Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0699979	04/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Anniston Family Practice	400 East 8th Street, Anniston, AL	

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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of the 2018 - 2021 proficiency testing (PT) records, and an interview with the Technical Consultant, the surveyor determined the Laboratory Director failed to sign the attestation statements for three of eight surveys reviewed. The findings include: 1. A review of the 2018 - 2021 PT records revealed the Laboratory Director failed to sign the attestation statement for the following Hematology surveys: A) MLE (Medical Laboratory Evaluation) 2019-M2 B) API (American Proficiency Institute) 2020 Event #1 C) API 2020 Event #3 2. During a review of the PT records and an interview conducted on 4/28/2021 at 11:20 AM, the Technical Consultant confirmed the above noted findings. .
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories

	failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on a review of the proficiency testing (PT) records and an interview with the current Technical Consultant, the surveyor determined the laboratory failed to submit results for the API (American Proficiency Institute) 2020-Event 3 Hematology survey before the cutoff date. This was noted on one out of eight 2018-2021 PT survey events reviewed. The findings include: 1. A review of the Hematology instrument printouts for the API 2020-Event 3 survey revealed the PT specimens were run on 11/10/2020. A note dated 11/18/2020 from a previous testing personnel revealed, "Entered, need double check and submit", however the API 2020-Event 3 received a score of 0% due to failure to participate. API instructions specified the results should be submitted on-line on or before 11/24/2020. 2. During a review of the PT records and an interview conducted on 4/28/2021 at 11:20 AM, the current Technical Consultant confirmed the above noted findings. .
D5805	TEST REPORT CFR(s): 493.1291(c) 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 acceptability. This STANDARD is not met as evidenced by: Based on reviews of patient test reports and an interview with the Technical Consultant, the laboratory failed to ensure patient reports included all required parameters after the facility implemented a new EHR (Electronic Health Record) in January 2020. The findings include: 1. On 4/28/2021 at 2:45 PM, the surveyor reviewed the post-analytical process in the facility. Upon the surveyor's request, the Technical Consultant provided two final patient reports with CBC (Complete Blood Count) results from the Athena EHR. 2. A review of the EHR reports for two patients revealed the "Performing Lab" name and address were incorrect. The report also failed to include units of measurement for CBC parameters except WBC (White Blood Cells). 3. As the review continued, the Technical Consultant then provided the instrument printouts for the CBC's, and stated these were also used as patient reports. Upon review however, the surveyor noted the "Patient ID" (200891 and 200894) on the printouts did not match the patients' Medical Records Number (MRN) on the EHR reports. 4. In an interview on 4/28/2021 at 3:00 PM, the surveyor reviewed the reports with the Technical Consultant who confirmed the above noted findings, stating the "Patient ID" on the CBC printout was a sequential number automatically generated by

	the Hematology instrument. The surveyor then asked when the facility implemented Athena as the new EHR; the Technical Consultant answered, "1/22/2020". SURVEYOR ID #32558 Licensure and Certification Surveyor