

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D2161177	(X3) Date Survey Completed 05/19/2021
Name of Provider or Supplier Avera Merrill Pioneer	Street Address, City, State 1100 S 10th Avenue, Rock Rapids, 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of proficiency testing records and confirmed by laboratory personnel identifiers #3 and #5 (refer to Laboratory Personnel Report) at approximately 9:00 am on 05/19/2021, the laboratory failed to enroll in an approved proficiency testing (PT) program for the analyte, blood alcohol, for three out of three years. At the time of the survey, personnel identifiers #3 and #5 confirmed that the laboratory did not enroll in PT for the analyte, blood alcohol, in 2019, 2020, or 2021.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for</p>

acceptability.

This STANDARD is not met as evidenced by:

Based on review of patient test reports, instrument printouts and confirmed by laboratory personnel identifiers #3 and #5 (refer to the Laboratory Personnel Report) at approximately 11:40 am on 05/19/2021, the laboratory failed to include all units of measure for two out of 13 patient test reports (patient identifiers A and B). The findings include: 1. Patient A had complete blood count (CBC) testing performed on 11/02/2020. 2. The electronic health record (EHR) test report for patient A did not include units of measure for the following CBC parameters: mean corpuscular volume (MCV) and mean corpuscular hemoglobin concentration (MCHC). 3. Patient B had erythrocyte sedimentation rate (ESR) testing performed on 11/06/2020. 4. The EHR test report for patient B did not include the unit of measure for the ESR. 5. At the time of the survey, personnel identifiers #3 and #5 confirmed that the EHR test reports for patients A and B did not include the units of measure listed above.