Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0520979	06/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Teton Valley Hospital	120 E Howard St, Driggs, 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
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 proficiency testing (PT) reviews, laboratory documents, and an interview with the laboratory manager, the laboratory failed to document and maintain records of proficiency testing to include each step in processing, testing, reporting, and signatures for the Attestation Statements for the specialties of hematology, chemistry, microbiology, immunohematology, and immunology. Findings: 1. A review of PT records from CAP revealed the laboratory failed to retain all instrument result data, intermediate worksheets, reporting worksheets for the Vitros 5600 chemistry /immunoassay analyzer, Sysmex XS-1000i hematology analyzer, Sysmex CA-620 coagulation analyzer, and microbiology worksheets for CAP 2019 event 1. 2. A review of PT records from CAP revealed the laboratory testing personnel and the laboratory director failed to sign the Attestation Statements for chemistry, hematology, microbiology, immunology, and immunohematology specialties for 2019 event 1. 3. A review of PT records from CAP and American Proficiency Institute (API) revealed the laboratory director failed to sign the Attestation Statements for chemistry, hematology, microbiology, immunology, and immunohematology

	specialties for 2018 event 1, 2, and 3. 4. An interview with the laboratory manager on June 5, 2019 at 10:50 AM, confirmed the laboratory director failed to sign the Attestation Statements from CAP and API.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) 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. This STANDARD is not met as evidenced by: A. Based on laboratory records review and an interview with the laboratory manager, the laboratory failed to retain the Sysmex CA-620 coagulation, Sysmex XS-1000i hematology, and the Vitros 5600 immunoassay manufacturer's quality control assay reference sheets since the last survey on July 24, 2017. Findings: 1. A review of the quality control documents for both hematology, hemostasis, and immunoassay quality controls revealed the laboratory failed to retain the manufacturer's quality control assay reference sheets. 2. An interview with the laboratory manager on June 5, 2019 at 1:10 PM, confirmed the laboratory failed to retain the quality control reference assay sheets for the analyzers. B. Based on instrument quality control records review and an interview with the laboratory manager, the laboratory failed to retain the Sysmex CA-620 coagulation instrument data for quality control test results since the last survey on July 24, 2017. Findings: 1. A review of quality control and patient data print-outs from the Sysmex CA-620 coagulation analyzer for Prothrombin Time (PT) and Partial Thromboplastin Time (PTT) revealed the laboratory failed to retain the instrument print-outs prior to June 1, 2019. 2. An interview with the laboratory manager on June 5, 2019 at 1:10 PM, confirmed the laboratory failed to retain the quality control and patient data from the instrument. C. Based on a record review and an interview with the laboratory manager, the laboratory failed to include the lot numbers, date of receipt and/or opened, and expiration dates for gram stain and catalase reagents since the last survey on July 24, 2017. Findings: 1. A review of the quality control worksheets for catalase and gram stain reagent revealed the laboratory failed to include the lot numbers, received dates, and expiration dates. 2. The laboratory documented 27 gram stain control reactions and 36 catalase reactions since the last survey. 3. An interview with the laboratory manager on June 6, 2019 at 11:05 AM, confirmed the laboratory failed to record all quality control documentation on the worksheets.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observations, record reviews, and interviews with the laboratory manager,

	the laboratory failed to monitor and evaluate the overall quality of the laboratory, as well as correct problems identified for the test systems for chemistry (D5411, D5439, and D5469), hematology, coagulation (D5403, D5411, D5469, and D5783), microbiology (D5415, D5445, 5471, D5477, D5507, and D5787) since the last survey on July 24, 2017.
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 procedure manual review and an interview with the laboratory manager, the laboratory failed to include quality control procedures to include the calculation of a mean normal prothrombin time (MNPT) for reporting patient Prothrombin Time International Normalized Ratio (INR) results and establishment of control limits, as well as corrective actions to take when control material fails to meet the laboratory's specified requirements since the last survey on July 24, 2017. Findings: 1. A review of the coagulation procedure revealed the procedure failed to include instructions to perform a MNPT value with new lots of Dade Innovin, corrective actions to perform when quality control levels fail, and to verify quality control ranges from the Insight Peer Group data reports since the last survey. 2. An interview with the laboratory manager on June 5, 2019 at 4:30 PM, confirmed the laboratory failed to have a procedure to include the quality control functions of Prothrombin Time testing.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: A. Based on a review of the Vitros 5600 prostate-specific antigen (PSA) reagent

