

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0038621	(X3) Date Survey Completed 09/20/2022
Name of Provider or Supplier Spencer Hospital	Street Address, City, State 1200 First Avenue East, Spencer, 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, the Spencer Hospital Laboratory Test List & Annual volume form, quality control and calibration records, and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 3:00 pm on 09/19/2022, the laboratory failed to enroll in an approved proficiency testing program for the analyte, fibrinogen in 2022. The findings include: 1. The Spencer Hospital Laboratory Test List & Annual volume form lists fibrinogen testing as being performed by the laboratory. 2. The laboratory performed quality control for the analyte, fibrinogen for the month of May 2022. 3. The laboratory performed calibration of the analyte, fibrinogen on 1/21/22 and 7/27/2022. 4. At the time of the survey, the laboratory did not enroll in an approved proficiency testing program in 2022 for the analyte, fibrinogen.</p>
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance</p>

(that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on review of proficiency testing (PT) records and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 3:00 pm on 09/19/2022, the laboratory failed to perform a self evaluation of ungraded PT scores for four out of five PT testing events from 1/1/2021 - 9/20/2022. The findings include: 1. For 2021 testing event 1, the laboratory received ungraded PT test scores for the following: *Beta lactamase, specimen ES-01; *Gentamicin synergy ES-01; *Cerebrospinal fluid minimum inhibitory concentration value, specimen SF-01; *Cerebrospinal fluid susceptibility interpretation, specimen SF-01; *Stool culture, specimen SC-01; *Urine culture minimum inhibitory concentration value, specimen UR-01; and *Urine culture susceptibility interpretation, specimen UR-01. 2. For 2021 event 2, the laboratory received ungraded PT test scores for the following: *Folate, specimen IA-07 and IA-08. 3. For 2022 testing event 1, the laboratory received ungraded PT test scores for the following: *Cerebrospinal fluid minimum inhibitory concentration value, specimen SF-01; *Gram stain, specimen GS-05; and *Urine culture minimum inhibitory concentration value, specimen UR-01. 4. For 2022 testing event 2, the laboratory received ungraded PT test scores for the following: *Urine culture minimum inhibitory concentration value, specimen UR-06; *Urine culture susceptibility interpretation, specimen UR-01; and *Compatibility testing, specimen ER-06. 5. At the time of the survey, the laboratory did not perform a self evaluation for the above ungraded PT test scores.

D5507

BACTERIOLOGY

CFR(s): 493.1261(b)(c)

(b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on Individualized Quality Control Plan (IQCP), review of antimicrobial susceptibility testing (AST) quality control (QC) and patient test reports, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 12:00 pm on 09/20/2022, the laboratory failed to ensure minimum inhibitory concentrations fell within the established limits for one out four weeks of patient testing in May 2022. The findings include: 1. The Susceptibility IQCP stated that the laboratory would perform susceptibility testing QC weekly. 2. On 5/23/22, the laboratory performed QC using the organism *Streptococcus pneumoniae* on the Gram positive *Streptococcus* species (AST-ST02) card (lot number 541203523, expiration date 6/23/2023). The laboratory established range a of 0.25 - 1 for the antibiotic, benzylpenicillin for this specific lot number of AST-ST02 cards using the organism *Streptococcus pneumoniae*. 3. On 5/23/22, the laboratory received a result

of TRM (terminated result) for the antibiotic benzylpenicillin for this specific lot number of AST-ST02 cards using the organism Streptococcus pneumoniae. 4. The laboratory performed testing on 2 patients using the AST-ST02 susceptibility card the week of 5/23/2022. 5. At the time of the survey, the laboratory did not document corrective action or ensure that QC results fell within the established limits for the AST-ST02 susceptibility card.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on review of personnel records and the Spencer Hospital Laboratory Test List & Annual Volume form and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 2:00 pm on 9/19/2022, the technical supervisor failed to evaluate the competency of each test system for nine out of nine testing personnel (identifiers #1 - #9) in 2021. The findings include: 1. The 2021 competency assessments for testing personnel identifiers #1 - #9 included a review of the following laboratory sections: urinalysis, chemistry, hematology/coagulations, microbiology and blood bank. 2. The Spencer Hospital Laboratory Test List & Annual Volume form indicated the laboratory also performed testing using the following test systems: Sure-Vue rheumatoid factor, ABL 800 Flex blood gas analyzer, Adeza TLiQ fetal fibronectin analyzer, Fiske Micro-Osmometer, BioRad rapid drug screen, sedimat II analyzer, and OrigioSemen analysis test kit. 3. At the time of the survey, the 2021 competency assessments did not include the test systems listed in finding #2.