

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0719555	<b>(X3) Date Survey Completed</b>  12/22/2020
<b>Name of Provider or Supplier</b>  Physicians Associates Pa	<b>Street Address, City, State</b>  10860 Sw 88th St, Miami, FL	
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>D0000</b>	A recertification survey was completed on 12/21/2020 to 12/22/2020 at PHYSICIANS ASSOCIATES PA. The facility was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following Condition was cited: -D3000
<b>D3000</b>	<p><b>FACILITY ADMINISTRATION</b> CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7).</p> <p>This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure that the testing laboratory reported positive and negative COVID-19 results to the Florida Health Department from June 2020 to December 2020. (See 3009 )</p>
<b>D3009</b>	<p><b>FACILITIES</b> CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure that the testing laboratory reported positive and negative COVID-19 results to the Florida Health Department from June 2020 to December 2020. Findings Included: No records available for documentation of reports to the Florida Health Department of COVID-19 for positive and negative results for Sofia 2 SARS Antigen FIA and Healgen</p>

Scientific LLC COVID-19 IgG /IgM Rapid Test Cassette . Review of FDOH Emergency Rule 64DER20-26 (64D-3.029) of April 10th 2020, revealed for COVID-19; the timeframe is immediately and had special reporting requirements. Results should be reported and accompanied by any testing conducted (positive and negative). For laboratories performing electronic laboratory reporting as described in subsection 64D-3.031 (5). F.A.C., all test results (positive and negative) are to be submitted, including screening test results (positive and negative). During an interview on 12/21 /2020 at 2:56 pm with the testing personnel confirmed that the laboratory does not have records of the notification to the Florida Health Department of positive and negative results .

**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 record review and interview, the laboratory failed to document and perform external positive and negative controls for Healgen Scientific LLC COVID-19 IgG /IgM Rapid Test Cassette from 6/4/2020 to 12/21/2020 Findings Included: Review of COVID-19 External Quality Control for Healgen revealed negative and positive controls not documented from 6/4/2020 to 12/21/2020. Review of COVID-19 testing log revealed Healgen Scientific LLC COVID-19 IgG /IgM Rapid Test Cassette in use 6/4/2020 to 12/21/2020. During an interview on 11-10-2020 at 4:49pm , the testing person confirmed failure to document and perform external positive and negative controls for Healgen Scientific LLC COVID-19 IgG /IgM Rapid Test Cassette from 6 /4/2020 to 12/21/2020.

**D6013**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(3)(ii)

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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:  
Based on record review and interview, the laboratory director (LD) failed to review and sign the validation for the Healgen Scientific LLC COVID-19 IgG /IgM Rapid Test Cassette used for COVID-19 testing from 6/4/2020 to present. Finding Included : Review of the Healgen Scientific LLC COVID-19 IgG /IgM Rapid Test Cassette Validation revealed LD did not sign and review the equipment for COVID-19 PCR Testing before use in 6/4/2020 to present . An interview on 12/21/2020 at 2:56 pm, the testing person confirmed the laboratory director (LD) failed to review and sign the

validation for the Healgen Scientific LLC COVID-19 IgG /IgM Rapid Test Cassette used for COVID-19 testing from 6/4/2020 to present.