	manufacturer's instructions, patient test report reviews, and an interview with the laboratory manager, the laboratory failed to follow the manufacturer's instructions to include the test methodology for PSA results on 1 out of 1 patient's test reports reviewed in May 2019. This is a repeat deficiency from the last survey on July 24, 2017. Findings: 1. A review the of Vitros 5600 assay instruction sheet for PSA reagent revealed the requirement for the test methodology be indicated on the patient results reported to providers. 2. A review of 1 out of 1 patient PSA reports from May 2018, revealed the patient report failed to include the identity of the PSA assay to providers. 3. The laboratory performed approximately 400 PSA tests in 2018. 4. An interview with the laboratory manager on June 6, 2019 at 2:45 PM, confirmed the patient PSA reports failed to include the identity of the PSA methodology. B. Based on an observation, a review of the Dade Innovin manufacturer's instructions, and an interview with the laboratory manager, the laboratory failed to follow the manufacturer's instructions to calculate a mean normal Prothrombin Time (MNPT) for the Prothrombin Time International Normalized Ratio (INR) results for the current lot of Innovin in use as of March 2019. Findings: 1. An observation of the laboratory on June 5, 2019 at 4:35 PM, revealed a Sysmex CA-620 coagulation analyzer with Dade Innovin reagent, lot # 549744A, in use as of March 2018, instrument MNPT entered as 10.2. 2. A review of the Innovin manufacturer's instructions revealed instructions to calculate the MNPT for each new lot of reagent and enter the number into the analyzer to establish the INR result. 3. A review of laboratory records revealed no documentation of established MNPT. 3. The laboratory performed approximately 245 Prothrombin Time tests in 2018. 4. An interview with the laboratory manager on June 5, 2019 at 4:45 PM, confirmed the laboratory failed to calculate a new MNPT with each new lot of Innovin.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on an observation of microbiology reagents and a record review, the laboratory failed to label the working bottle of catalase reagent with a preparation date and/or expiration date, concentration, and lot number. Findings: 1. An observation on June 6, 2019 at 10:05 AM of the catalase reagent on the laboratory bench revealed the bottle failed to be labeled with the open/expiration date, concentration, and lot number. 2. An interview with testing person on June 6, 2019 at 10:05 AM, revealed the laboratory failed to label the catalase bottle with the information for use.
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 calibration record reviews and an interview with the laboratory manager, the laboratory failed to perform and document calibration verification procedures for chloride (urine and serum), potassium (serum), sodium (serum), vitamin D, and vitamin B-12 assays at least once every 6 months performed on the Vitros 5600 chemistry/immunoassay analyzer since installation of the analyzer on November 2018. Findings: 1. A record review of calibration reports for the Vitros 5600 chemistry /immunoassay analyzer revealed the laboratory failed to perform and document calibration verifications procedure for chloride (urine and serum), potassium (serum), sodium (serum), vitamin D, and vitamin B-12 since the installation of the analyzer in November 2018. 2. The laboratory performed approximately 3,280 total chlorides, potassiums, and sodiums in 2018. Test volumes for vitamin D and vitamin B-12 tests were not available for for 2018. 3. An interview with the laboratory manager on June 6, 2019, at 10:30 AM, confirmed the laboratory failed to perform calibration verifications on the analytes: chloride (urine and serum), potassium (serum), sodium (serum), vitamin D, and vitamin B-12 on the Vitros 5600 analyzer.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the Vitek Individualized Quality Control Plan (IQCP) and an interview with the laboratory manager, the laboratory failed to specify the control procedures to include the number, type, and frequency of control organisms for the identification and susceptibility of microorganisms since the last survey. This is a repeat deficiency from the last survey on July 24, 2019. Findings: 1. A review of the IQCP revealed the plan failed to include the number, type, and frequency of control

