

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  25D2189264	<b>(X3) Date Survey Completed</b>  01/28/2021
<b>Name of Provider or Supplier</b>  Physical Medicine & Rehab	<b>Street Address, City, State</b>  9344 Three Rivers Rd, Gulfport, MS	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5403</b>	<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: 1. Based on review of the laboratory procedure manual and interview with Testing Personnel #2, listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, on 1-28-21 at 11:00 a.m., the laboratory failed to establish a written procedure for specimen collection and labeling or for entering results in the patient record and reporting patient results for COVID-19 IgG/IgM antibody testing with the Healgen Scientific COVID-19 IgG/IgM Rapid Test Cassette. Findings include: Interview with Testing Personnel #2 on 1-28-21 at 11:00 a.m. revealed specimen collection is performed by fingerstick outside the building; the specimen is dropped</p>

onto the Healgen Scientific COVID-19 IgG/IgM Rapid Test Cassette; and the cassette is brought inside the building by the testing personnel for interpretation and reporting of results. Review of the laboratory procedure manual revealed no procedure for specimen collection and labeling or for entering results in the patient record and reporting patient results. 2. 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 8-13-20 through 12-8-20, 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. 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 8-14-20 through 9-17-20, 9-22-20 through 10-2-20, and 10-6-20 through 12-7-20, when patient testing was performed for 230 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 moderate complexity Healgen Scientific COVID-19 IgG/IgM Rapid Test Cassette from 8-13-20 through 12-8-20, lack of documentation of an Individualized Quality Control Plan (IQCP), and confirmation by the laboratory director, the laboratory failed to include a positive and negative control each day of patient testing during this time frame, when a total of 230 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 8-13-20 through 12-8-20 revealed a positive and negative control were documented on 8-13-20, 9-21-20, 10-5-20, and 12-8-20. Positive and negative controls were not documented, as performed, for the following time frames when patient testing was performed and results were reported: 8-14-20 through 9-17-20--83 patients reported. 9-22-20 through 10-2-20--32 patients reported. 10-6-20 through 12-7-20--115 patients reported. The laboratory director confirmed an IQCP had not been established for COVID-19 IgG/IgM antibody testing with the Healgen Scientific COVID-19 IgG/IgM Rapid Test Cassette.

**D6020**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and

maintained to assure the quality of laboratory services provided.

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 8-13-20 through 12-8-20, the laboratory director failed to ensure a quality control program was established and maintained to assure the quality of laboratory services provided.

Findings include: Review of quality control records and patient test logs for COVID-19 IgG/IgM antibody testing from 8-13-20 through 12-8-20 revealed no documentation of the performance of controls from 8-14-20 through 9-17-20, 9-22-20 through 10-2-20, and 10-6-20 through 12-7-20, when patient testing was performed for 230 patients. 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. Refer to D5403 (Failure to establish quality control procedures for COVID-19 IgG/IgM antibody testing). Refer to D5449 (Failure to include a positive and negative control each day of patient testing).

**D6031**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(13)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on review of the laboratory procedure manual and interview with Testing Personnel #2, listed on the CMS 209 personnel form, on 1-28-21 at 11:00 a.m., the laboratory director failed to ensure that an approved procedure manual that includes written procedures for specimen collection and labeling, entering results in the patient record, and reporting patient results was available to all personnel responsible for performing COVID-19 IgG/IgM antibody testing with the Healgen Scientific COVID-19 IgG/IgM Rapid Test Cassette. Findings include: Interview with Testing Personnel #2 on 1-28-21 at 11:00 a.m. revealed specimen collection is performed by fingerstick outside the building; the specimen is dropped onto the Healgen Scientific COVID-19 IgG/IgM Rapid Test Cassette; and the cassette is brought inside the building by the testing personnel for interpretation and reporting of results. Review of the laboratory procedure manual revealed no procedure for specimen collection and labeling or for entering results in the patient record and reporting patient results. Refer to D5403 (Failure to establish written procedures for specimen collection, labeling, and results reporting).