Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0520679	08/15/2018
Name of Provider or Supplier	**Street Address, City, State**	
North Canyon Medical Center	267 North Canyon Dr, Gooding, ID	

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
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 record review and an interview with the laboratory supervisor, the laboratory failed to include quality control and calibration activities for testing of complete blood counts (CBCs) performed on the Sysmex XN-2000 analyzer and failed to write a policy for the acceptance of verbal orders since the last survey on September 20, 2016. Findings: 1. A review of the laboratory's procedure manual revealed the laboratory failed to include written procedures for performing quality control and calibration activities for the hematology analyzer since the last survey. 2. A review of the procedure manual revealed the laboratory failed to write a policy for

	the acceptance of verbal order test requests. 3. An interview on August 15, 2018 at 1: 45 PM, with the laboratory supervisor, confirmed the laboratory's procedure manual failed to include all requirements for testing CBCs and accepting verbal orders.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review and an interview with the laboratory supervisor, the laboratory failed to establish and document unscheduled maintenance activities for the instruments in the laboratory since the last survey on September 20, 2016. Findings: 1. A review of instrument maintenance and trouble-shooting logs revealed the laboratory failed to have a system in place to document unscheduled maintenance and trouble-shooting activities. 2. An interview on August 15, 2018 at 1:45 PM, with the laboratory supervisor, confirmed the laboratory failed to establish and document unscheduled maintenance activities in for the analyzers in the laboratory.
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 a record review and an interview with the laboratory supervisor, the laboratory failed to perform and document calibration verification procedures at least once every 6 months for D-dimers performed on the Sysmex CA660 coagulation analyzer since the last survey on September 20, 2016. Findings: 1. A record review of calibration reports for D-dimers revealed the laboratory failed to perform calibration verification at least once every 6 months since the last survey. 2. An interview on

	August 15, 2018, at 1:30 PM, with the laboratory supervisor, confirmed the laboratory failed to perform calibration verifications on D-dimers.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on quality control records and an interview with the laboratory supervisor, the laboratory failed to establish the Quality Control Plan (QCP) for the Individualized Quality Control Plan (IQCP) for the tests performed on the Cepheid Gene Xpert test system since December 2017. Findings: 1. A review of the laboratory's Monthly Quality Control Checklist revealed the laboratory failed to follow the IQCP and document quality control for the following tests since January 2018: a. Clostridium difficle quality control records revealed the laboratory failed to perform quality control during May through June of 2018 with 7 patient tests performed. b. Group A Streptococcus quality control records revealed the laboratory failed to perform quality control during June and July of 2018 with 7 patient tests performed. c. Methicillin-resistant Staphylococcus aureus (MRSA) quality control records revealed the laboratory failed to perform quality control from March through July of 2018 with 7 patient tests performed. 2. An interview on August 15, 2018 at 4:30 PM with the laboratory supervisor, confirmed the laboratory testing personnel failed to perform quality control procedures.
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 a record review and an interview with the laboratory supervisor, the laboratory failed to establish and follow a Quality Assessment Plan (QAP) for the Cepheid Gene Xpert test system since December 2017. Findings: 1. An Individualized Quality Control Plan (IQCP) review for the tests performed on the Cepheid Gene Xpert revealed the laboratory failed to establish and follow a quality assessment plan. 2. An on August 15, 2018 at 10:30 AM with the laboratory supervisor, confirmed the laboratory the failed to write the QAP for the Cepheid test system.

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 a record review of final patient reports and an interview with the laboratory supervisor, the laboratory failed to indicate the name and the address of the reference laboratory where laboratory tests were reported on patients for the period reviewed between February 2018 through July 2018. Findings: 1. A review of patient laboratory test reports, revealed the name and address of the reference laboratory where tests were performed failed to be included on the patient's test reports. 2. An interview on August 15, 2018, at 3:15 PM, with the laboratory supervisor, confirmed the name and address of the reference laboratory failed to be indicated on patient laboratory reports.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory supervisor, the laboratory director failed to specify in writing the delegation of duties and responsibilities for the supervisor responsible for all phases of testing since the last survey on September 20, 2016. Findings: 1. A record review of policies and procedures revealed the laboratory director failed to specify in writing the delegation of duty for signing attestation statements for proficiency testing (PT). 2. An interview on August 15, 2018 at 10:30 AM with the laboratory supervisor, confirmed the laboratory director failed to delegate in writing the signing of attestation statements for the PT program.