

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D2115879	(X3) Date Survey Completed 04/30/2021
Name of Provider or Supplier Boone County Family Medicine- North	Street Address, City, State 120 S Story St, Boone, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by testing personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 2:30 pm on 4/30/2021, the laboratory director failed to attest to the routine integration of samples into the patient workload by signing attestation statements for six out of six PT events from 1/1/2019 - 12/31/2020. The findings include: 1. For 2019 PT first event, the laboratory director failed to sign the hematology/coagulation, chemistry, microbiology, and immunology attestation statements. 2. For 2019 PT second event, the laboratory director failed to sign the hematology/coagulation, chemistry, microbiology, and immunology attestation statements. 3. For 2019 PT third event, the laboratory director failed to sign the hematology/coagulation, chemistry, microbiology, and immunology attestation statements. 4. For 2020 PT first event, the laboratory director failed to sign the hematology/coagulation attestation statements. 5. For 2020 PT second event, the laboratory director failed to sign the hematology/coagulation, chemistry, microbiology, and immunology attestation statements. 6. For 2020 PT third event, the laboratory director failed to sign the hematology/coagulation, chemistry, microbiology, and immunology attestation statements.</p>
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-</p>

approved proficiency testing program.

This STANDARD is not met as evidenced by:

Based on review of proficiency testing (PT) records and confirmed by laboratory testing personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 2:30 pm on 04/30/2021, the laboratory failed to evaluate the accuracy of ungraded analytes for two out of six PT testing events from 1/1/2019 - 12/31/2020. The findings include: 1. For 2019 PT first event, the laboratory did not evaluate the accuracy of the ungraded analytes: alanine aminotransferase, sample CH-01; urine sediment, sample US-02; and vaginal wet preparation, sample VKP-01. 2. For 2020 PT first event, the laboratory did not evaluate the accuracy of the ungraded analyte alanine aminotransferase, sample CH-01.