Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0698823	12/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Franklin County Medical Center	44 N 1st E, Preston, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a proficiency testing (PT) record review from the College of American Pathologists (CAP) and an interview with the laboratory manager, the laboratory failed to enroll in PT for the subspecialty of Parasitology since the last survey on July 27, 2017. Findings: 1. A CAP PT record review revealed the laboratory failed to enroll in PT for Giardia/ Cryptosporidium performed on the Cardinal Health combo kit since the last survey. 2. An interview on December 12, 2018 at 9:45 A.M., with the laboratory manager, confirmed the laboratory was not enrolled in a CMS-approved PT program since the last survey.
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: Based on a record review and an interview with the laboratory manager, the laboratory failed to retain quality control results, calibration results, and patient test results printed from the Tosoh AIA immunoassay analyzer and the iStat analyzer since the last survey on July 27, 2017. Findings: 1. A review of calibration verification records revealed the laboratory failed to retain all the analyzer printouts for beta human chorionic gonadotropin, prostate-specific antigen, blood gases, and brain natriuretic peptide performed on the iStat and Tosoh. 2. An interview on December 12, 2018 at 11:45 A.M., with the laboratory manager, confirmed the laboratory failed to retain patient, quality control, and calibration verification data from the iStat and Tosoh.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) record review from the College of American Pathologists (CAP) and an interview with the laboratory manager, the laboratory failed to verify the accuracy of the chemistry analyte beta human chorionic gonadotropin (HCG) not scored for all three events in 2018. Findings: 1. A review of CAP PT documents revealed the laboratory failed to evaluate HCG test results not scored by CAP for all three events in 2018. 2. An interview on December 12, 2018 at 9:45 A.M., with the laboratory manager, confirmed HCG results that were not evaluated and scored by AAB and were not verified for accuracy for 2018.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on proficiency a testing (PT) record review from the College of American Pathologists (CAP) and an interview with the laboratory manager, the laboratory failed to verify the accuracy of chemistry analytes scored an artificial 100% for all three events in 2018. This is a repeat deficiency from the previous survey performed on July 27, 2017. Findings: 1. A review of CAP PT documents revealed the laboratory failed to evaluate artificial 100% scores received from CAP for the analytes D-dimer, gamma-glutamyl transferase (GGT), free thyroxine (FT4), free triiodothyronine (FT3), myoglobulin, troponin, phosphorus-serum, and thyroid stimulating hormone (TSH) for all three events in 2018. 2. An interview on December 12, 2018 at 9:45 A. M., with the laboratory manager, confirmed artificial scores of 100% received from CAP for the chemistry analytes were not evaluated and verified for accuracy.

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 a proficiency testing (PT) record review from the College of American Pathologists (CAP) and an interview with the laboratory manager, the laboratory failed to verify the accuracy at least twice a year for chemistry, immunology, toxicology, hematology, and endocrinology analytes since the last survey on July 27, 2017. Findings: 1. A review of CAP PT documents revealed the laboratory failed to verify the accuracy at least twice a year for the following chemistry analytes performed on the Vitros 350: conjugated and unconjugated bilirubin and C-reactive protein; analytes performed on the Tosoh AIA: vitamin D, testosterone, and prostate-specific antigen; MedTox Profile V urine toxicology; iStat: Brain Natriuretic Peptide; Cardinal Health kit: Helicobacter pylori and Horiba Pentra: body fluid counts. 2. An interview on December 12, 2018 at 9:45 A.M., with the laboratory manager, confirmed the analytes were not verified for accuracy at least twice a year.
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 a proficiency testing (PT) record review from the College of American Pathologists (CAP) and an interview with the laboratory manager, the laboratory failed to establish and follow a written policy to monitor, correct, and document problems with proficiency testing since the last survey on July 27, 2017. Findings: 1. A review of proficiency testing (PT) records from the College of American Pathologists revealed the laboratory failed to review, evaluate, and document corrective actions for PT results and failed to evaluate test scores with artificial scores or not graded. 2. An interview on December 12, 2018 at 10:05 A.M., with the laboratory manager, confirmed the laboratory failed to monitor, assess, and document problems with PT.
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 review of the procedure manual and an interview with the laboratory manager, the laboratory failed to write a procedure for tests performed on body fluids since the last survey on July 27, 2017. Findings: 1. A review of the procedure manual revealed the laboratory failed to write a procedure for body fluid tests performed on the Horiba Pentra hematology analyzer and manually on a hemocytometer. 2. An interview on December 12, 2018 at 3:05 P.M., with the laboratory manager, confirmed the laboratory failed to write a body fluid test procedure.
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 manager, the laboratory failed to perform and document calibration verification procedures for the analytes prostate-specific antigen (PSA) and beta human chorionic gonadotropin (HCG) at least once every 6 months on the Tosoh AIA immunoassay analyzer since the last survey on July 27, 2017. This is a repeat deficiency from the last survey on July 27, 2017. Findings: 1. A record review of calibration reports for PSA and HCG revealed the laboratory failed to perform calibration verification since the last survey. 2. An interview on December 12, 2018 at 3:25 P.M., with the laboratory manager,

