

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D2175316	<b>(X3) Date Survey Completed</b>  05/11/2022
<b>Name of Provider or Supplier</b>  Infinity Health	<b>Street Address, City, State</b>  219 W Washington Street, Osceola, 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>D3037</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 8:30 am on 5/11/2022, the laboratory failed to retain proficiency testing records for two out of four testing events from 1/1/2021 - 5/18/2022. The findings include: 1. For 2021 event 2, the laboratory failed to retain the signed PT attestation forms and the forms submitted to the PT company. 2. For 2022 event 1, the laboratory failed to retain the signed PT attestation forms and the forms submitted to the PT company. 3. At the time of the survey, the laboratory did not have the above PT forms.</p>
<b>D6018</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(iii)</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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing records and confirmed by laboratory personnel #1 (refer to the Laboratory Personnel Report) at approximately 8:30 am on 5/11/2022,</p>

	<p>the laboratory director failed to document corrective action when the laboratory received a score of zero for 2021 event 3 analytes, white blood cell count, automated white blood cell differential, red blood cell count, hematocrit, hemoglobin, and platelets.</p>
<p><b>D6030</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> 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 the laboratory procedure manual and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 9:00 am on 5/11/2022, the laboratory director failed to ensure the laboratory established policies and procedures for performing training, semiannual competencies, and annual competencies for moderate complexity testing personnel.</p>
<p><b>D6053</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel records and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 8:15 am on 05/11/2022, the technical consultant failed to assess the competency of individuals performing moderate complexity testing at least semiannually during the first year the individual tests patient specimens for two out of three new testing personnel (laboratory personnel identifiers #2 and #3). The findings include: 1. Testing personnel #2 began performing moderate complexity testing on 3/17/2021. 2. Testing personnel #3 began performing moderate complexity testing on 7/6/2021. 3. At the time of the survey, the laboratory did not have semiannual competencies for personnel #2 and #3.</p>
<p><b>D6054</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p>

This STANDARD is not met as evidenced by:  
Based on review of personnel records and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 8:15 am on 05/11 /2022, the technical consultant failed to assess and document the competency of individuals performing moderate complexity testing at least annually for four out of four testing personnel (laboratory personnel identifiers #1, #4, #5 and #6) in 2021.