

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 47D0091266	(X3) Date Survey Completed 03/20/2018
Name of Provider or Supplier Pediatric Medicine Plc	Street Address, City, State 52 Timber Ln, South Burlington, VT	
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
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to test bacteriology proficiency samples the same number of times that it routinely tests patient samples in 2016 and 2017. Findings include: 1) Review on 3/20/18 of College of American Pathologists (CAP) proficiency testing (PT) records from 2016 revealed 4 of 5 testing personnel tested 5 of 5 throat culture PT samples in CAP event D1-B 2016 before the date results were due to be submitted to the PT company for evaluation. Review of CAP PT records from 2017 revealed 5 of 5 testing personnel tested all 5 throat culture PT samples in CAP event D1-A 2017 before the date results were due to be submitted to the PT company for evaluation, and 5 of 5 testing personnel tested all 5 throat culture PT samples in CAP event D1-B 2017 before the date results were due to be submitted to the PT company for evaluation. 2) Review on 3/20/18 of the laboratory's "Throat Culture" procedure effective 6/16/16 revealed no instruction to for patient culture plates to be read by multiple testing personnel before reporting results. 2) Interview on 3/20/18 at 10:45 a.m. with a registered nurse who has administrative responsibilities for the laboratory confirmed the above findings and that the laboratory did not test the throat culture PT samples the same number of times that it routinely tests patient samples.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and</p>

identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory test reports from 2016, 2017, and 2018 for the presumptive identification of beta-hemolytic group A Streptococcus failed to include the test result. Findings include: 1) Review on 3/20/18 of two patient final reports revealed the name of the test was "Throat Culture" and the result was reported as either "negative" or "positive." The throat culture report did not indicate what it was positive or negative for and if negative indicated there was growth or no growth. 2) Review on 3/20/18 of the "Strep Select Agar" package insert for the throat culture media used by the laboratory revealed the media was intended to be used with bacitracin discs and results interpreted as "beta hemolytic Streptococci, presumptive group A by bacitracin" or "beta-hemolytic Streptococci species, presumptively not group A by bacitracin." 3) Interview on 3/20/18 at 12:15 p.m. with a registered nurse (RN) who had administrative roles for the laboratory confirmed the above findings. The RN revealed that all test reports from 2016, 2017, and 2018 for the presumptive identification of beta-hemolytic group A Streptococci have been reported as described in the first finding above.