

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0675959	(X3) Date Survey Completed 09/20/2021
Name of Provider or Supplier Pediatric Associates Of Dayton Inc	Street Address, City, State 5450 Far Hills Ave Ste 110, Kettering, OH	
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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: ITEM 1 Based on direct observation and an interview with the Nurse Manager, the laboratory failed to follow the manufacturer's instructions for the storage and stability of Quindel Sofia SARS antigen kits utilized for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in direct anterior nasal swab specimens. This deficient practice had the potential to affect 599 patient SARS-CoV-2 anterior nasal swab specimens performed from 07/22/2021 to 09/19/2021. Findings Include: 1. Review of the Sofia SARS antigen manufacturer's instructions revealed the following statement: "Store the kit at room temperature, 59F to 86F (15C to 30C) out of direct sunlight." "Inadequate or inappropriate sample collection, storage, and transport may yield false test results." 2. Direct observation on 09/20/2021 at 11:30 AM of the laboratory's Quindel Sofia SARS-CoV-2 antigen kit storage location revealed no thermometer and no documentation of storage location temperatures. 3. The Nurse Manager confirmed the laboratory did not follow the manufacturer's instructions and did not monitor storage temperatures for the Quindel Sofia SARS-CoV-2 antigen kits. The interview occurred on 09/20/2021 at 11:15 AM. F; degrees Fahrenheit C; degrees Celsius ITEM 2 Based on record review and an interview with the Nurse Manager, the laboratory failed to follow the manufacturer's instructions for training procedures for the Quindel Sofia SARS antigen kits utilized for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in direct anterior nasal swab specimens. This deficient practice had the potential to affect 599 patient SARS-CoV-2 anterior nasal swab specimens performed from 07/22/2021 to 09/19/2021. Findings Include: 1. Review of the form CMS 209 signed and dated by the</p>

Laboratory Director on 09/23/2021 found 20 staff listed as testing personnel. 2. Review of the Sofia SARS antigen manufacturer's instructions revealed the following statements: "Sample collection and handling procedures require specific training and guidance." 3. Review of laboratory records found no training documentation for the Quindel Sofia SARS antigen kits. 4. The Nurse Manager confirmed the laboratory did not follow the manufacturer's instructions and did not document training for the Quindel Sofia SARS-CoV-2 antigen kits. The interview occurred on 09/20/2021 at 11:40 AM.

D1002

REPORTING OF SARS-CoV-2 TEST RESULTS

During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.

This CONDITION is not met as evidenced by:
Based on record review and an interview with the Nursing Manager, the laboratory failed to report all SARS-Co-V-2 test results as required for 599 out of 599 patients tested from 07/22/2021 through 09/19/2021. Findings Include: 1. Review of the laboratory's "PAD Policy", policies and procedures binder, provided for inspection found no mention of a SARS-Co-V-2 reporting procedure. 2. The laboratory's "COVID" patient log was reviewed from 07/22/2021 through 09/18/2021 and found 599 COVID-19 individuals tested that were not reported to the Ohio Department of Health. 3. The Inspector requested the laboratory's evidence that the above mentioned 599 COVID-19 test results were reported to the Ohio Department of Health from the Nursing Manager. The Nursing Manager confirmed the laboratory did not report any COVID results to the Ohio Department of Health and was unable to provide the requested documentation.