

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D0386363	<b>(X3) Date Survey Completed</b>  04/13/2021
<b>Name of Provider or Supplier</b>  Veterans Memorial Hospital	<b>Street Address, City, State</b>  40 First Street Se, Waukon, IA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of proficiency testing records and confirmed by laboratory personnel identifier #8 (refer to the Laboratory Personnel Report) at approximately 9:30 am on 01/12/2021, the laboratory failed to enroll in an approved proficiency testing program for the subspecialty, bacteriology (Streptococcus agalactiae screen by PCR) for two out of two years from 2020- 2021. The findings include: 1. The Laboratory Test List &amp; Annual volume form indicated that the laboratory performed bacteriology testing including Streptococcus agalactiae screens by PCR. 2. At the time of the survey, personnel identifier #8 confirmed that the laboratory did not enroll in an approved proficiency testing program for the subspecialty of bacteriology (Streptococcus agalactiae screen by PCR) from 2020- 2021.</p>
<b>D5421</b>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the</p>

manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
Based on review of performance specification records and confirmed by Laboratory Personnel identifier #8 (refer to the Laboratory Personnel Report) at approximately 3:15 pm on 04/13/2021, the laboratory failed to verify the performance specifications of precision and reportable range for the HemoCue WBC (white blood cell) test system. The findings include: 1. The laboratory implemented the HemoCue WBC test system in August 2020. 2. At the time of the survey, the laboratory did not have precision or reportable range performance specification records for the HemoCue WBC test system.

**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 review of the laboratory's Individualized Quality Control Plans (IQCP) and confirmed by laboratory personnel identifier #8 (refer to the Laboratory Personnel Report) at approximately 1:00 pm on 04/13/2021, the laboratory failed to establish written quality control and quality assessment plans for the following test system IQCPs: FilmArray BioFire and Clearview PBP2a SA Culture Colony Test.

**D5481**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on review of coagulation (D-dimer) and erythrocyte sedimentation rate (ESR) quality control (QC) records and confirmed by laboratory personnel identifier #8 (refer to the Laboratory Personnel Report) at approximately 3:30 pm on 04/13/2021, the laboratory failed to ensure that results of control materials met the laboratory's and manufacturer's test system criteria for acceptability before reporting coagulation (D-dimer) patient test results for 2 out of 11 days of patient testing and ESR patient test results for seven out of 24 days of patient testing in September 2020. Refer to D5783 for findings.

**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:

A. Based on review of coagulation quality control (QC) records and confirmed by laboratory personnel identifier #8 (refer to the Laboratory Personnel Report) at approximately 1:00 pm on 04/13/2021, the laboratory failed to take and document corrective action when coagulation (d-dimer) QC failed to meet the laboratory's established criteria for two out of 11 days of patient testing in September 2020. The findings include: 1. For Innovance D-dimer control lot number 562161 (expiration 02/12/2022), the laboratory had an acceptable range of 2.34- 3.52 mg/l. 2. On 09/15/2020, the laboratory recorded a QC result of 3.53 mg/l. 3. On 09/16/2020, the laboratory recorded a QC result of 3.59 mg/l. 4. At the time of the survey, the laboratory did not have corrective action for the out of range QC on 09/15/2020 and 09/16/2020. B. Based on review of erythrocyte sedimentation rate (ESR) quality control (QC) records and confirmed by laboratory personnel identifier #8 (refer to the Laboratory Personnel Report) at approximately 3:30 pm on 04/13/2021, the laboratory failed to take and document corrective action when ESR QC failed to meet the laboratory's established criteria for seven out of 24 days of patient testing in September 2020. The findings include: 1. For Hematechnologies ESR control lot number SR 0720-2 (expiration 01/05/2021), the laboratory had an acceptable range of 54-94 mm/hr. 2. On 09/02/2020 and 09/14/2020, the laboratory recorded a QC result of 47 mm/hr. 3. On 09/03/2020, the laboratory recorded a QC result of 40 mm/hr. 4. On 09/05/2020 and 09/30/2020, the laboratory recorded a QC result of 45 mm/hr. 5. On 09/20/2020, the laboratory recorded a QC result of 49 mm/hr. 6. On 09/23/2020, the laboratory recorded a QC result of 46 mm/hr. 7. At the time of the survey, the laboratory did not have corrective action for the out of range QC on the dates listed above.