

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0385515	(X3) Date Survey Completed 05/20/2021
Name of Provider or Supplier Avera Holy Family Hospital	Street Address, City, State 826 North Eighth Street, Estherville, 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 laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 9:15 am on 05/20/2021, the laboratory director failed to attest to the routine integration of PT samples into the patient workload for five out of six proficiency testing events (2019 events 1 and 2; 2020 events 1, 2 and 3) from 1/1/2019 - 12/31/2020. The findings include: 1. For 2019 event 1, the laboratory director did not sign the following PT attestation statement: miscellaneous chemistry. 2. For 2019 event 2, the laboratory director did not sign the following PT attestation statements: immunology /immunohematology and core chemistry. 3. For 2020 event 1, the laboratory director did not sign the following PT attestation statement: microbiology. 4. For 2020 event 2, the laboratory director did not sign the following PT attestation statements: miscellaneous chemistry and microbiology. 5. For 2020 event 3, the laboratory director did not sign the following PT attestation statements: hematology/coagulation, immunology/immunohematology, and SARS-CoV2.</p>