Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0698823	04/13/2021
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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a direct observation and an interview with the laboratory manger on 4/13 /2021, the laboratory failed to discontinue the use of expired specimen collection tubes. The findings include: 1. A direct observation of the phlebotomy draw trays on 4 /13/2021 identified that the laboratory failed to discontinue the use of seven (7) BD buffered sodium citrate 3.2%, 1.2 ml tubes, lot 0184335, expiration 1/31/2021 and sixteen (16) BD PST with polymer gel and lithium heparin tubes, lot 8249569, expiration 9/30/2019. 2. An interview with the laboratory manager on 4/13/2021 at 12: 00 pm confirmed the above finding.
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 a random review of maintenance logs and an interview with the laboratory manager on 4/12/2021, the laboratory failed to perform and document maintenance with the frequency defined by the manufacturer. The findings include: 1. A random review of laboratory maintenance logs from 2019, 2020 and 2021 identified the

	laboratory failed to perform and document maintenance as required by instrument manufacturers. No monthly maintenance was performed in January, February and March 2021 on the Tosoh AIA 900. The laboratory performed 348 tests on the Tosoh in January 2021, 298 tests in February 2021 and 382 tests in March 2021. No weekly maintenance was performed the third and fourth weeks in February 2021 on the Vitros 350. The laboratory performed testing on 151 patient samples the third week in February and 155 patient samples the fourth week in February on the Vitros 350. No daily maintenance was performed on the Horiba ABX Pentra, Tosoh AIA 900 and Vitros 350 on February 18, 2021. The laboratory performed tests on 47 patient samples on February 18, 2021. 2. An interview with the laboratory manager on 4/12 /2021 at 1:55 pm confirmed the above findings.
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 random record review of Quality Control (QC) documentation and an interview with the laboratory manager on 4/12/2021 the laboratory failed to successfully perform two levels of QC daily for each quantitative procedure. The findings include: 1. A random record review of QC documents from the Vitros 350 for 2019, 2020 and 2021 identified that the laboratory failed to document QC results for all chemistry analytes on 9/8/2020. The laboratory performed chemistry tests on 60 patient samples on 9/8/2020. 2. A random record review of QC documents from the Sysmex CA-600 for 2019, 2020 and 2021 identified that the laboratory failed to document QC results for level 1 for D-dimer on 2/1/2021 and level 2 for D-dimer on 2 /15/2021. The laboratory performed one patient D-dimer test on each of the above days. 3. A random record review of QC documents from the Horiba ABX Pentra XL 80 for 2019, 2020 and 2021 identified that the laboratory failed to document QC results for level 1 and 2 for complete blood counts on 2/19/2021. The laboratory performed 25 compete blood counts on the Horiba ABX Pentra XL 80 on 2/19/2021. 4. An interview with the laboratory manager on 4/12/2021 at 3:55 confirmed the above findings.
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(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-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a random review of immunohematology quality control (QC) records and an

	interview with testing personnel 2 (TP2) on 4/13/2021, the laboratory failed to document control material results with graded or titered reactivity and include negative control material. The findings include: 1. A random record review of immunohematology QC for 2019 and 2020 identified that the laboratory failed to document positive QC (1-4+) and negative QC on 1/8/2020, 2/22/2020 and 11/10 /2020 as required by regulation for blood and Rh type, antibody screen and crossmatch testing. 2. One prenatal screen and one blood and Rh type, antibody screen and crossmatch of two units were performed on 1/8/2020. One blood and Rh type, antibody screen and crossmatch of two units was performed on 2/22/2020. One blood and Rh type, antibody screen and crossmatch of two units was performed on 11/10 /2020. 3. An interview with TP2 on 4/13/2021 at 10:30 am confirmed the above findings. 4. The laboratory reports performing 300 immunohematology tests annually.
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 a record review and an interview with the laboratory testing personnel 1 (TP1) on 4/13/2021, the laboratory failed to check each lot of media for its ability to support growth and/or inhibit growth. The findings include: 1. A review of media quality control (QC) records that came with media received from Intermountain Laboratories identified that the laboratory failed to perform and document QC to show the ability of the media to support growth on MacConkey Agar lot number 21014081 (Becton Dickinson), Trypticase Soy Agar 5% Sheep Blood lot number 1007815 (Becton Dickinson), and Thioglycollate Liquid Medium (Becton Dickinson). 2. A review of patient test records and invoices from Hardy Diagnostics identified that the laboratory failed to perform and document QC to show the ability of the media to support growth in Strep B Carrot Broth and on GBS Detect Agar. 3. A review of media invoices Hardy Diagnostics and QC records that came with media received from Intermountain Laboratories identified that the laboratory failed to perform and document QC to show the ability of the media to inhibit growth on MacConkey Agar and in Strep B Carrot Broth. 4. An interview with TP1 on 4/13/2021 at 11:40 am confirmed that the laboratory failed to perform QC on media before it was used for patient testing. 5. The laboratory reports performing 830 bacterial cultures annually.