Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0920264	03/26/2021
Name of Provider or Supplier	**Street Address, City, State**	
Southside Medical Clinic	546 West Seminary Drive, Fort Worth, TX	

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
D0000	Laboratory representatives were present at the entrance conference conducted 02/23 /2021. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives on 02/23 /2021. The laboratory was found to be in substantial compliance for the specialties /subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas State Health and Human Services Commission, Health Facility Compliance Arlington Group.
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 review of laboratory SARS-Co-V-2 patient testing records, review of laboratory SARS-Co-V-2 result reporting records, and staff interview, it was revealed that the laboratory failed to report SARS-Co-V-2 negative test results for 33 of 33 days reviewed from 01/08/2021 through 03/25/2021. Findings: 1. Review of SARS-Co-V-2 patient tests records (test performed using the Abbott ID NOW COVID-19 Test kit and instrumentation) from 01/08/2021 through 03/25/2021 revealed 117 patients tested for SARS-CoV-2. 2. Further review of the SARS-Co-V-2 patient tests

	results revealed of the 117 patients tested for SARS-Co-V-2, 49 patients tested negative. 3. Review of the laboratory's SARS-Co-V-2 result reporting documentation revealed the laboratory faxed SARS-Co-V-2 positive patient results Sunday through Saturday from 01/08/2021 through 03/25/2021 to the County Health Department. Further review of the laboratory's SARS-Co-V-2 reporting documentation revealed the laboratory failed to report the 49 negative test results to the County Health Department or to the Department of State Health Services. 4. During an interview on 03/26/2021 at 12:04 pm, the Technical Consultant and Compliance Officer confirmed that only positive SARS-Co-V-2 results were reported.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory policy, manufacturer's instructions for CDS 3PD Hematology Control, quality control (QC) records, and confirmed in interview, the laboratory failed to establish its own mean and acceptability ranges for complete blood count (CBC) controls for 3 of 3 lot of control materials used from January 2021 through March 2021. Findings: 1. Review of the laboratory policy "Analytic Policies and Procedures" revealed: "Verifying New Lot Numbers of Control At least one day before the current lot number of controls expires, verify the acceptability of the new lot number. Run the current quality control material as usual and use these QC results to judge whether or not to accept patient test results. During the same run, run all 3 levels of the new control material in PATIENT mode, 1 to 5 times each. Examine results by verifying that all control values are within the manufacturer's stated range. If the data are acceptable, the new lot number of controls is now ready to use. Print the results and attach to the manufacturer's assay sheet. Mark "OK" on the new lot numbers of controls and sign and date this approval. Do the same on the assay sheet to document that the new lot number of controls has been verified." 2. Review of CDS 3PD Hematology Control instructions for use stated: "INSTRUCTIONS ... (9) Before expiration of the current lot, good laboratory practice requires that a new lot of cell control be analyzed in parallel with the existing lot until a laboratory mean is established on the new lot." 3. Review of CDS 3PD Hematology Control assay sheet and CBC QC records revealed the laboratory was utilizing the range of means from the assay sheet for the acceptability of QC. The laboratory did not establish its own means and limits for each parameter for the following lots: Low Control Lot 320111, expiration date: 04/09/2021, date put into use: 01/13/2021 Normal Control Lot 320112, expiration date: 04/09/2021, date put into use: 01/13/2021 High Control Lot 320113, expiration date: 04/09/2021, date put into use: 01/13/2021 4. During an interview on 03/26/2021 at 10:34 am, the Technical Consultant stated that the laboratory did not establish its own mean and ranges for complete blood counts and the assay sheets were used for QC acceptability, confirming the above findings.