

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0385651	(X3) Date Survey Completed 09/20/2018
Name of Provider or Supplier Horn Memorial Hospital	Street Address, City, State 701 East Second Street, Ida Grove, IA	
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	<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 interview with laboratory personnel identifier #9 (refer to Laboratory Personnel Report) at approximately 9:30 am on 09/20/2018, the laboratory failed to enroll in an approved proficiency testing program for two out of two years (2017 and 2018) for the subspecialty, bacteriology - throat cultures. The findings include: 1. During the tour of the facility, laboratory personnel identifier #9 stated the laboratory performed throat cultures on all patients that had a negative rapid Group A Streptococcus test result. 2. At the time of the survey, the laboratory failed to enroll in an approved proficiency testing program for subspecialty, bacteriology - throat cultures.</p>
D5024	<p>HEMATOLOGY CFR(s): 493.1215</p> <p>If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.</p>

This CONDITION is not met as evidenced by:
Based on review of coagulation reagent studies, observations of the coagulation analyzer and confirmed by laboratory personnel identifier #9 (refer to the Laboratory Personnel Report) at approximately 1:30 pm on 09/20/2018, the laboratory failed to meet the hematology (coagulation) requirements for test system/equipment/reagent verification as specified in the standard D5411 (A and B).

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

A. Based on observations made during the survey, review of coagulation reagent studies and confirmed by laboratory personnel identifier #9 (refer to the Laboratory Personnel Report) at approximately 1:15 pm on 09/20/2018, the laboratory failed to program the correct normal patient mean for lot number N1072885, expiration date 10/31/2019 of Prothrombin Time (PT) reagent into the ACL Elite coagulation analyzer. The findings include: 1. The laboratory must establish a normal patient mean with each new lot number of PT reagent. 2. For lot number N1072885, expiration date 10/31/2019 of PT reagent the laboratory calculated a normal patient mean of 11.8 seconds. 3. At the time of the survey, the laboratory had programmed into the ACL Elite coagulation analyzer the normal patient mean as 10.8 seconds. 4. Laboratory personnel identifier #9, confirmed the laboratory programmed the wrong normal patient mean into the ACL Elite coagulation analyzer. B. Based on review of coagulation reagent studies and confirmed by laboratory personnel identifier #9 (refer to Laboratory Personnel Report) at approximately 1:30 pm on 09/20/2018, the laboratory failed to verify the manual calculation of the international normalized ratio (INR) using the correct normal patient mean value for one out of one lot number of Prothrombin time (PT) reagent (N1072885, expiration date 10/31/2019) in July 2018. The findings include: 1. For lot number N1072885, expiration date 10/31/2019 of PT reagent the laboratory calculated a normal patient mean of 11.8 seconds. 2. In July 2018, the laboratory verified a manual calculation of the INR incorrectly, using the normal patient mean of 11.1 seconds. 3. Laboratory personnel identifier #9, confirmed the laboratory used the wrong normal patient mean when verifying the manual calculation of the INR. C. Based on review of the throat culture procedure, QuickVue In-Line Strep A manufacturer's instructions, and confirmed by laboratory personnel identifier #9 (refer to the Laboratory Personnel Report) at approximately 2:00 pm on 09/20/2018, the laboratory failed to follow manufacturer's instructions and performed testing outside of the stated performance specifications while performing confirmatory Streptococcus Group A testing using the waived QuickVue In-Line Strep A test kit for one out of one patient (Patient identifier A) on 03/02/2018. The findings include: 1. Patient A had a throat culture performed on 03/02/2018. 2. The laboratory throat culture procedure stated, "At 48 hours, observe the blood agar plate by holding the plate up to the light and looking at the uncovered side of the agar. If beta hemolysis is present, retrieve a Rapid Strep A kit and using the swab from the kit collect colonies showing beta hemolysis. Place swab in test cartridge and proceed as indicated by the test kit procedure." 3. The QuickVue In-Line Strep A manufacturer's

instructions stated, "The QuickVue In-Line Strep A Test allows for the rapid detection of Group A Streptococcal antigen directly from patient throat swab specimens." The manufacturer's instructions do not allow for confirmatory testing to be performed directly from a blood agar plate. 4. At the time of the survey, the laboratory failed to follow manufacturer's instructions and performed testing outside of the stated performance specifications when performing confirmatory throat cultures.

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 review of media records and confirmed by laboratory personnel identifier #9 (refer to Laboratory Personnel Report) at approximately 2:30 pm on 09/20/2018, the laboratory failed to check each lot of media for sterility and the ability to support growth for two lot numbers of media (lot numbers 384932 and 381082) received in September 2018. The findings include: 1. The laboratory retained the manufacturer's quality control (QC) certificates for lot number 384932, expiration date 10/16/2018 and lot number 381082 expiration date 10/09/2018 of blood agar 5% sheep blood. 2. Laboratory personnel identifier #9 indicated that the laboratory intended to retain the manufacturer's QC certificates and not perform additional QC. 3. At the time of the survey, the laboratory did not have an Individualized Quality Control Plan (IQCP) for media.