Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0987779	(X3) Date Survey Completed 03/09/2021
Name of Provider or Supplier Prattville Medical Clinic	Street Address, City, State 1739 East Main Street, Prattville, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a review of API (American Proficiency Institute) proficiency testing (PT) records, and an interview with Testing Personnel #2, the surveyor determined the laboratory failed to ensure proficiency testing samples were rotated between all personnel who performed patient testing. This was noted on seven out of eight Hematology surveys reviewed for 2018 (2nd and 3rd Event), 2019 (all three events), and 2020 (all three events). The findings include: 1. A review of API attestation statements revealed Testing Personnel #2 had performed all the testing on seven out of eight Hematology surveys reviewed. 2. During an interview on 03/09/2021 at 01:25 PM, Testing Personnel #2 confirmed the proficiency testing was not rotated to the other two testing personnel since 2nd Event 2018. .
D2127	HEMATOLOGY CFR(s): 493.851(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on the review of the API (American Proficiency Institute) Proficiency Testing (PT) records and an interview with Testing Personnel #2, the surveyor determined the

	laboratory failed to submit proficiency testing results by the submission deadlines for Hematology testing for Event #3 2020. The laboratory scored zero percent (0%) for this event, due to the failure to timely submit the results. The findings include: 1. A review of the PT records revealed the due date to submit API proficiency testing results for the 3rd Event 2020 was 11/24/2020. The samples were tested on 11/19 /2020, however the results were not postmarked until 11/27/2020 to be mailed into API. 2. During an interview on 03/09/2021 at 12:15 PM, Testing Personnel #2 confirmed the results were not mailed in by the due date of 11/24/2020.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on record review and interviews, the laboratory failed to report SARS-Co-V-2 (Severe Acute Respiratory Syndrome Coronovirus 2) test results for positive and negative Coronovirus Disease 2019 (COVID-19) performed on the Sofia COVID test kit from January 8, 2021 [the date State Surveyors received CMS guidance for surveying on this deficiency] to March 8, 2021. The laboratory failed to report or attempt to report SARS-Co-V-2 for the COVID-19 antigen test results to the Alabama Department of Public Health with the timing and frequency prescribed. Findings include: 1. A review of SARS-Co-V-2 test results in two handwritten notebooks revealed patients were tested for SARS-Co-V-2 using the Sofia COVID test kit, starting September 21, 2020 through March 09, 2021. Most of the entries in the notebooks did not include the date the test was performed; the testing personnel had only documented the names of 1410 patients, and occasionally the COVID-19 test results. 2. During an interview on March 09, 2021 at 10:45 AM, Testing Personnel #2 stated the facility had not known about the reporting requirements; the testing personnel were only recording COVID-19 results in each patient's paper chart. Testing Personnel #2 confirmed the laboratory had never reported or attempted to report positive and negative SARS-Co-V-2 patient test results to the Alabama Department of Public Health from the 1410 patient tests performed from September 21, 2020 through March 09, 2021. 3. During a phone interview on March 12, 2021 at 12:12 PM, the surveyor asked Testing Personnel #1 how many patients were tested for COVID-19 from January 08, 2021 [the date State Surveyors received CMS guidance for surveying on this deficiency] through March 09, 2021. Testing Personnel #1 inquired at the Billing Office, and stated 782 patients were tested.