Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0057923	06/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
North Country Healthcare Inc	300 S 6th Street, Williams, AZ	

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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) records from 2017 for testing performed in the specialty of Hematology and interview with the facility personnel, the laboratory failed to maintain a copy of the signed PT attestation statement from the 2nd testing event of 2017. Findings include: 1. No documentation was presented for review to indicate the laboratory maintained a copy of the PT attestation statement signed by the laboratory director for the 2nd testing event of 2017, for testing performed in the specialty of Hematology. 2. The facility personnel confirmed that the PT attestation statement indicated above could not be located during the survey.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

	This STANDARD is not met as evidenced by: Based on lack of verification documentation and interview with the laboratory director, the laboratory failed to verify the accuracy of Microbiology testing at least twice annually during 2015. Findings include: 1. The laboratory performs vaginal wet prep testing under the specialty of Microbiology, with an approximate annual test volume of 1. 2. No documentation was presented for review during the survey to indicate the laboratory verified the accuracy of the vaginal wet prep test, which is not included subpart I, at least twice annually during 2017. 3. The laboratory participates in proficiency testing (PT) as a means to verify accuracy for the vaginal wet prep testing, but scored 0% for the 1st and 3rd PT events of 2017, and no corrective action was presented for review to indicate the laboratory identified and corrected the unsatisfactory PT results. 4. The facility personnel acknowledged that the laboratory failed to verify the accuracy of the test indicated above at least twice annually during 2017.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of Quality Assessment (QA) records, Proficiency Testing (PT) records and interview with the facility personnel, the laboratory failed to (A) follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated correct problems identified in the general laboratory systems, including but not limited to proficiency testing performance; (B) the laboratory failed to document corrective action for unsatisfactory PT scores; and (C) the laboratory director failed to sign the PT attestation statements in a timely manner. Findings include: 1. The laboratory performs patient testing in the specialties of Microbiology and Hematology, with an approximate annual test volume of 1,297. A1. The laboratory performs a "Monthly Quality Assurance Checklist" to monitor the following areas: Personnel, Quality Control, Procedure Manual, Patient Test Management, Proficiency Testing and Communications/Process Improvement. A2. No documentation was presented for review during the survey conducted on June 13, 2018 to indicate the laboratory performed and documented the monthly QA Checklist since August 2016. A3. The facility personnel confirmed that the laboratory could not produce evidence of a completed monthly QA checklist since the last documented review dated August 2016. B1. The laboratory participates in PT for the following regulated analytes tested in the specialty of Hematology: WBC, RBC, HCT, HGB, Platelets and WBC Diff. The laboratory also participates in PT to verify the accuracy of KOH and Wet Mount testing performed in the specialty of Microbiology. B2. The proficiency testing section of the monthly QA checklist indicated above states, "Any failed proficiency testing was evaluated and communicated to the lab director. A corrective action was created and implemented to prevent repeat failure of the proficiency item". B3. The laboratory received an unsatisfactory PT score of 60% for the analyte, RBC, for the 3rd testing event of 2016. No corrective action documentation was presented for review during the survey to indicate the laboratory identified and corrected the error of the unsatisfactory PT score. B4. The laboratory

	received an unsatisfactory PT score of 67% for the analyte, WBC Diff, for the 1st testing event of 2017. No corrective action documentation was presented for review during the survey to indicate the laboratory identified and corrected the error of the unsatisfactory PT score. B5. The facility personnel confirmed that the laboratory failed to document corrective action for the unsatisfactory PT scores referenced above. C1. The PT attestation statements for the 1st and 3rd events of 2017 and the 1st event of 2018 which were presented for review during the survey conducted on June 13, 2018 indicated the laboratory director signed the attestation statements on June 8, 2018. C2. The facility personnel confirmed that the PT attestation statements referenced above were not signed until June 8, 2018.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual and interview with the facility personnel, the laboratory failed to have the current laboratory director approve and sign test procedures before use. Findings include: 1. The laboratory director listed on the CMS-209, Laboratory Personnel Form presented for review during the survey conducted on June 13, 2018 became the laboratory director on March 10, 2017. 2. The policy and procedure manual presented for review during the survey was not approved, signed and dated by the current laboratory director. 3. The facility personnel confirmed that the policy and procedure manual indicated above was not approved, signed and dated by the current laboratory director before use.
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 manufacturer's specified environmental conditions in the instrument user manual, lack of humidity logs presented for review and interview with the facility personnel, the laboratory failed to monitor and document the ambient humidity reading where the Coulter AcT Diff2 instrument is utilized for patient testing under the specialty of Hematology. Findings include: 1. The laboratory performs patient testing on the Coulter AcT Diff2 hematology analyzer, with an approximate annual test volume of 1,296. 2. The Coulter AcT Diff2 user manual indicates a relative ambient humidity of 20-85% while the instrument is in use. 3. No documentation was presented for review during the survey to indicate the laboratory

