humidity readings available for review for eight of eight months reviewed August 2021 through March 2022). 3. The laboratory manager confirmed during an onsite interview on 03/10/2022 at 2:00pm that the laboratory been performing and reporting the Sysmex hematology test results since August 2021 and had failed to document proper room temperature and humidity recordings for eight of eight months reviewed August 2021 through March 2022).