	confirmed the laboratory failed to perform calibration verifications on HCG and PSA analytes.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory testing personnel failed to perform two levels of quality control material for endocrinology tests prior to reporting patient test results for the dates reviewed May 2 through 18, 2018. Findings: 1. A quality control review and patient report review during May 2-18, 2018 revealed the following number of patients tested without quality control performed: Free Thyroxine: 15 patients; Prostate-Specific antigen: 6 patients; Thyroid Stimulating Hormone: 23 patients; Free Triiodothyronine: 9 patients; and Testosterone: 8 patients. 2. An interview on December 12, 2018 at 4:05 P.M., with the laboratory manager, confirmed the laboratory failed to perform quality control at least once per day of patient testing.
D5503	BACTERIOLOGY CFR(s): 493.1261(a)(2) (a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(2) Each week of use for gram stains. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory failed to performed quality control on gram stains at least once a week since the last survey. Findings: 1. A review of the laboratory documents revealed the laboratory failed to perform quality control once per week or write an Individualized Control Quality Plan (IQCP). 2. An interview on December 12, 2018 at 2:05 P.M., with the laboratory manager, confirmed the laboratory failed to perform quality control at least once a week or write an IQCP for quality control performed on gram stains.
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 procedure review and an interview with the laboratory manager, the

	laboratory failed to establish and follow a written policy or procedure to monitor, assess, and correct problems identified with the analytic system to include the iStat analyzer for the performance of blood gas analytes and brain natriuretic peptide (BNP), as well as problems in the quality control and calibration verification procedures since the last survey on July 27, 2017. Findings: 1. A review of the Individualized Control Quality Plan (IQCP) for blood gas and BNP revealed the laboratory failed to write a Quality Assessment Plan (QAP) for BNP and blood gases performed on the iStat. 2. A review of laboratory documents revealed the laboratory failed to establish and follow procedures to ensure the quality of laboratory tests performed without proficiency testing and accuracy documentation. 3. An interview on December 12, 2018 at 12:55 P.M., with the laboratory manager, confirmed the laboratory failed to establish a QAP for the iStat analytes and failed to ensure the laboratory established a system to monitor and document the accuracy of laboratory tests.
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 indicate the name and the address of the reference laboratory where laboratory tests were reported on patients for the period reviewed between September 2018 through December 2018. This is a repeat deficiency from the last survey on July 27, 2017. Findings: 1. A review of patient laboratory test reports, revealed the address of the reference laboratory where tests were performed failed to be included on the patient's test reports. 2. An interview on December 12, 2018 at 2:05 P.M., with the laboratory manager, confirmed the address of the reference laboratory failed to be indicated on patient laboratory 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 deficient practices in the laboratory, the laboratory director failed to provide overall management and direction for the laboratory. This is a repeat deficiency from the last inspection on July 27, 2107. Refer to D6088, D6091, D6093, D6094, and D6097.

D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) records from the College of American Pathologists (CAP) and an interview with the laboratory manager, the laboratory director failed to ensure the subspecialty of Parasitology was properly enrolled in PT since the last survey on July 27, 2017. Findings: 1. A record review of PT documents from CAP revealed the laboratory director failed to ensure the laboratory was enrolled in a CMS-approved PT program for the type of testing performed in Parasitology. 2. An interview on December 12, 2018 at 5:05 P.M., with the laboratory manager, confirmed the laboratory director failed to ensure the laboratory was properly enrolled in PT for type of testing performed.
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 proficiency testing (PT) record reviews and an interview with the laboratory manager, the laboratory director failed to ensure all proficiency testing scores are reviewed by the appropriate personnel to evaluate and identify problems with proficiency testing from the time reviewed between 2017 event 3 through 2018 event 3. Findings: 1. A review of PT documents from the College of American Pathologists (CAP) revealed the laboratory director failed to evaluate and identify problems in the laboratory's performance of testing in the specialty of chemistry and immunology. 2. An interview on December 11, 2018 at 4:45 PM, with the laboratory manager, confirmed the laboratory director failed to evaluate and identify problems that would require corrective actions and verification of accuracy in the laboratory's performance of PT.
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 in the laboratory, the laboratory director failed to ensure the laboratory quality control procedures for the test systems met all CLIA regulations since the last survey on July 27, 2017. Findings: 1. A review of the

	quality control documents for immunoassays performed on the Tosoh and chemistries analytes performed on the Vitros 350 revealed quality control requirements were not followed according to manufacturer recommendations and CLIA regulations.
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 a review of laboratory documents the laboratory director failed to ensure the laboratory established and followed a quality assessment program to monitor, assess and correct problems in the laboratory since the last survey on July 27, 2017. Findings: 1. A review of laboratory documents revealed the laboratory director failed to monitor, identify, and correct problems in proficiency testing, retention, and quality programs for the test systems.
D6097	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: Based on reviews and the lack of proficiency testing records, as well as reviews of the quality control activities for the laboratory, the laboratory director failed to ensure that patient test results are reported only when the test systems are functioning.