	was monitoring and documenting the humidity of the laboratory where the instrument is used for testing patient specimens. 4. The facility personnel confirmed that the humidity of the laboratory was not monitored and documented.
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 lack of calibration records for the Coulter AcT Diff2 hematology analyzer and interview with the facility personnel, the laboratory failed to perform and document calibration procedures as required. Findings include: 1. The laboratory utilizes the Coulter AcT Diff2 hematology analyzer to perform patient testing, with an approximate annual test volume of 1,296. 2. No documentation was presented for review during the survey conducted on June 13, 2018 to indicate the laboratory performed and documented calibration procedures every 6 months as required by the manufacturer for the analyzer indicated above. Calibration records reviewed from 2016 through the date of the survey indicated the analyzer was only calibrated in November 2017. 3. The facility personnel confirmed that the laboratory could not produce evidence of calibration records from 2016 and the first half of 2017.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assessment (QA) policies and procedures, review of hematology Quality Control (QC) records and interview with the testing personnel, the laboratory failed to follow written policies and procedures with regard to QA activities in the analytic systems. Findings include: 1. The laboratory's established QA policy titled, "Medical Laboratory Quality Assurance Procedures, Quality Control Assessment" states, "The laboratory director reviews quality control logs on a quarterly basis." 2. No evidence was presented for review during the survey to indicate the laboratory director reviewed hematology QC records from August 2016 through the date of the survey on June 13, 2018. 3. The testing

	personnel confirmed that the hematology QC records were not being reviewed by the laboratory director. 4. The laboratory director is also listed as the Technical Consultant on the CMS-209, Laboratory Personnel Form.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of Quality Assessment (QA) policies and procedures and interview with the facility personnel, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems. Findings include: 1. The laboratory's established QA policy titled, "Medical Laboratory Quality Assurance Procedures, Patient Results Management" states, "An internal audit is done once per quarter to verify transcribed lab results are being entered into the patient's electronic chart accurately. A random sample of 10 CMP/BMP, 10 CBC, and 5 u-dip printed test results are compared to the corresponding entries in the electronic chart...The results are documented and reviewed by the Medical Laboratory Director. Corrective action plans will be created if any error trends are identified." 2. No documentation was presented for review to indicate the laboratory performed the internal audit process referenced above from August 2016 through the date of the survey on June 13, 2018. The last documented internal audit was dated 7/30/16. 3. The facility personnel confirmed that the laboratory did not perform an internal audit since July 2016.
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: Due to the number and severity of deficient practices identified during the survey, the Condition of Laboratory Director was found to be not met as evidenced by: D6019 - failure to ensure that an approved corrective action plan is followed when PT results are found to be unsatisfactory; D6020 -failure to ensure that the quality control program was maintained to assure the quality of patient testing performed on the AcT Diff2 hematology analyzer; D6021 - failure to ensure that quality assessment programs are maintained to assure the quality of laboratory services provided; and D6023 - failure to ensure that acceptable levels of analytical performance for each test system were maintained
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on lack of documented corrective action for unsatisfactory proficiency testing (PT) results and interview with the facility personnel, the laboratory director failed to ensure that an approved corrective action plan is followed when PT results are found to be unsatisfactory. See D5291-B for findings.
D6020	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 the quality control program is 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 Control (QC) records and policies and interview with the facility personnel, the laboratory director failed to ensure that the quality control program was maintained to assure the quality of patient testing performed on the AcT Diff2 hematology analyzer. See D5791 for findings.
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 quality assessment policies and forms, the laboratory director failed to ensure that the quality assessment program is maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5291, D5791 and D5891 for findings.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on laboratory personnel interview and calibration documentation record review, the laboratory director failed to ensure that acceptable levels of analytical performance for each test system were maintained. Findings include: 1. The laboratory failed to perform and document hematology complete blood count (CBC) instrument calibration procedures every six months as required. Refer to D5437.
D6053	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on lack of performance evaluation documentation and interview with the facility personnel, the technical consultant failed to evaluate and document the performance of one testing personnel, at least semiannually during the first year the individual tested patient specimens. Findings include: 1. No semiannual competency evaluation documentation was presented for review for one testing personnel who began patient testing in February 2017. 2. The facility personnel confirmed that the laboratory did not have documentation of a semiannual competency evaluation for the testing personnel indicated above.
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 lack of competency evaluation documentation for review and interview with the facility personnel, the technical consultant failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least annually. Findings include: 1. During the survey conducted on June 13, 2018, no 2016 annual competency evaluation documentation was presented for review for one testing personnel. 2. No 2017 annual competency evaluation documentation was presented for review for two out of two testing personnel. 3. The facility personnel confirmed that the laboratory failed to provide documentation of an annual competency evaluation from 2016 and 2017 for the testing personnel indicated above.