| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 21D0213045 | 06/25/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Bethesda Pediatrics | 11325 Seven Locks Rd, Potomac, 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 |
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| **D5211** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(a)<br><br>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory failed to ensure that PT results were reviewed by the laboratory director or designee for two of eight PT events reviewed. Findings: 1. Records for four microbiology and four hematology PT events from 2024 and 2025 were reviewed. 2. The PT provider's results evaluations for the 2024 Hematology /Coagulation 2nd and 2024 Microbiology 2nd events were missing from the PT records. 3. During the exit interview on 06/25/2025 at 2:15 PM, the TC confirmed that the results evaluations for the 2024 2nd PT events were not printed and reviewed by the laboratory director or designee prior to the survey on 06/25/2025. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the manufacturer's operating manual, review of maintenance records, and interview with the technical consultant (TC), the laboratory failed to perform maintenance on the Cepheid GeneXpert system with the frequency defined by the manufacturer. Findings: 1. Table "9-1 Maintenance Tasks and Frequency" of the manufacturer's operating manual listed each maintenance task and the frequency |

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| | with which each task should be performed. The table included two monthly and four quarterly maintenance tasks. 2. All maintenance tasks were listed on the monthly "GeneXpert System Maintenance Log" and monthly logs from 11/2023 through 05 /2025 were reviewed for a total of 19 months. 3. Monthly maintenance activities were not documented for 15 of the 19 months. 4. Only one of the two listed monthly activities was documented as performed for 2 of the 19 months. 5. Quarterly maintenance activities were documented as performed twice in 19 months (10/09 /2024 and 02/14/2024). On 02/14/2024, only two of four quarterly activities were documented as performed. 6. During the exit interview on 06/25/2025 at 2:15 PM, the TC confirmed that maintenance activities for the GeneXpert system were not performed with the frequency defined by the manufacturer. |
| **D5441** | CONTROL PROCEDURES<br>CFR(s): 493.1256(a)(b)(c)(g)<br><br>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the individualized quality control plan (IQCP) and interview with the technical consultant (TC), the laboratory's IQCP for the Cepheid GeneXpert system was not specific to the testing performed in the laboratory. Findings: 1. The laboratory performed microbiology testing on the Cepheid GeneXpert system and, per manufacturer's recommendations, performed external QC for every new lot number and shipment of reagent cartridges. 2. The laboratory used a generic IQCP template that was signed by the laboratory director on 10/20/2023. The IQCP template was not modified for the specific testing performed in the laboratory. Some examples of how the IQCP template was not modified are listed below: a. The template stated "Please note that some references to protocol, publications, performance data etc. are fictitious in this EXAMPLE. Please use your own DATA for your IQCP," "The following represents one example of how you might organize your IQCP for QC of a commercial cartridge-based molecular test system for detection of a single or multiple targets," and "Laboratories should modify this template and examples to support their practice." b. The title listed was "IQCP for QC of molecular test system XYZ" and the facility was listed as "ABC Hospital" c. The "Historical Quality Review" section stated that "This laboratory has been using the XYZ molecular test to detect Pathogen Q from XX to XX dates (this time period recommended to be greater than 30 d) without any significant QC problems. Issues related to QC performance have included XX (e.g., list examples such as contamination or deterioration of QC materials)." d. The "Specimen: Summary of Testing" section stated that "During the assessment period (XX to XX dates), testing was performed on # positive and # negative specimens." e. The "Summary of in-house data from QC testing" section stated that "Review of QC records for the past 12 months (XX to XX dates) that contained approximately XX results demonstrated: __ % occurrence of random QC errors that corrected upon repeat testing." f. The risk assessment included a section for "if testing |

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| | is performed from culture" which the laboratory does not perform. g. The "How can identified sources of error be reduced" section for "1A: Specimen- Biological" stated to "Adhere to procedures in SOP #XX that addresses patient identification and specimen collection, labeling, transport, storage and remedial actions to control improperly handled specimens or delayed processing." The laboratory's procedure name was not inputted into this section and the laboratory only tested specimens collected in-house. h. The "Final QCP for Cartridge based molecular test system XYZ" stated "Based on our risk assessment and Quality Assessment, the QCP consists of following the instructions that are provided in explicit detail in SOP #XX 'XYZ System for Molecular Detection of Microbe Q'." 3. During the exit interview on 06/25/2025 at 2:15 PM, the TC confirmed that the laboratory's IQCP was not specific to the laboratory's testing performed on the Cepheid GeneXpert system. |
| **D6046** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)<br><br>(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. The procedures for evaluation of the competency of the staff must include, but are not limited to--<br><br>This STANDARD is not met as evidenced by:<br>Based on review of proficiency testing (PT) and personnel records and interview with the technical consultant (TC), competency evaluations were not performed for the TC in their role as testing personnel (TP). Findings: 1. The Laboratory Personnel Report (form CMS-209) listed two TCs and PT records showed that TC2 performed patient testing. 2. Personnel records showed that there were no competency evaluations of TC2 in their role as TP. 3. During the exit interview on 06/25/2025 at 2:15 PM, TC2 confirmed that competency evaluations were not performed for their role as TP. |