Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0521434	08/29/2024
Name of Provider or Supplier	**Street Address, City, State**	
Weiser Memorial Hospital	645 E 5th St, Weiser, 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
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 laboratory's policies and procedures, a lack of quality control (QC) documents for the AmniSure ROM assay and an interview with the laboratory manager on 8/29/2024, the laboratory failed to perform QC as established by the laboratory and specified by the manufacturer in 2022, 2023 and 2024. The findings include: 1. A review of the laboratory's policies and procedures identified that the laboratory established QC frequency based on the manufacturer's recommendation in their Individualized Quality Control Plan (IQCP) for the AmniSure ROM assay as external QC performed with each new lot and monthly. 2. A lack of documents for QC testing for the AmniSure ROM assay identified that the laboratory failed to ensure QC was performed by labor and delivery at least once per month as established in the IQCP since the last inspection (10/6/2022). 3. An interview with the laboratory manager on 8/29/2024 at 12:13 pm confirmed the above findings. 4. The laboratory reports performing 11 AmniSure ROM assays annually. 5. This is a repeat deficiency for failure to perform QC for the AmniSure ROM Assay from the previous inspection (10/6/2022).
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 review of Quality Control (QC) documentation and an interview with the laboratory manager on 8/28/2024 the laboratory failed to successfully perform two levels of QC for each day of patient testing for ferritin in 2023. The findings include: 1. A random record review of QC documents from the Vitros 5600 for 2023 and 2024 identified that the laboratory failed to perform two levels of QC for ferritin on 12/14 /2023. The laboratory performed one patient ferritin test (10021887) on 12/14/2023. 2. An interview with the laboratory manager on 8/28/2024 at 2:27 pm confirmed the above finding. 3. The laboratory reports performing 152 ferritin tests annually.
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 review of patient test reports and an interview with the laboratory manager on 8/29/2024, the laboratory failed to clearly indicate the name of the performing laboratory for the reported tests. The findings include: 1. A review of laboratory patient test reports for chemistry and toxicology testing identified that the laboratory failed to clearly indicate the name of the performing laboratory when testing was performed by a reference laboratory. 2. An interview with the laboratory manager on 8 /29/2024 at 12:54 pm confirmed the above finding. 3. The laboratory reports performing 125,286 tests annually.