

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D0946682	<b>(X3) Date Survey Completed</b>  07/03/2018
<b>Name of Provider or Supplier</b>  Western Wayne Medical Center	<b>Street Address, City, State</b>  2280 Highway 70 West, Goldsboro, NC	
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>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2017 and 2018 American Proficiency Institute (API) proficiency testing (PT) records 07/03/18, the laboratory director and testing personnel failed to sign attestation statements for laboratory PT testing performed. Review of 2017 and 2018 API PT records revealed the laboratory participated in 2 of 4 API PT testing events. There were no attestation statements signed by the laboratory director and testing personnel for the 2 API PT testing events in which they participated: 1. API 2017 Hematology/Coagulation - 1st Event 2. API 2018 Hematology/Coagulation - 1st Event</p>
<b>D5024</b>	<p><b>HEMATOLOGY</b> CFR(s): 493.1215</p> <p>If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory procedure manual, review of Abbott Cell-Dyn Emerald "Quick Reference Guide" and "log reports", review of maintenance log book, review of calibration records, and testing personnel (TP) interview 07/03/2018, the laboratory failed to monitor and evaluate the overall quality of testing on the Abbott Cell-Dyn</p>

	<p>Emerald hematology analyzer. 1. The laboratory failed to have a comprehensive quality control policy for the Abbott Cell-Dyn Emerald hematology analyzer (see D5403). 2. The laboratory failed to document and perform required maintenance on the Abbott Cell-Dyn Emerald hematology analyzer (see D5429). 3. The laboratory failed to document and perform calibration on the Abbott Cell-Dyn Emerald hematology analyzer (see D5439).</p>
<p><b>D5403</b></p>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual, lack of operator's manual for the Abbott Cell-Dyn Emerald hematology analyzer and testing personnel (TP) interview 07/03/18, the laboratory's procedure manual was not complete and current for the testing performed. Review of laboratory procedure manual revealed procedure; "Cell-Dyn Running Controls" which stated "Start up and Controls must be run daily..." The procedure included instructions for running controls, and the statement "If controls do not pass, please refer to the Cell-Dyn Operators Manual." The procedure failed to include: a. The number and type of control material to be tested each day; b. The criteria to determine the acceptability of control results; c. The corrective action to take when control results fail to meet the laboratory's criteria for acceptability. Review of laboratory records revealed the laboratory had a "CELL-DYN Emerald - Quick Reference Guide" but did not have an operator's manual for the Abbott Cell-Dyn Emerald hematology analyzer to refer to if controls did not pass. Interview with TP #4, office manager, at approximately 11:00 a.m. confirmed the laboratory did not have an operator's manual for the Abbott Cell-Dyn Emerald hematology analyzer. She stated she was not sure where it was but maybe it lost due to flood of office in January 2018. This deficiency was previously cited 06/28/16.</p>
<p><b>D5429</b></p>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at</p>

