

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0521434	(X3) Date Survey Completed 10/06/2022
Name of Provider or Supplier Weiser Memorial Hospital	Street Address, City, State 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
D2003	<p>ENROLLMENT CFR(s): 493.801(a)(2)(ii)</p> <p>For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1)</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records from American Proficiency Institute (API), and an interview with the laboratory manager on 10/6/2022, the laboratory failed to enroll in proficiency testing to verify the accuracy of testing for the AmniSure Rom assay in accordance with 493.1236(c)(1). The findings include: 1. A review of proficiency testing records from API identified that the laboratory failed to ensure the verification of testing accuracy for the AmniSure Rom assay biannually for 2021 and 2022. 2. An interview with the laboratory manager on 10/6/2022 at 9:13 am confirmed that the laboratory failed to ensure the verification of testing accuracy for the AmniSure Rom assay biannually for 2021 and 2022. 3. The laboratory reports performing 11 AmniSure Rom Assays annually.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of Cepheid GeneXpert maintenance logs and an interview with the laboratory manager on 10/6/2022, the laboratory failed to perform maintenance as</p>

required by the manufacturer. The findings include: 1. A lack of Cepheid GeneXpert maintenance logs identified that the laboratory failed to perform daily, weekly, monthly and quarterly maintenance as required by the manufacturer since beginning testing in January of 2021. 2. An interview with the laboratory manager on 10/6/2022 at 9:00 am confirmed that the laboratory failed to document maintenance on the Cepheid GeneXpert. 3. The laboratory reports performing 268 tests annually on the Cepheid GeneXpert.

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, quality control (QC) documents for the Triage, lack of QC documents for the AmniSure ROM assay and interviews with the laboratory manager and labor and delivery charge nurse on 10/5 /2022 and 10/6/22 respectively, the laboratory failed to perform QC once each day of patient testing. The findings include: 1. A review of the laboratory's policies and procedures identified that the laboratory failed to have an Individualized Quality Control Plan (IQCP) for D-Dimer testing performed on the Triage and the AmniSure ROM assay. 2. A review of QC for D-Dimer testing on the Triage identified that the laboratory failed to perform QC each day of patient testing. 3. A lack of documents for QC testing for the AmniSure ROM assay identified that the laboratory failed to ensure QC was performed each day of patient testing. 4. An interview with the laboratory manager on 10/5/2022 at 9:42 am confirmed that the laboratory did not have an IQCP for D-Dimer testing performed on the Triage and only performed QC once per month. 5. An interview with the labor and delivery charge nurse on 10/6 /2022 at 11:30 am confirmed that the laboratory did not have an IQCP for AmniSure ROM assay and did not perform QC.

D5545

HEMATOLOGY
CFR(s): 493.1269(b)(d)

(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) 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 of Sysmex CA 620 coagulation quality control (QC) documentation, patient logs, and an interview with testing personnel 1 (TP1) on 10/5 /2022, the laboratory failed to include two levels of QC material every 8 hours of patient testing. The findings include: 1. A random record review of prothrombin time

(PT) and partial thromboplastin time (PTT) QC identified that the laboratory failed to document two levels of QC every 8 hours when patient testing occurred for three days in July 2021, four days in October 2021, one day in December 2021 and two days in January 2022. 2. A review of the laboratory's patient results identified three patient PT/INRs reported on 7/3/2021, one patient PT/INR and PTT reported on 7/14/2021, one patient PT/INR and PTT reported on 7/15/2021, one patient PT/INR and PTT reported on 10/1/2021, one patient PT/INR reported on 10/2/2021, one patient PT/INR and PTT reported on 10/7/2021, one patient PT/INR and PTT reported on 10/14/2021, one patient PT/INR reported on 12/31/2021, one patient PT/INR reported on 1/1/2022, two patient PT/INRs reported on 1/14/202. 3. An interview with TP1 on 10/5/2022 at 12:42 pm confirmed that QC was not documented every 8 hours of patient testing on the above dates. 4. This is a repeat deficiency from the previous inspection on 4/21/2021. 5. The laboratory reports performing 975 PT/INR and PTT tests annually.

D6013

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(ii)

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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:
Based on a record review of the Cepheid test verifications, BioFire test verification and an interview with the laboratory manager on 10/5/2022, the laboratory director failed to ensure that the instrument verifications were adequate. The findings include:
1. A record review of the new test verification of Xpert C. difficile, performed on the Cepheid, identified that the laboratory director failed to review and approve the verification results for accuracy and precision to ensure that they were adequate before beginning patient testing in January 2021. 2. A record review of the new test verification of Xpert MRSA/SA SSTI, performed on the Cepheid, identified that the laboratory director failed to review and approve the verification results for accuracy and precision to ensure that they were adequate before beginning patient testing in January 2021. 3. A record review of the new test verification of Xpert Xpress SARS-CoV-2, performed on the Cepheid, identified that the laboratory director failed to review and approve the verification results for accuracy and precision to ensure that they were adequate before beginning patient testing in June 2021. 4. A record review of the new test verification of Xpert Xpress SARS-CoV-2/Flu/RSV, performed on the Cepheid, identified that the laboratory director failed to review and approve the verification results for accuracy and precision to ensure that they were adequate before beginning patient testing in December 2021. 5. A record review of the new test verification of BioFire Respiratory 2.1 (RP2.1) Panel, performed on the BioFire FilmArray Torch System, identified that the laboratory director failed to review and approve the verification results for accuracy and precision to ensure that they were adequate before beginning patient testing in January 2021. 6. An interview with the laboratory manager on 10/5/2022 at 4:34 pm confirmed the above findings. 7. The laboratory reports performing 982 Cepheid and BioFire tests annually.

D6072

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(3)

Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:

Based on a review of Sysmex CA 620 quality control (QC) documents, patient records, laboratory procedures and an interview with the laboratory manager on 10/5/2022, the testing personnel failed to perform and document QC as stated in the laboratory procedure and required by federal regulations. The findings include: 1. A review of QC and patient records from the Sysmex CA 620, used for prothrombin time (PT) and partial thromboplastin time (PTT) testing, and a review of the "CA 620: Principle and Operation," procedure identified that the testing personnel failed to perform and document QC every eight hours of patient testing as required by the laboratory procedure and federal regulations. See D5545 2. An interview with the laboratory manager on 10/5/2022 at 4:57 pm confirmed that the procedure and regulations were not followed by testing personnel. 3. The laboratory reports performing 975 of PT/INR and PTT tests annually.