Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0680088	11/12/2020
Name of Provider or Supplier	**Street Address, City, State**	
Warrington Clinic	551 Medical Drive, Clarksdale, 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 testing records for the Healgen COVID-19 IgG/ IgM Rapid Test Cassette, lack of documentation of verification for performance specifications, and interview with staff on 11/12/20 at 10:00 am, the laboratory failed to ensure that performance specifications were verified before reporting patient test results. The lab started using this antibody test on 9/21/20. Findings: 1. No documentation of verification of performance specifications for the Healgen COVID-19 IgG/IgM Rapid Test Cassette was available for review on the day of survey. 2. Interview with laboratory staff on 11/12/20 at 10:00 pm revealed no verification of performance specifications was completed before testing patients.
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 quality control (QC) and patient records for the Healgen COVID-19 IgG/IgM Rapid Test Cassette from 9/21/20 through 10/1/20 and an interview with the laboratory staff on 11/12/20 at 10:00 am, the laboratory failed to include a positive and negative control on each day of patient testing for antibodies to SARS-CoV-2. Findings Include: 1. Review of the QC and patient records for the Healgen COVID -19 IgG/IgM Rapid Test Cassette performed from 9/21/20 through 10/1/20 revealed that two levels of QC (positive or negative) were not performed each day of patient testing. 2. Interview with the laboratory testing personnel and TC on 11/12/20 at 10: 00 am confirmed that laboratory testing personnel were not performing two levels of QC each day of patient testing with the Healgen COVID-19 IgG/IgM Rapid Test Cassette. 3. Review of the patient COVID -19 Antibody test log from 9/21/20 through 10/1/20 revealed a total of 12 patient specimens were tested and reported with no documentation of the performance of 2 levels of controls each day of testing.