	organisms for the identification and susceptibility of gram-negative and gram-positive organisms as required by the manufacturer or established by the laboratory. 2. An interview with the laboratory manager on June 6, 2019, at 10:50 AM, confirmed the laboratory failed to specify the number, type, and frequency of control organisms in the IQCP.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: A. Based on quality control record reviews and an interview with the laboratory manager, the laboratory failed to establish and verify the acceptability criteria for unassayed quality control materials for Prothrombin Time (PT) and Partial Thromboplastin Time (PTT) performed on the Sysmex CA-620 analyzer since the last survey on July 24, 2017. Findings: 1. A review of quality control records for PT and PTT revealed the laboratory failed to establish and verify the acceptability of Dade CiTrol levels 1 and 2 quality control reference ranges as produced by the Insight Peer Group data for the analyzer. 2. The laboratory performed approximately 245 PT and 185 PTT tests in 2018. 3. An interview with the laboratory manager on June 5, 2019, at 4:30 PM, confirmed the laboratory failed to verify the acceptability of the Insight Peer Group data ranges. B. Based on a quality control record review and an interview with the laboratory manager, the laboratory failed to establish the BioRad Liquid and Immunoassay baseline control reference range criteria within the Vitros 5600 operating system for the analytes Iron, Thyroid Stimulating Hormone (TSH), and Total Iron-Binding Capacity (TBIC) since the installation of the Vitros 5600 in December 2018. Findings: 1. A review of quality control reports from the Vitros 5600 chemistry/immunoassay analyzer, revealed the laboratory failed to establish the baseline quality control reference ranges within the Vitros operating system for the following analytes reviewed: a. Iron, level 1 and 3, no quality control ranges established from December 31, 2018 through April 3, 2019. b. Thyroid stimulating hormone (TSH), level 3, no quality control ranges established from December 31, 2018 through January 18, 2019. c. Total iron-binding capacity (TBIC), level 1 and 3, no quality control ranges established from dates available May 1, 2019 through May 31, 2019. 2. The laboratory performed approximately 31 TIBC, 435 iron, and 1,180 TSH tests since January 2019. 3. An interview with the laboratory manager on June 6, 2019, at 10:30 AM, confirmed the laboratory failed to establish the reference quality control ranges in the Vitros 5600. C. Based on a quality control record review and an interview with the laboratory manager, the laboratory failed to update or correct the BioRad Liquid Assay control baseline statistics within the Vitros 5600 operating

	system with either the recorded mean or other laboratory verified mean for the analytes: Iron on April 4, 2019 and Thyroid Stimulating Hormone (TSH) on January 18, 2019. Findings: 1. A review of the Vitros 5600 chemistry/immunoassay analyzer quality control reports revealed the laboratory failed to enter the updated or corrected baseline quality control (QC) reference ranges within the Vitros operating system for the following analytes reviewed: a. Iron, level 1: entered baseline mean was 69.4 ug /dL and standard deviation (SD) 6.630. The recorded mean from the QC report date range from the Vitros, 4/1/2019-4/30/2019, was 76.6 ug/dL and SD 2.571. b. Iron, level 3: entered baseline mean was 268.4 ug/dL and SD 11.96. The recorded mean from the QC report date range from the Vitros, 4/1/2019-4/30/2019, was 271.8 ug/dL and SD 2.4. c. TSH, level 3, entered baseline mean was 29.50 mIU/L and SD 3.250. The recorded mean from the QC report date range from the Vitros, 12/31/2018-1/31 /2019, was 26.87 mIU/L and SD 0.767. 2. A review of the BioRad manufacturer Liquid Assay sheet for current lot #45790, revealed the mean for Iron level 1 was 59.7 and level 3 mean was 269. The TSH stated mean for BioRad Immunoassay, lot #40950, level 3 was 33.8. 3. The laboratory performed approximately 435 iron and 1,180 TSH tests since January 2019. 4. An interview with the laboratory manager on June 6, 2019, at 2:30 PM, confirmed the laboratory failed to enter the baseline mean reference values and failed to show the verification of control range data for the changed values.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on an observation, a record review, and an interview with the laboratory manager, the laboratory failed to perform a positive and a negative control reaction for each reagent on the Vitek mircobiology identification system for gram-negative (GN) and gram-positive (GP) identification panels from the quality control reviewed on May 28, 2019. Findings: 1. An observation on June 6, 2019 at 9:30 AM revealed a Vitek microbiology identification instrument for gram-negative and gram-positive cultures. 2. A review of quality control records from the Vitek GN panel on May 28, 2019, revealed the laboratory failed to demonstrate a positive and a negative biochemical reaction for 21 out of 47 biochemicals used in the identification of organisms. 3. A review of quality control records from the Vitek GP panel on May 28, 2019, revealed the laboratory failed to demonstrate a positive and a negative biochemical reaction for 15 out of 28 biochemicals used in the identification of organisms. 4. An interview with the laboratory manager on June 6, 2019 at 1:45 PM, confirmed the laboratory failed to verify the positive and negative biochemical reactions for each of the gram-negative and the gram-positive idenfication systems.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)

