

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0869868	(X3) Date Survey Completed 10/29/2019
Name of Provider or Supplier Scott County Health Department	Street Address, City, State 600 West 4th Street, Davenport, 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
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of patient test reports, the Laboratory Test List & Annual Volume form, and confirmed by laboratory personnel identifier #5 (refer to the Laboratory Personnel Report) at approximately 10:00 am on 10/29/2019, the laboratory failed to indicate the name and address of the testing facility for four out of four patient test reports (patient identifiers A, B, C, and D). The findings include: 1. Patient identifier A had a gram stain performed on 04/12/2019. Patient A also had the following testing performed on 04/17/2019: Reagin antibody, Treponema pallidum antibody, Neisseria gonorrhoeae rRNA (urine), and Chlamydia trachomatis rRNA (urine). 2. Patient identifier B had a gram stain performed on 04/09/2019. Patient B also had the following testing performed on 04/15/2019: Neisseria gonorrhoeae rRNA (throat), Chlamydia trachomatis rRNA (throat), Neisseria gonorrhoeae rRNA (urine), and Chlamydia trachomatis rRNA (urine). 3. Patient identifier C had a wet prep examination performed on 04/12/2019. Patient C also had the following testing performed on 04/17/2019: Neisseria gonorrhoeae rRNA (cervix) and Chlamydia trachomatis rRNA (cervix). 4. Patient identifier D had a wet prep examination performed on 04/30/2019. Patient D also had the following testing performed on 05/06/2019: Neisseria gonorrhoeae rRNA (throat), Chlamydia trachomatis rRNA (throat),</p>

Neisseria gonorrhoeae rRNA (cervix), and Chlamydia trachomatis rRNA (cervix). 5. The Laboratory Test List & Annual Volume form indicated the laboratory performed the following non-waived testing: gram stain, potassium hydroxide (KOH) preparation, and wet prep examination. 6. Personnel identifier #5 confirmed that the laboratory sent additional testing to a reference laboratory. 7. Test reports for Patients A, B, C, and D did not include the name and address of the laboratory or the reference laboratory. In addition, the test reports did not identify which tests the laboratory performed and which tests the reference laboratory performed.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's chart audit policy, review of chart audit documentation, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 11:00 am on 10/29/2019, the laboratory director failed to ensure that the laboratory maintained the quality assessment program for seven out of seven time periods from 01/01/2018- 09/30 /2019. The findings include: 1. The laboratory's "Practice Fusion Chart Audit Procedure" policy stated, "Chart audits shall be conducted each fiscal year for the following time periods: July 1- September 30; October 1- December 31; January 1- March 31; April 1- June 30." The policy also stated, "Ten percent of the total number of clients seen each quarter shall be audited." 2. At the time of the survey, personnel identifier #2 confirmed that the laboratory did not perform chart audits from 01/01 /2018- 09/30/2019.