

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D0919367	<b>(X3) Date Survey Completed</b> 07/31/2018
<b>Name of Provider or Supplier</b> Pediatric Associates Of Charlottesville-North	<b>Street Address, City, State</b> 1522 Insurance Lane - Suite A, Charlottesville, VA	
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>	An announced CLIA recertification survey was conducted at Pediatric Associates of Charlottesville-North on July 31, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
<b>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of instrument maintenance records, manufacturer's operations manual, and an interview, the laboratory failed to document hematology instrument monthly maintenance in three (3) of twenty-four (24) months reviewed from July 2016 to the date of the survey on July 31, 2018. Findings include: 1. Review of the laboratory's Medonic M Series hematology maintenance logs revealed preventative maintenance procedures for Monthly Cleaning with Boule Cleaning Kit listed as "perform on a monthly basis". The inspector noted that the available hematology maintenance logs revealed no monthly maintenance was documented in June, September, and November in calendar year 2017. 2. Review of the Medonic M Series Operations Manual revealed manufacturer's instructions to "perform the Cleaning and Clot Prevention (Enzymatic) procedures monthly". 3. In an interview with the technical consultant and primary testing personnel at approximately 11:45 AM, it was confirmed that the laboratory failed to document the Medonic M Series hematology monthly preventative maintenance for the three (3) months outlined above in 2017.</p>
<b>D5477</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(4)(g)</p>

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of quality control (QC) log sheets, Individualized Quality Control Plan (IQCP), patient logsheets, and an interview, the laboratory failed to document, before or concurrent with use, fifty (50) lot numbers of culture media's ability to grow and inhibit growth in the twenty-four (24) of twenty-four (24) months reviewed. Findings include: 1. Review of the laboratory's QC log sheets from 08/01/16 to the date of the survey on 07/31/18 revealed the following lot numbers of HealthLink Strep Select and Trypticase Soy (TSA) / Levine EMB Agar media was received and utilized for patient culture testing: Strep Select Agar (throat cultures)- 1615211, 1615205, 1617913, 1622804, 1622114, 1700505, 1631312, 1632612, 1700507, 1702305, 1703904, 1704413, 1708612, 1714204, 1706512, 1708612, 1708709, 1715002, 1726801, 1728900, 1730300, 1731903, 1734500, 1736005, 1801700, 1800901, 1803000, 1802911, 1804504, 1804508, 1805301, 1812706; TSA/EMB Agar (urine cultures)- 1620102, 1620103, 1622203, 1622204, 1625702, 1700403, 1627803, 1632003, 1704502, 1719900, 1708203, 1712103, 1721302, 1728402, 1733202, 1736202, 1804502, 1807202; The QC log sheets revealed no documentation of the media's ability to grow and inhibit growth for the fifty (50) lot numbers listed above. 2. Review of the laboratory's IQCP for culture testing revealed instructions that the laboratory would "maintain documentation of the media's quality control performance". The inspector requested to review the recorded QC reactions and/or observations for the lot numbers utilized from 08/01/16 to 07/31/18. The laboratory was unable to provide the requested documentation. 3. Review of the laboratory's patient logs revealed one thousand four hundred four (1,404) throat cultures and three hundred thirty (330) urine cultures were reported in the twenty-four month period while utilizing the lot numbers of media outlined above. 4. During an interview with the technical consultant and primary testing personnel at approximately 11:45 AM, it was confirmed that QC was not documented as performed on the fifty (50) lot numbers of culture media as outlined for the timeframe above.