	(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on an observation, a review of quality control documents, and an interview with the laboratory director, the laboratory failed to document the sterility, biochemical response, ability to select or inhibit organisms, and the physical characteristics of each lot or shipment of microbiology media used for the identification and susceptibility of throat, urine, wound, blood, and Methicillin-resistant Staphylococcus aureus (MRSA) culture specimens since the last survey on July 24, 2017. Findings: 1. An observation on June 6, 2019 at 10:00 AM revealed the laboratory refrigerator stored the following microbiology media: trypticase soy agar, chocolate agar, Columbia CNA agar, MacConkey agar, and MRSA agar. 2. A review of microbiology media quality control records revealed the laboratory failed to check and document each shipment or lot number of media for biochemical response, sterility, and inhibition or selection of specific organisms. 3. The laboratory performed approximately 800 microbiology cultures in 2018. 4. An interview with the laboratory manager on June 6, 2019 at 11:05 AM, confirmed the laboratory manager failed to document the control procedures for the microbiology media.
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory failed to include the lot numbers, date of receipt and/or opened, and expiration dates for gram stain and catalase reagents since the last survey on July 24, 2017. Findings: 1. A review of the quality control worksheets for catalase and gram stain reagent revealed the laboratory failed to include the lot numbers, received dates, and expiration dates. 2. The laboratory documented 27 gram stain control reactions and 36 catalase reactions since the last survey. 3. An interview with the laboratory manager on June 6, 2019 at 11:05 AM, confirmed the laboratory failed to record all quality control documentation on the worksheets.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f)

	(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on an observation, a record review, an interview with the laboratory manager, the laboratory failed to ensure the refrigerator for the storage of blood products and blood testing reagents had an adequate temperature alarm system and failed to document blood bank temperature alarm checks prior to May 30, 2018 and after August 27, 2018. Findings: 1. An observation on June 5, 2019 at 2:45 PM of the blood bank refrigerator alarm system, revealed the blood storage refrigerator failed to alarm when the temperature was manually forced checked lower than 1 C and over 6 C. 2. A record review of the Blood Bank Temperature Alarm Log revealed the laboratory failed to record inspections of the blood storage refrigerator audible alarm system prior to May 30, 2018 and after August 27, 2018. Last available alarm check was from a temperature wheel dated March 4 through March 11, 2019. 3. A review of the laboratory procedure manual for performing inspections of the blood storage refrigerator temperature alarm system, revealed the procedure stated to "periodically" check the alarm system. 4. An interview with the laboratory manager on June 5, 2019 at 3:30 PM, confirmed the laboratory failed to document the alarm checks for the refrigerator. .
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on quality control record reviews and an interview with the laboratory manager, the laboratory failed to take corrective actions and evaluate patient Partial Thromboplastin Time (PTT) test results performed on the Sysmex CA-620 analyzer for 10 out of 13 days in December 2018 when quality control results failed to meet the laboratory's established criteria for acceptability. Findings: 1. A review of quality control results revealed the laboratory failed to evaluate patient PTT test results when on 10 out of 13 days of testing in December 2018 CiTrol level 2 quality control did not meet the laboratory's stated acceptable quality control range. 2. Patient records were not available for review at the day of survey, June 5, 2019. 3. The laboratory performed approximately 185 PTT tests in 2018. 4. An interview with the laboratory manager on June 5, 2019, at 3:45 PM, confirmed the laboratory failed to take corrective actions and evaluate patient PTT results when quality control results were outside of the laboratory's acceptable quality control limits.