least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on review of Abbott Cell-Dyn Emerald "Quick Reference Guide", review of laboratory procedure manual, review of "log reports", review of maintenance log book and testing personnel (TP) interview 07/03/18, the laboratory failed to document and perform required maintenance of the Abbott Cell-Dyn Emerald hematology analyzer. Review of Abbott Cell-Dyn Emerald "Quick Reference Guide" page 68 revealed "Monthly Maintenance...Bleach Cleaning...Cleaning the system with a bleach solution is performed monthly or as needed when a measurand is repeatedly rejected." and page 72 revealed "Semi-annual Maintenance...Lubricating the Pistons..For optimal operation, the Syringe Pistons should be lubricated every six months as described below." 1. Review of laboratory procedure manual revealed policy "Cell-Dyn Monthly maintenance....Bleach Cleaning....Clean with bleach solution monthly or as needed when measures are repeatedly rejected...." Review of Abbott Cell-Dyn Emerald "log reports" revealed the laboratory had printed "log reports" for the period of 12/09/16 through 03/20/17 and 09/01/17 through 12/11/17. The "Log reports" documented a bleach cleaning on 12/08/17. a. There was no documentation that monthly bleach cleaning was performed from time of last survey, 06/28/16 until 12/08/17, a period of approximately 17 months. b. There was no documentation that monthly bleach cleaning was performed from 12/08/17 until time of survey 07/03/18, a period of approximately 7 months. 2. Review of Abbott Cell-Dyn Emerald "log reports" and laboratory "Maintenance Log" revealed no documentation that "Semi-annual Maintenance....Lubricating the Pistons.." was performed from time of last survey, 06/28/16 until time of current survey, 07/03/18, a period of approximately 24 months. 3. Review of laboratory folder labeled "Maintenance Log" revealed the folder contained one paper entitled "Lab Director Review" and the statement "I have reviewed the Maintenance Log and confirm that they are accurate and up to date." This was signed by laboratory director on 8/2/12, 10/15/13, 6/28/16 and 6/28/18. The "Maintenance Log" folder contained no maintenance records. Interview with TP #4, office manager, at approximately 11:00 a.m., confirmed no documentation of monthly bleach cleaning as required for the Abbott Cell-Dyn Emerald analyzer. She stated she does the monthly bleach cleaning but was unaware it needed documented. She also stated she was unaware that the analyzer also required a "Semi-annual maintenance... Lubricating the Pistons" and that the "log reports" maintained by the Abbott Cell-Dyn Emerald analyzer document when quality control, calibration and maintenance procedures have been performed.

**D5439**

**CALIBRATION AND CALIBRATION VERIFICATION**  
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the

range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on review of Abbott Cell-Dyn Emerald "Quick Reference Guide", review of laboratory procedure manual, review of 2016, 2017, and 2018 hematology calibration records, review of "log reports" and testing personnel (TP) interview 07/03/18, the laboratory failed to calibrate the Abbott Cell-Dyn Emerald hematology analyzer every six months as required. Review of Abbott Cell-Dyn Emerald "Quick Reference Guide" page 45 revealed "When to calibrate...Indicated by Quality Control data... After major maintenance and service procedures....At least every six months...As directed by the regulatory agencies governing the laboratory." Review of laboratory procedure, "Cell-Dyn Calibration" revealed "When to Calibrate:....If indicated by Quality Control Data. After major maintenance and service procedures. At least every six months. As directed by the regulatory agencies governing the laboratory." Review of 2016, 2017 and 2018 calibration records for the Abbott Cell-Dyn Emerald hematology analyzer revealed calibration was performed 9/26/16. There was no documentation of calibration from 9/26/16 through time of survey 07/03/18, a period of approximately 21 months in which calibration was not performed. Review of Abbott Cell-Dyn Emerald "log reports" revealed the laboratory had only printed "log reports" for the period of 12/09/16 through 03/20/17 and 09/01/17 through 12/11/17. There were no calibrations documented during these periods. Interview with TP #4, office manager, at approximately 11:00 a.m., confirmed there was no documentation of calibration since 9/26/16. She stated she was unaware that calibration was required every six months, and maybe the calibration was performed but documentation lost during flood of office in January 2018. This deficiency was previously cited 06/28/16.

**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 2016, 2017 and 2018 laboratory records and interview with testing personnel (TP) 07/03/2018, the laboratory director failed to provide overall management and direction for the laboratory. 1. The laboratory director failed to ensure the overall quality of testing on the Abbott Cell-Dyn Emerald hematology analyzer (see D5024). 2. The laboratory director failed to ensure the establishment of an effective quality assessment program to identify, correct and prevent problems identified during survey and failed to prevent the recurrence of problems identified during survey (see D6021). 3. The laboratory director failed to ensure that competency evaluation policies were established and followed to ensure personnel were performing all testing operations accurately (see D6030 and D6054).

