

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0385677	(X3) Date Survey Completed 03/22/2023
Name of Provider or Supplier Manning Regional Healthcare Center	Street Address, City, State 1550 6th Street, Manning, 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
D3037	<p>RETENTION REQUIREMENTS 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 (PT) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 9:30 am on 03/22/2023, the laboratory failed to retain PT records for two out of six testing events from 1/1/2021 - 12/31/2022. The findings include: 1. For 2021 event 1, the laboratory failed to retain the signed PT attestation form for the WSLH PT 2021 Coag1 testing event. 2. For 2022 event 3, the laboratory failed to retain the signed PT attestation form for the WSLH PT 2022 Cardiac3 testing event. 3. At the time of the survey, the laboratory did not have the PT attestation statements listed above.</p>
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel records and confirmed by laboratory personnel</p>

identifier #1 (refer to the Laboratory Personnel Report) at approximately 8:20 am on 03/22/2023, the laboratory director failed to ensure that prior to testing patient specimens, testing personnel performing moderate complexity testing received the appropriate training for one out of five new testing personnel (personnel identifier #3) hired since the last survey on 07/15/2021. At the time of the survey, the laboratory did not have training records available for personnel identifier #3.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

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.

This STANDARD is not met as evidenced by:

Based on review of personnel records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 8:20 am on 03/22/2023, 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 one out of five new testing personnel (personnel identifier #6) who began performing patient testing since the last survey on 07/15 /2021. At the time of the survey, the laboratory did not have a semiannual competency assessment for personnel identifier #6.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on review of personnel records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 8:20 am on 03/22/2023, the technical supervisor failed to assess and document the competency of individuals performing high complexity testing at least annually for one out of one testing personnel (laboratory personnel identifier #2) in 2021.