

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D2189267	(X3) Date Survey Completed 02/10/2021
Name of Provider or Supplier Hattiesburg Pain & Injury	Street Address, City, State 6125 Hwy 49, Hattiesburg, 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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, quality control records, and patient test logs for COVID-19 IgG/IgM antibody testing with the moderate complexity Healgen Scientific COVID-19 IgG/IgM Rapid Test Cassette from 8-12-20 through 1-7-21, the laboratory failed to establish quality control procedures for COVID-19 IgG/IgM antibody testing, to include the number, type, and frequency of testing control materials. Findings include: Review of the laboratory procedure manual revealed no quality control procedure for COVID-19 IgG/IgM antibody testing to include the number, type, and frequency of testing control materials, prior to</p>

an an Individualized Quality Control Plan (IQCP) dated 2-9-21. Review of the quality control records and patient test logs for COVID-19 IgG/IgM antibody testing revealed no documentation of the performance of controls from 8-26-20 through 1-7-21, when patient testing was performed for 30 patients. Refer to D5449 (Failure to include a positive and negative control each day of patient testing).

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 records and patient test logs for COVID-19 IgG /IgM antibody testing with the Healgen Scientific COVID-19 IgG/IgM Rapid Test Cassette from 8-12-20 through 1-7-21 and lack of documentation of an Individualized Quality Control Plan (IQCP) prior to 2-9-21, the laboratory failed to include a positive and negative control each day of patient testing during this time frame, when a total of 30 patient specimens were tested and reported. Findings include: Review of quality control records and patient test logs for COVID-19 IgG/IgM antibody testing from 8-12-20 through 1-7-21 revealed a positive and negative control were documented on 8-12-20 and 8-25-21. Positive and negative controls were not documented, as performed, from 8-26-21 through 1-7-21, when patient testing was performed and results were reported for 30 patients.