

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0706982	(X3) Date Survey Completed 11/11/2020
Name of Provider or Supplier Warrington Clinic - Shelby	Street Address, City, State 1209 1/2 Broadway, Shelby, 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	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>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 of the performance specifications, and interview with staff on 11/11/20 at 2:30 pm, the laboratory failed to ensure that performance specifications were verified before reporting patient test results. The lab started using this antibody test on 9/18/20. 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 2:30 pm revealed no verification of performance specifications was completed before testing patients.</p>
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>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.</p>

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 9/18/20 through 11/11/20 and an interview with the laboratory staff on 11/11/20 at 2:30 pm, 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 9/18/20 through 11/11/20 revealed that two levels of QC (positive or negative) were not performed on each day of patient testing. 2. Interview with the laboratory testing personnel and TC on 11/11/20 at 2:30 pm, 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 9/18/20 through 11/11/20 revealed a total of 21 patient specimens were tested and reported with no documentation of the performance of 2 levels of controls each day of testing.