D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on patient record reviews, College of American Pathology microbiology proficiency testing (PT) records, and an interview with the laboratory manager, the laboratory testing personnel failed to include all steps of microbiology culture test performance, which included colony description and morphology, count, set-up of cultures on the Vitek, and the identity of the testing personnel performing all steps of testing for the dates reviewed in May 2018 and 2019. Findings: 1. A review of 4 out of 4 patient and PT microbiology laboratory worksheets revealed the microbiology worksheets failed to include: a description of the organism, identity of the testing personnel, and set-up of the Vitek system. 2. The laboratory performed approximately 802 microbiology cultures in 2018. 3. An interview with the laboratory manager on June 6, 2019 at 10:15 AM, confirmed the laboratory microbiology worksheets failed to indicate all steps of testing and the identity of testing personnel.
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 record reviews and an interview with the laboratory manager, the laboratory failed to follow the laboratory policy to monitor, assess, and correct problems with the analytic test systems for chemistry, coagulation, hematology, immunohematology and microbiology since the last survey on July 24, 2017. Findings: 1. A review the Laboratory Quality Assessment Plan revealed the laboratory failed to follow their policy to review and monitor quality control data to ensure accurate patient results for coagulation, chemistry, microbiology, and immunohematology. Refer to D5507, D5471, D5477, and D5783. 2. A review the Laboratory Quality Assessment Plan revealed the laboratory failed to follow their policy to review monthly temperature logs, quality control, and calibrations logs to ensure compliance. Refer to D5439, D5445, D5555, and D5469. 3. An interview with the laboratory manager on June 6, 2019 at 3:45 PM, confirmed the laboratory failed to follow their Laboratory Quality Assessment Plan.
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 a patient record review and an interview with the laboratory manager, the laboratory failed to ensure patient microbiology test results were sent to the final report destination for 2 out of 2 patients reviewed between May 4, 2018 and May 5, 2018. Findings: 1. A review of 2 out of 2 patient microbiology reports from May 4 and May 5, 2018, revealed the final patient urine culture reports failed to be entered into the patient's electronic medical record.. 2. An interview with the laboratory manager on June 6, 2019, at 1:45 PM, confirmed the laboratory failed to ensure the patient's final urine culture results were reported back to the patient's electronic medical record.
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 manager, the laboratory failed to document the name and the address of the laboratory on patient test reports since the last survey on July 24, 2017. Findings: 1. A review of 5 out of 5 chemistry, hematology, and microbiology laboratory patient reports, revealed the name and address of the laboratory failed to be included on the patient's test reports. 2. An interview with the laboratory manager on June 5, 2019, at 2:20 PM, confirmed the name and address of the laboratory failed to be documented on patient's final reports.
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 record reviews and interviews with the laboratory manager, the laboratory

	director failed to provide overall management of the laboratory operations since the last survey on July 24, 2017. Refer to D6079, D6091, D6093, D6094, D6095, D6096, D6103, and D6107.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on record reviews and interviews with the laboratory manager and testing personnel, the laboratory director failed to ensure that the overall operation and administration of the laboratory met regulatory requirements since the last survey on July 24, 2017. Findings: 1. A review of laboratory testing personnel records revealed the laboratory director failed to ensure 3 out of 6 testing personnel received training prior to performing and reporting patient test results since the last survey. 2. A review of laboratory testing personnel records revealed the laboratory director failed to ensure a general supervisor was available to provide supervision for the laboratory performing high-complexity testing in the specialties of hematology, chemistry, microbiology, immunology, and immunohematology since the last survey. 3. An interview with the laboratory manager on June 5, 2019 at 9:00 AM, confirmed the laboratory director failed to ensure a qualified general supervisor was employed and available on-site and testing personnel were trained before reporting patient test results.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure 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 a review of proficiency testing (PT) records and an interview with the laboratory manager, the laboratory director failed to evaluate the laboratory's PT testing and identify problems that require corrective actions since the last survey on July 24, 2017. Findings: 1. A review of the College of American Pathologists (CAP) and American Proficiency Institute (API) testing Attestation Statements revealed the laboratory director failed to sign the attestation statements and failed to delegate the responsibility to a qualified consultant. 2. A review of the CAP 2019 event 1 records revealed the laboratory failed to retain all PT documents for handling, testing, reporting, and documenting corrective actions for unacceptable results for cerebral

	spinal fluid analysis and carbon dioxide. 3. An interview with the laboratory manager on June 5, 2019 at 10:30 AM, confirmed the laboratory director failed to ensure the proficiency testing program was evaluated and reviewed.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of quality control records and procedures, the laboratory director failed to ensure the laboratory quality control procedures for the chemistry, coagulation, and microbiology test systems met all CLIA regulations since the last survey on July 24, 2017. Refer to D5403, D5445, and D5469.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record reviews and an interview with the laboratory manager, the laboratory director failed to ensure the quality assessment for the laboratory was established to identify errors and correct problems in proficiency testing, retention, quality control testing, chemistry and coagulation test systems, and patient test reporting. Refer to D2015, D3031, D5403, D5411, D5439, D5445, D5469, D5471, D5555, D5783, D5791, and D6096.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must 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 records reviewed in the laboratory, the laboratory director failed to ensure the Vitros 5600 chemistry analyzer, the Sysmex CA-620 coagulation analyzer, and the Vitek microbiology identification system met acceptability levels of performance. Refer to D5439, D5469, and D5471.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified.

