

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0214310	(X3) Date Survey Completed 03/23/2023
Name of Provider or Supplier Davidsonville Pediatrics	Street Address, City, State 2772 Rutland Road, Davidsonville, MD	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory did not ensure that the attestation statement provided by the PT program was signed by the testing person (TP), documenting that proficiency testing samples were tested in the same manner as patient specimens. Findings: 1. A review of PT records from 2021 and 2022 showed that the attestation statement for the 3rd event of 2021 in microbiology was not signed by the TP who performed the PT. 2. During an interview on 03/23/2023 at 1:15 PM, the TC confirmed that the PT attestation statement did not include the name of the TP who performed the test as required.</p>
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p>

This STANDARD is not met as evidenced by:
Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory did not ensure that a copy of all PT documents was maintained by the laboratory for a minimum of two years from the date of the PT testing event. Findings: 1. A review of PT records from 2021 and 2022 showed that signed attestation statements and instrument printouts and testing records were not available at the time of the survey for the 2nd PT event of 2021 in hematology and microbiology; and 2. Testing records were not available for the 3rd event of 2021 in microbiology. 3. During an interview on 03/23/2023 at 1:15 PM, the TC confirmed that the laboratory did not maintain all PT documents for a minimum of two years from the date of the PT testing event.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based on hematology instrument maintenance record review and interview with the technical consultant (TC), the laboratory did not ensure that monthly maintenance was performed on the hematology analyzer as recommended by the manufacturer. Findings: 1. The laboratory uses a Medonic M-Series hematology analyzer to perform CBC (complete blood cell count) analysis. The instrument manual recommends that the instrument be cleaned monthly using the "Boule Cleaning Kit." 2. A review of monthly hematology analyzer maintenance records from January through December, 2022 showed that monthly instrument cleaning was not recorded for 5 out of 12 months. 3. During an interview on 03/23/2023 at 11:15 AM, the TC confirmed that monthly hematology analyzer maintenance was not documented.

D6021

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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on procedure manual review and interview with the technical consultant (TC), the laboratory director failed to ensure that the laboratory had a written quality assessment (QA) program to evaluate the ongoing status of the operation of the laboratory. Findings: 1. A review of the laboratory's procedure manual showed that the table of contents listed 11 QA procedures, however further review showed that there were no QA procedures included in the written procedure manual. 2. During an interview on 03/23/2023 at 12:30 PM, the TC stated that they had a QA policy on their laptop from another laboratory which was intended for use at this laboratory but

that the procedures had not been edited for use at the laboratory being surveyed. They confirmed that the QA policy was not available in the procedure manual or on the laboratory's "shared drive" at the time of the survey.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on record review and interview with the technical consultant (TC), the TC failed to evaluate the competency of all testing personnel (TP) and to assure that the staff maintain their competency to perform test procedures and report test results promptly, accurately, and proficiently. Findings: 1. The laboratory currently has 7 TP listed on the "Laboratory Personnel Report (CLIA)" (CMS-209). 2. A review of competency assessment records from 2021 to 2023 showed that there was no documentation that a six month competency assessment had been performed for 2 of 7 TP; and 3. There was no documentation of an annual competency assessment for 1 of 7 TP in 2021. 4. During the survey on 03/23/2023 at 1:15 PM, the TC confirmed that competency assessments were not performed in a timely manner.