Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2097667	05/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Madison Core Laboratories	2705 Artie Street Sw, Suite 30, Building 400, Huntsville, AL	

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 abbreviated survey was conducted on 5/24/2018 for the investigation of complaint report number AL00035635. As a result of the investigation of this complaint, 493.1251 Standard: Procedure Manual, 493.1291 Standard: Test Report, and 493.1441 Condition: Laboratories performing high complexity testing; Laboratory Director were cited as deficiencies. The facility, Madison Core Laboratories was not in substantial compliance with the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). .
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

	This STANDARD is not met as evidenced by: Based on a lack of procedure for the manual microscopic examinations of blood smears, reviews of patient CBC (Complete Blood Count) reports, and interviews with Testing Personnel, the CEO (Chief Executive Director) and the current Laboratory Director, the surveyor determined the laboratory failed to ensure a procedure written by a person qualified in the Hematology specialty was developed and available for testing personnel performing manual reflex testing on CBCs. The findings include: 1. During the entrance tour and interview on 5/24/2018 at 0935, Testing Personnel (TP) #1 was asked what was the protocol on performing manual microscopic examinations of blood smears. TP #1 explained testing personnel performed a differential based on parameters pre-set in the Orchard Laboratory Information System (LIS); a pop-up box specified the reason for the scan. TP #1 further stated personnel performed a manual WBC (White Blood Cell) differential on all blood smears, even on cases where only the Platelets or RBCs (Red Blood Cells) showed abnormalities on the CBC results. 2. As the interview continued, the surveyor asked if there was a written procedure for blood smear reviews and/or manual differentials; TP #1 stated they just followed the prompting in the LIS. When asked who had developed the protocol for the reflex manual differential/scan, TP #1 stated she thought it was Dr [Name of the CEO]. [Note: The CEO was not current or the previous Laboratory Director.] 3. In the absence of a written procedure, the surveyor noted the testing personnel performed high-complexity testing (RBC Morphology and manual differentials on very immature and atypical WBCs) when their Laboratory Director was only qualified to oversee moderate complexity testing. (Refer to D6076.) This was evidenced by a review of patient reports as follows: A) Patient #1 with a CBC drawn on 5/16/2018 with WBC differentials including 13 atypical Lymphocytes, 22 Blasts, and RBC morphology of 1+ Macrocytosis and Occasional Target Cells. B) Patient #2 with a CBC drawn on 3/13/18 had RBC morphology of Occasional Microcytosis; the WBCs were normal, however a differential was also performed. C) Patient #3 with a CBC drawn on 3/13/18 had RBC morphology of 1+ Macrocytosis; the WBCs were normal, however a differential was also performed. 4. On 5/24/2018 at 9:45 AM, during an interview with the CEO and the current Laboratory Director (who had assumed the position on the day of the complaint survey--5/24/2018), the surveyor asked if there was a written procedure for blood smear reviews and/or manual differentials. The Director returned at 10:33 AM with numerical parameters for each CBC analyte that would prompt the pop-up window on the LIS screen for the manual reflex testing. This was printed directly from the Orchard LIS. No other written procedure or protocol for blood smear review was provided. When asked who had developed the LIS protocol, the CEO stated he and the Sysmex Hematology Analyzer representative had determined the criteria. The surveyor then asked about the CEO's educational background and experience; the CEO explained he was a Medical Doctor, not currently practicing in Alabama who had concentrated more on the business aspects of medicine. 5. During the exit interview on 5/24/2018 at approximately 12:30 PM, the surveyor reviewed and confirmed the above noted concerns with the Laboratory Director and the CEO. .
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to

	network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on reviews of patient CBC (Complete Blood Count) reports, and interviews with the Testing Personnel, the CEO (Chief Executive Director) and the current Laboratory Director, the surveyor determined the laboratory failed to ensure test results for Segmented Neutrophils and Bands were reported as entered by the testing personnel who performed the manual WBC (White Blood Count) differentials. The finding include: 1. A review of patient CBC reports printed from the Orchard LIS (Laboratory Information System) revealed the LIS combined manually counted Segmented Neutrophils and immature Bands under the "Test Name", "Neutrophilic Segs and Bands". 2. During an interview on 5/24/2018 at 12:00 Noon, the surveyor reviewed patient reports versus what the testing personnel had actually found while performing the manual differential, as follows: A) LIS report for Patient # 1: Neutrophilic Segs and Bands: 28; results actually entered during the manual differential: 25 Segs and 3 Bands. B) LIS report for Patient # 2: Neutrophilic Segs and Bands: 35; results actually entered during the manual differential: 34 Segs and 1 Band. 3. During an interview with the CEO on 5/24/2018 at approximately 12:10 PM, the surveyor asked why their LIS did not report the actual Segmented Neutrophil and Band counts when staff performed a manual differential. The CEO explained the lab was following a protocol a previous testing personnel had said a local hospital used. The CEO also stated a doctor at that hospital liked his results reported in that manner, however neither the CEO or the current Laboratory Director were able to specify the name of the doctor. The surveyor explained it was important to ensure the LIS reported the actual manually entered differential results because this information provided diagnostic data a physician needed when assessing his patients. 4. During the exit interview on 5/24/2018 at approximately 12:30 PM, the surveyor reviewed and confirmed the above noted concerns with the Laboratory Director and the CEO. .
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on reviews of high-complexity parameters reported on patient CBC (Complete Blood Count) reports, the educational documentation for the current and previous Laboratory Directors, and interviews with Testing Personnel, the CEO (Chief Executive Director) and the current Laboratory Director, the surveyor determined the laboratory failed to employ a Laboratory Director with the required qualifications to direct a laboratory performing high complexity Hematology testing. The findings include: 1. A review of patient CBC reports revealed the testing personnel performed and resulted high-complexity test results when performing microscopic examination of blood cell smears. The laboratory performed reflex manual WBC (White Blood Cell) differentials which included very immature Granulocytes, atypical Lymphocytes and RBC (Red Blood Cell) morphology, with examples as follows: A) Patient #1 with a CBC drawn on 5/16/2018 with WBC differentials including 13 atypical Lyphocytes,

	22 Blasts, and RBC morphology of 1+ Macrocytosis and Occasional Target Cells. B) Patient #2 with a CBC drawn on 3/13/18 had RBC morphology of Occasional Microcytosis C) Patient #3 with a CBC drawn on 3/13/18 had RBC morphology of 1+ Macrocytosis 2. A review of the educational and professional documentation for the current and previous Laboratory Directors revealed neither was qualified to direct a laboratory performing high complexity Hematology testing, as follows: A) The current Laboratory Director (who had assumed the position the day of the complaint survey on 5/24/2018) had a PhD (Doctor of Philosophy) in Intergrative Life Sciences with documentation of more than two years of experience as the Technical Supervisor of two high complexity laboratories. However, the currrent director did not have a board certification required to qualify as a high complexity Laboratory Director. B) The previous moderate-complexity Director (who had resigned without notice on 5/22 /2018) had qualified by completing the 20-hour on-line Laboratory Directors course. There were no records available to indicate she could have qualified as a Laboratory Director of a high-complexity laboratory. 3. During the exit interview on 5/24/2018 at approximately 12:30 PM, the surveyor reviewed and confirmed the above noted concerns with the Laboratory Director and the CEO. SURVEYOR:Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor