

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0247266	(X3) Date Survey Completed 11/29/2018
Name of Provider or Supplier Ruby A Grimm Md	Street Address, City, State 738 Bryant Street, Statesville, NC	
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
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of 2017 and 2018 API (American Proficiency Institute) proficiency testing records 11/29/18, the laboratory failed to test proficiency samples the same number of times that patient specimens are routinely tested. The laboratory's "Critical Values List" policy states "... Repeat any specimen with results occurring within the parameters listed below. ..." The policy specifies critical values for WBC (white blood cell count), hemoglobin, platelets, and glucose. Review of 2017 and 2018 API proficiency testing records revealed: 1. On the 2017 1st hematology test event, samples ABT #1 - ABT #5 were tested in duplicate. Review of results revealed only 2 of the 5 samples should have been repeated for critical hemoglobin values. Records did not include documentation why the testing was repeated. 2. On the 2017 2nd hematology test event, samples ABT #6 - ABT #10 were tested in duplicate. Review of results revealed 1 of the 5 samples should have been repeated for a critical hemoglobin value and another 1 of the 5 samples should have been repeated for a critical platelet value. Records did not include documentation why the testing was repeated.</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p>

This STANDARD is not met as evidenced by:
Based on review of 2017 and 2018 hematology records and interview with the RN (registered nurse) 11/29/18, the laboratory failed to retain all analytic systems records for at least two years. Findings: 1. Review of 2017 and 2018 Cell-Dyn Ruby hematology records revealed the laboratory failed to retain quality control assay sheets for the following lot numbers of Streck control material: a. lot #7030, expiration 4/14/17; b. lot #7142, expiration 8/4/17; c. lot #7254, expiration 11/24/17; d. lot #7310, expiration 1/19/18; e. lot #8001, expiration 3/16/18; f. lot #8057, expiration 5/11/18; g. lot #8113, expiration 7/6/18; h. lot #8169, expiration 8/31/18; i. lot #8225, expiration 10/26/18. 2. Review of 2017 and 2018 Cell-Dyn Ruby hematology records revealed the laboratory failed to retain instrument maintenance records documenting the performance of manufacturer's specified daily, weekly, monthly, and as-needed maintenance for 2017. 3. Review of 2017 and 2018 Cell-Dyn Ruby hematology records revealed the laboratory failed to retain startup/background counts obtained during 2017 and 2018. The RN stated during interview at approximately 1:15 p.m. that the instrument hard drive crashed and the laboratory was unable to retrieve and print the data.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies and procedures, review of job descriptions, review of personnel records, and interview with the RN (registered nurse) 11/29/18, the laboratory director failed to ensure that policies and procedures were established and followed for evaluating the competency of the TC (technical consultant) and TP (testing personnel). Findings: The "QUALITY ASSESSMENT PLAN" states "COMPETENCY EVALUATION OF LABORATORY PERSONNEL Laboratory staff performing testing will have adequate, specific training and orientation to perform the tests and demonstrate satisfactory levels of competency at least annually. ..." 1. The TC job description states "... Major Job Tasks: The responsibilities listed below are carried out in consult with and approval of (as needed) the Laboratory Director. ... 8. Evaluate the competency of all testing personnel on an on-going basis utilizing the following methods: Direct observation of test performance, maintenance, and instrument checks. Monitor the recording of test results. Review worksheets, QC records, PT results and preventive maintenance records. Testing of previously analyzed specimens, blind samples and external Proficiency Testing. Assessment of problem solving skills. ..." Review of personnel records revealed the TC used a "Competency Evaluation Summary" form to document TP competency. The form included the six methods of evaluation listed in the TC job description. The TC failed to utilize all methods for evaluation of testing personnel competency. Examples: a. In 2017, the competency evaluation for TP #1 (the RN) did not include method #2 - "Review of Recording/Reporting of Results" and did not include method #4 - "Direct Observation of Instrument Maintenance". Both methods were left blank on the form. b. In 2017, the competency evaluation for TP #6 consisted of a written test only. The test was used routinely by the TC to evaluate method #6 - "Evaluation of Problem Solving Skills" for all TP. There was no

documentation that TP #6 was evaluated utilizing the other 5 methods. c. In 2018, the competency evaluation for TP #6 did not include method #3 - "Review of Intermediate Test Results or Worksheets" and did not include method #4 - "Direct Observation of Instrument Maintenance". Both methods were marked "NA" on the form. 2. The quality assessment plan did not include instructions for evaluation of technical consultant competency by the laboratory director. During interview at approximately 12:20 p.m., the RN confirmed they did not have a procedure for TC competency evaluation. She stated there was no documentation of TC competency evaluation for laboratory's previous TC who recently retired, and she stated the new TC just started.

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 procedure manual review and interview with the RN (registered nurse) 11/29/18, the laboratory's procedure manual was not complete and current for the testing performed. Findings: 1. The procedure manual did not include a written step-by-step procedure for reporting patient test results in the EMR (electronic medical records system). The "PATIENT TEST MANAGEMENT SYSTEM" procedure states " ... When the Lab Test has been performed, any results with critical values will be verbally reported to the physician or PA-C. All other lab reports will be placed in the Laboratory in-box in the Physician's Office for her to review and initial before placing in the patient's chart. ..." The "Allscripts Workflow" procedure included instructions for ordering tests, but no instructions for result entry in the Allscripts EMR. The RN stated during interview at approximately 9:35 a.m. that Allscripts was installed in the laboratory in September 2017. She confirmed the procedure manual did not include instructions for entering patient test results in Allscripts. 2. The "CBC Analysis on CellDyn Ruby" procedure includes information not applicable to the laboratory. For example, on page 8 "... 10. LIMITATIONS: ... 10.2 When WBC, RBC, HGB, and PLT are above linear limits the specimen can be diluted to bring it within range of the instrument. 10.3 Make a dilution with saline or diluent and run it. Multiply your results by the appropriate dilution factor. ..." During interview at approximately 10:05 a.m. the RN stated they do not make dilutions. 3. The laboratory's "BLOOD SMEAR

REVIEW" procedure states "Manual Differentials are not performed in this Laboratory. However, (the laboratory director) will occasionally stain a blood smear in order to scan for platelet clumps or abnormal white cells if the CBC indicates. ..." The "CAMCO QUIK STAIN PROCEDURE" is printed on the same page, and states "1. Prepare Blood Smear 2. Dip Slide in Stain for 10 Seconds 3. Dip Slide in Distilled Water for at least 20 Seconds 4. Air Dry". The procedures did not include instructions for making a peripheral blood smear, interpretation of the stained smear under the microscope, or how and where the results are reported.

D5437

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies and procedures, review of 2016, 2017, and 2018 calibration records, and interview with the RN (registered nurse) 11/29/18, the laboratory failed to perform and document calibration of the Cell-Dyn Ruby at least once every six months. The laboratory's "CBC Analysis on CellDyn Ruby" procedure states on page 3 "... 4. CALIBRATIONS: 4.1 The Cell-Dyn Ruby is calibrated twice a year with Cell-Dyn HemCal Plus calibrator. ..." Review of 2016, 2017, and 2018 Cell-Dyn Ruby calibration records revealed the laboratory calibrated the analyzer on the following dates: 11/23/16, 6/2/17, and 9/21/18. The calibration records also included a pre-calibration checklist dated 1/29/18. Review of field service reports indicated calibration was performed by a field service engineer on 2/12/18 and 7/31/18, but there were no other calibration records available. During interview at approximately 1:15 p.m. the RN stated that the instrument's hard drive crashed and the laboratory was unable to retrieve any data, so she was unsure whether any other calibrations were performed.

D5473

CONTROL PROCEDURES
CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies and procedures, the absence of records, and interview with the RN (registered nurse) 11/29/18, the laboratory failed to

perform and document quality control of the Camco stain to ensure accurate staining characteristics for peripheral blood smears. The laboratory's "BLOOD SMEAR REVIEW" procedure states "Manual Differentials are not performed in this Laboratory. However, (the laboratory director) will occasionally stain a blood smear in order to scan for platelet clumps or abnormal white cells if the CBC indicates. ..." During interview at approximately 1:55 p.m., the RN confirmed the laboratory did not perform and document quality control of the Camco stain used to stain peripheral blood smears during 2017 or 2018.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on review of 2 random patient test reports (patient # 1726030, #716960) printed from the EMR (electronic medical records system) and interview with the RN (registered nurse) 11/29/18, the laboratory's test reports did not include all required information. Review of 2 random patient CBC (complete blood count) test reports (patient # 1726030, #716960) printed from the Allscripts EMR revealed the test reports did not indicate the name and address of the laboratory where the tests were performed. During interview at approximately 2:10 p.m., the RN confirmed the test reports did not include the laboratory's name and address.

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on review of a random patient test report (patient #716960) and interview with the RN (registered nurse) 11/29/18, the laboratory's test reports did not include hematology reference ranges that were consistent with the reference ranges listed on the instrument printout from the hematology analyzer. Review of a random patient test report (patient #716960) printed from the Allscripts EMR (electronic medical records system) revealed the following reference ranges: WBC (white blood cell count) 4.00 - 10.8 RBC (red blood cell count) 4.00 - 6.10 Hemoglobin 12.0 - 18.0 Hematocrit 37.0 - 52.0 Platelet count 130 - 400 Review of the Cell-Dyn Ruby instrument printout for the same patient (patient #716960) revealed the following reference ranges: WBC 3.70 - 10.1 RBC 4.06 - 4.69 Hemoglobin 12.9 - 14.2 Hematocrit 37.7 - 53.7 Platelet count 155 - 366 During interview at approximately 2:10 p.m. the RN stated the reference range in the Cell-Dyn Ruby is selected for each

patient based on age, sex, etc., but she thought there was only one reference range in the EMR.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iii)

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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on review of 2017 and 2018 API (American Proficiency Institute) proficiency testing records and interview with the RN (registered nurse) 11/29/18, the laboratory director failed to ensure that proficiency testing results were reviewed to evaluate the laboratory's performance and identify any problems requiring corrective action. Review of API proficiency testing records revealed the laboratory did not have copies of 2017 API graded results. The results for the 2017 1st, 2nd, and 3rd hematology test events were printed from the API website during the survey by the RN. The results had not been reviewed and evaluated by the laboratory director. During interview at approximately 10:50 a.m., the RN verified that the results had not been reviewed and evaluated by the laboratory director.

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 the laboratory's quality assessment plan and review of 2017 and 2018 laboratory records 11/29/18, the laboratory director failed to ensure the establishment and maintenance of an effective quality assessment program designed to identify and correct problems and prevent their recurrence. The laboratory's "QUALITY ASSESSMENT PLAN" signed and dated by the laboratory director in 2005 states "PURPOSE: The laboratory has an ongoing plan of Quality Assessment to monitor and evaluate the ongoing and overall quality of the total testing process including preanalytic, analytic, and postanalytic processes. The Laboratory's Quality Assessment Program evaluates the effectiveness of its policies and procedures, identifies and corrects problems, assures the accurate, reliable, and prompt reporting of test results, and assures the adequacy and competency of the staff. As a result of these evaluations, the Laboratory Director and the Laboratory Consultant will revise policies and procedures to ensure the overall quality of the Laboratory services provided. ..." The "QUALITY ASSESSMENT PLAN" describes activities the

laboratory is supposed to perform as part of their routine quality assessment program, as well as additional monitors to evaluate the preanalytic, analytic, and postanalytic systems. During 2017 and 2018, the only quality assessment activities performed by the laboratory were patient chart reviews and split sample comparisons with the hospital laboratory. There was no documentation the split samples were evaluated by the technical consultant or laboratory director to determine whether results were acceptable or whether corrective action was needed. The "QUALITY ASSESSMENT PLAN" failed to identify problems identified during the survey in the following areas: 1. proficiency testing (see D2010, D6018); 2. record retention (see D3031); 3. personnel competency (see D5209); 4. procedures (see D5403); 5. calibration (see D5437); 6. quality control (see D5473); 7. test reports (see D5805, D5807).

D6033

TECHNICAL CONSULTANT-MODERATE COMPLEXITY
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:
Based on review of personnel records 11/29/18 and the deficiency cited at D6034, the laboratory failed to have personnel in place who met the qualification requirements to serve as technical consultant in a moderate complexity laboratory.

D6034

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

This STANDARD is not met as evidenced by:
Based on review of personnel records and interview with the TC (technical consultant) 11/29/18, the laboratory failed to have personnel in place who met the qualification requirements to serve as technical consultant in a moderate complexity laboratory. Review of personnel records revealed the laboratory's TC had a bachelor of arts degree, an associate degree in medical laboratory technology, and a MLS (medical laboratory scientist) certification. The bachelor of arts degree did not indicate the major. During interview at approximately 11:20 a.m., the TC stated the laboratory's previous TC had recently retired, so he had only been serving as the laboratory's TC for a short time. He stated he was unaware his bachelor's degree did not include the major, and he confirmed he did not have a college transcript available for review.