Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D1024743	04/07/2021
Name of Provider or Supplier	**Street Address, City, State**	
Crossroads Family Health Clinic	2427 Proper St, Corinth, MS	

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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the records for the Diagnostar COVID-19 IgG/IgM Rapid Test Cassette kit (manufactured by Healgen), lack of documentation of verification of performance specifications, and interview with laboratory director and testing personnel (TP) #2 as listed on the CMS (Centers for Medicare & Medicaid) 209 personnel form at 12:30 pm, the laboratory failed to verify the manufacturer's performance specifications before reporting patient test results. The lab started using the Diagnostar antibody test on 1/13/21 and had performed approximately 30 tests on patients. Findings: 1. No documentation of verification of performance specifications for the Diagnostar COVID-19 IgG/IgM Rapid Test Cassette was available for review on the day of survey. 2. Interview with the laboratory director and TP #2 on 4/7/21 at 12:30 pm revealed no verification of performance specifications was completed before testing patients. 3. Approximately 30 patients had been tested by the laboratory since the testing was started on 1/13/21 according to an inventory of tests ordered and those still on-hand. The lab director and TP#2 confirmed the count on interview. No patient log was available for an exact count.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)

	Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of the Sysmex pocH-100i hematology analyzer records since the last survey on 9/26/18, the laboratory procedure manual, and interview with testing personnel (TP) #2 listed on the CMS (Center for Medicare & Medicaid Services) 209 personnel form at 2:30 pm on the day of survey, the laboratory failed to perform calibration on the Sysmex pocH-100i hematology analyzer every 6 months as required by the laboratory procedure manual. Findings include: 1. Review of the laboratory procedure manual revealed a written hematology procedure that stated calibration would be performed every 6 months on the Sysmex pocH-100i hematology analyzer. 2. Review of the Sysmex pocH-100i calibration records from 9/26/18 through 4/7/21 revealed calibration been performed on 1/28/19, 9/10/19 and 6/17/20. These time periods exceed the 6 month calibration requirement specified in the laboratory procedure manual. 3. Interview with TP #2 at 2:30 pm on 4/7/21 confirmed that calibrations on the Sysmex pocH-100i hematology analyzer were not performed every 6 months as required in the written laboratory procedure manual.
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 lack of documentation of quality control records for the Diagnostar COVID-19 IgG/IgM Rapid Test Cassette (manufactured by Healgen) and interview with lab director and testing personnel (TP) #2 as listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form on 4/7/21 at 12:30 pm, the laboratory failed to include a positive and negative control on each day of patient testing for the Diagnostar COVID-19 IgG/IgM Rapid Test Cassette performed from 1/13/21 through 4/7/21 for antibodies to SARS-CoV-2. Findings Include: 1. Review of the Diagnostar IgG/IgM Rapid Test Cassette kit revealed there was no quality control (QC) material (positive or negative) provided in the kit. 2. Interview with the laboratory director and TP #2 on 4/7/21 at 12:30 pm confirmed that the manufacturer had not provided QC material in the kit and none had been obtained by the laboratory. 3. Review of the Diagnostar IgG/IgM Rapid Test Cassette kits ordered and kits on-hand on the day of survey revealed approximately 30 patients had been tested with the Diagnostar IgG

	/IgM Rapid Test Cassette kit. 4. Interview with the lab director and TP #2 on 4/7/21 at 12:30 pm confirmed that TP were not performing two levels of QC each day of patient testing with the Diagnostar COVID-19 IgG/IgM Rapid Test Cassette.