

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0383057	(X3) Date Survey Completed 05/12/2021
Name of Provider or Supplier Dallas County Hospital Family Medicine Panora	Street Address, City, State 319 East Main Street, Panora, 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 identifiers #1 and #7 (refer to the Laboratory Personnel Report) at approximately 2:00 pm on 05/12/2021, the laboratory failed to retain all PT records for a minimum of two years for two out of seven PT testing events (2020 events 1 and 3) from 2019- 2021. The findings include: 1. For 2020 event 1, the laboratory did not retain the following complete blood count (CBC) PT records: testing records, results submitted to the PT company, the signed attestation statement, graded PT results and scores, and documentation of result review. 2. For 2020 event 3, the laboratory did not retain the following CBC PT records: the signed attestation statement. 3. At the time of the survey, the laboratory did not have the records 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>

This STANDARD is not met as evidenced by:
Based on review of personnel records and confirmed by laboratory personnel identifiers #1 and #7 (refer to the Laboratory Personnel Report) at approximately 1:30 pm on 05/12/2021, the laboratory director failed to ensure that prior to testing patient specimens, all testing personnel performing moderate complexity testing received the appropriate training for three out of four new testing personnel (identifiers #3- #5) who began patient testing since the last survey on 03/26/2019. The findings include:
1. Personnel identifier #4 began performing patient testing in September 2020. 2. Personnel identifiers #3 and #5 began patient testing in December 2020. 3. At the time of the survey, personnel identifiers #1 and #7 confirmed that the laboratory did not have training records for personnel identifiers #3- #5.

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 identifiers #1 and #7 (refer to Laboratory Personnel Report) at approximately 1:30 pm on 05/12/2021, 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 four new testing personnel (laboratory personnel identifier #2) who began patient testing since the last survey on 03/26/2019. At the time of the survey, the laboratory did not have a semiannual competency assessment for personnel identifier #2.