

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D0454733	(X3) Date Survey Completed 07/17/2019
Name of Provider or Supplier Jefferson Community Health & Life - Fairbury	Street Address, City, State 825 22nd Street, Fairbury, NE	
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
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of 2017 and 2018 competency records and lack of approved procedure manual the laboratory director, who is filling the role of technical consultant, failed to provide technical oversight and failed to fulfill technical consultant responsibilities. Refer to D6030, D6031, and D6033.</p>
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by: Based on review of testing personnel listed on the CMS-209, review of 2017 and 2018</p>

	<p>testing personnel competencies, and interview with Lab Manager, not listed on CMS-209, the laboratory director (who is filling the role of technical consultant) failed to perform competencies on personnel performing moderate complexity testing. Refer to D6046.</p>
<p>D6031</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)</p> <p>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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;</p> <p>This STANDARD is not met as evidenced by: Based on lack of procedure manual and interview with Lab Manager, not listed on CMS-209, the laboratory director failed to have an approved procedure manual available to personnel. Findings are: 1. No approved procedure manual was available on day of survey. 2. Interview with Lab Manager, not listed on CMS-209, on 7/17 /2019 at 11:00 AM confirmed no approved procedure manual was available to personnel.</p>
<p>D6033</p>	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of competency records and review of quality control records the technical consultant failed to provide technical oversight and failed to fulfill technical consultant responsibilities. Refer to D6046 and D6049.</p>
<p>D6046</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of testing personnel listed on the CMS-209, review of 2017 and 2018 testing personnel competencies, and interview with Lab Manager, not listed on CMS-209, the laboratory failed to have technical consultant perform competencies on personnel performing moderate complexity testing. Findings are: 1. Review of the CMS-209 personnel form presented by the laboratory at the time of survey on 7/17 /2019 revealed five testing personnel performing moderate complexity testing. 2. Review of 2017 and 2018 annual competencies for the five testing personnel revealed</p>

	<p>the Lab Manager, not listed on CMS-209, had signed off on competencies. The Lab Manager is not qualified as a technical consultant. 3. Interview with the Lab Manager, not listed on CMS-209, on 7/17/2019 at 1:00 PM revealed the technical consultant did not perform competencies on the five testing personnel performing moderate complexity testing.</p>
<p>D6049</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.</p> <p>This STANDARD is not met as evidenced by: Based on review of hematology quality control records and an interview with testing personnel #3, as listed on the CMS-209, the laboratory failed to document the review of hematology quality control records for 2019. Findings are: 1. Review of hematology quality control records for 2019 revealed laboratory director, who performs the function of the technical consultant, did not review hematology quality control records. 2. Interview with testing personnel #3, as listed on the CMS-209, on 7 /17/2019 at 1:15 PM revealed testing personnel #3, who is not qualified as a technical consultant, reviewed hematology quality control records for 2019.</p>
<p>D6063</p>	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: Based on lack of documentation the laboratory failed to have proof of education on testing personnel #5, as listed on the CMS-209, performing moderate complex testing. Refer to D6065.</p>
<p>D6065</p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and</p>

This STANDARD is not met as evidenced by:

Based on lack of documentation and interview with testing personnel #5, as listed on the CMS-209, on 7/17/2019 at 12:15 PM the laboratory failed to have proof of education on one out of five testing personnel performing moderate complexity testing. Findings are: 1. No proof of education documentation for testing personnel #5, as listed on the CMS-209, performing moderate complex testing was presented. 2. Interview with testing personnel #5, as listed on the CMS-209, confirmed no documentation was available.