	This STANDARD is not met as evidenced by: Based on quality control records and interviews with the laboratory manager, the laboratory director failed to ensure that corrective actions were taken and documented when quality control performance or calibrations failed to meet the performace specifications. Refer to D5411, D5439, D5469, D5471, D5555, and D5783.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must 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 a record review and an interview with the laboratory manager, the laboratory director failed to establish a policy or procedure to document competency assessments for the technical supervisor, general supervisor, and the testing personnel for the laboratory since the last survey on July 24, 2017. Findings: 1. A review of the procedure manual revealed the laboratory failed to have a policy or procedure for the performance of competency assessment for the testing personnel, general supervisor, and the technical supervisor. 2. A review of personnel records revealed competency assessments failed to be performed for 2 out of 8 testing personnel, the general supervisor, and the technical supervisor. 3. An interview with the laboratory manager on June 5, 2019 at 8:55 AM, revealed the laboratory failed to establish a policy to assess competency assessments for the personnel.
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 review of proficiency testing (PT) records, a policy review, and an interview with the laboratory manager, the laboratory director failed to specify in writing the duties and responsibilities for each supervisor and testing personnel engaged in patient testing since the last survey on July 24, 2017. Findings: 1. A review of the College of American Pathologists (CAP) and American Proficiency Institute (API) testing Attestation Statements revealed the laboratory director did not write a delegation of responsibility for the laboratory manager, who was also the technical supervisor, to sign the statements for all events in 2018 and event 1 in 2019.

	2. A review of the procedure manual revealed the laboratory failed to have a written policy which identifies the duties and responsibilities for the supervisors and testing personnel in the laboratory for all phases of testing. 3. An interview with the laboratory manager on June 5, 2019 at 9:30 AM, confirmed the laboratory director did not provide a written authorization for the laboratory manager to sign the attestation statements.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on record reviews and an interview with the laboratory manager, the laboratory failed to ensure a technical supervisor fulfilled the responsibilities of the position since the last survey. Refer to D6112 and D6117.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on record reviews and an interview with the technical supervisor, the technical supervisor failed to provide technical oversight for the laboratory to ensure accurate and reliable test results since the last survey on July 24, 2017. Findings: 1. A review of the records for the Vitros 5600 chemistry analyzer, the Sysmex CA-620 coagulation analyzer, and microbiology Vitek system revealed the technical supervisor failed to ensure the test systems met the manufacturer's performance specifications or the laboratory established parameters. Refer to D5439, D5469, and D5471. 2. An interview with the technical supervisor on June 5, 2019 at 8:50 AM, confirmed the technical supervisor failed to provide the technical oversight.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on record reviews and an interview with the laboratory manager, the technical supervisor who is also the laboratory manager, failed to ensure the quality control

	procedures for the specialties of hematology and chemistry was established since the last survey on July 24, 2017. Findings: 1. A review of the quality control records revealed the technical supervisor failed to establish the quality control statistical parameters for each lot number of quality control for the Vitros 5600 chemistry analyzer and the Sysmex CA-620 coagulation test systems to ensure all levels of quality control were maintained through testing to reporting of patient hematology and chemistry specimens. Refer to D5439 and D5469. 2. An interview with the laboratory manager on June 6, 2019 at 3:45 PM, confirmed the technical supervisor failed to ensure the quality control statistical parameters for the Vitros and the Sysmex test systems were established and maintained.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on record reviews and interviews with the laboratory manager, the laboratory failed to provide an on-site general supervisor to provide day-to-day supervision for high-complexity testing. Refer to D6142.
D6142	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results. This STANDARD is not met as evidenced by: Based on laboratory documents and an interview with the laboratory manager, the laboratory failed to provide an on-site general supervisor to provide day-to-day supervision and ensure patient testing for high-complexity testing is reliable and accurate since the last survey on July 24, 2017. Findings: 1. A review of personnel records revealed the laboratory manager, who is also the technical supervisor, failed to ensure 3 out of 6 testing personnel receive proper training and education prior to testing and reporting patients. 2. An interview with the laboratory manager on June 5, 2019 at 8:50 AM, confirmed the laboratory manager was a remote employee working from a different state.
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of

	the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on record reviews, and an interview with the laboratory manager, the laboratory failed to make patient test records and test analyte records available to the surveyor in order to make a determination of the laboratory's compliance. Refer to D5783 and D5805.