**D6021**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on review of laboratory quality assessment (QA) policy, review of laboratory records and interview with testing personnel (TP) 07/03/18, the laboratory director failed to ensure the establishment of an effective quality assessment program to identify, correct and prevent problems identified during survey and failed to prevent the recurrence of problems identified during survey. 1. Review of laboratory policy "Monthly Quality Assessment Checklist" revealed "At the beginning of every month a "Monthly Quality Assessment Checklist" must be filled out for the prior month. This form is a checklist for personnel, procedures, QC, proficiency testing, and communications. The lab director must sign off on these forms and they can be filed in the "Lab Log" notebook....." Review of laboratory records revealed no documentation of monthly quality assessments. Interview with TP #4, office manager, at approximately 11:00 a.m., confirmed the laboratory had no documentation of monthly quality assessments. She stated the laboratory doesn't do a monthly quality assessment. 2. Review of 2016 and 2017 American Proficiency Institute (API) proficiency testing (PT) records revealed the laboratory failed to participate in 2 of 3 API PT events in 2017, failed to document if patient testing was suspended, failed to notify the inspecting agency (CLIA), and failed to participate in two previous successful PT events for the API 2017 Hematology/Coagulation 3rd Event. a. Review of 2017 API PT records revealed the laboratory failed to participate in the 2nd and 3rd API 2017 Hematology/Coagulation PT events. b. Review of laboratory records revealed no documentation that patient testing was suspended during the time frame allotted for testing and reporting PT results for the 2nd and 3rd API events of 2017. c. Review of 2017 API PT records revealed the laboratory notified the API testing program of "Instrument Out of Service" for the 2nd and 3rd API Hematology /Coagulation PT events, but failed to notify the inspecting agency (CLIA) if patient testing was suspended and/or the circumstances for the laboratory's failure to participate in the PT events. d. Review of 2016 and 2017 API PT records revealed the laboratory participated in the 2016 API 3rd Event, but failed to participate in two previous PT events before the failure to participate in the API 2017 Hematology /Coagulation - 3rd Event. e. Interview with TP #4, office manager, at approximately 11:00 a.m. confirmed the laboratory did not participate in the 2nd and 3rd API PT events of 2017. She stated she was unsure exactly when the analyzer was down, and she did not know why they have the hematology analyzer because they generally send the testing out. 3. Review of laboratory records revealed the laboratory's QA program failed to identify and correct problems identified during survey and failed to prevent the recurrence of problems identified during survey (see D2009, D5403, D5429, D5439, D6030 and D6054).

**D6030**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:  
Based on review of laboratory procedure manual, review of personnel records and testing personnel (TP) interview 07/03/18, the laboratory director failed to ensure that competency evaluation policies were established and followed to ensure personnel were performing all testing operations accurately. 1. Review of laboratory procedure manual and interview with TP #4, office manager, revealed no written policies or procedures to assess employee competency. Interview with TP #4, office manager, confirmed there were no written policies or procedures to assess employee competency. She stated she was unsure where they would be located and that they could have been lost in flood of office in January 2018. 2. Review of personnel records and interview with TP #4, office manager, revealed no documentation of annual competency assessments for 2 of 2 testing personnel in 2016, 2017 or 2018 (see D6054).

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:  
Based on review of personnel records, the absence of documentation and testing personnel (TP) interview 07/03/18, the technical consultant (laboratory director) failed to perform annual competency assessments of personnel who perform testing on the Abbott Cell-Dyn Emerald hematology analyzer. Review of TP records revealed the technical consultant (laboratory director) failed to perform and document an annual competency for 2 of 2 testing personnel in 2016, 2017 and 2018. Interview with TP #4, office manager, at approximately 10:00 a.m. confirmed there was no documentation of competency assessments for the TP who perform testing on the Abbott Cell-Dyn Emerald hematology analyzer. She stated she was unsure where they would be as the laboratory director was on vacation but she thought they might have been lost in the flood of the office in January 2018. This deficiency was previously cited 5/30/12 and 3/20/14.