

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0226874	(X3) Date Survey Completed 11/07/2018
Name of Provider or Supplier Pediatric & Adolescent Medicine, Llp	Street Address, City, State 8002 Discovery Drive Suite 110, Richmond, VA	
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
D0000	An announced CLIA Recertification survey was conducted at the Pediatric and Adolescent Medicine on November 7, 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:
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records, Laboratory Personnel Report Form (CLIA) (CMS-209 Form), and interviews, the laboratory failed to rotate proficiency testing among the three (3) testing personnel (TP) for five (5) of the six (6) events reviewed. Findings include: 1. The review of the American Academy of Family Physicians (AAFP) PT records revealed that the same TP, TP A, performed the following 5 events (See attached personnel code list): 2017 Event B and C, 2018 Events A, B and C. 2. Review of the CLIA CMS 209 laboratory personnel form revealed three (3) testing personnel performing patient testing in 2017 and up to the date of survey on November 7, 2018. 3. An interview with the laboratory director at approximately 2:00 PM confirmed that the laboratory failed to rotate the AAFP PT events among all testing personnel for the above-specified events.</p>
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform</p>

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 the review of the Quality Assurance (QA) policy and interviews, the laboratory director failed to ensure that the QA Personnel Assessment policy addressed new testing personnel (TP) for training and competency assessments in 2017 and 2018 (Cross Reference D6029). Findings include: 1. Review of the QA policy for Personnel Assessment revealed the following statement: "at least annually, the laboratory director and or technical consultant will review the performance of each employee working in the laboratory to assure employee competency. The written results of the review will be filed in the individuals personnel file. Opportunities will be made available to laboratory personnel for continuing education and noted in the record at the time of this review." 2. An interview with the laboratory at approximately 2:00 PM revealed that there were two (2) new TP in 2017 and 2018, there were no training and competency assessments available for review and that the current policy does not address the training and competency assessments for new TP.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), hematology correlation records, quality control (QC) records, instrument maintenance records, testing personnel (TP) records, and interviews, the laboratory director failed to ensure that two (2) of two (2) new TP had documented training and competency assessments prior to performing testing procedures for hematology in 2017 and 2018. Findings include: 1. Review of the CLIA CMS-209 form revealed that TP C and TP D were new TP. 2. An interview with primary TP, at approximately 12:30 PM, revealed that TP C and TP D performed procedures on the Sysmex XP 300 hematology analyzer from the date of last survey in November 2016. An interview with the laboratory director, at approximately 2:00 PM, revealed that TP D was performing testing procedures during the calendar year 2017 and that TP C began testing procedures during the calendar year 2018 (exact timeframe's could not be determined at the date of survey on November 7, 2018). 3. Review of the hematology correlation study documentation for transcript accuracy revealed that TP D performed the following patient testing: Accession number 14542 on 03/02/2017, Accession number 14408 on 04/13/2017, Accession number 13903 on 11/16/2017, Accession number 14827 on 12/26/2017, Accession number 8337 on 12/28/2017, Accession number 15683 on 01/04/2018, Accession number 15060 on 01/08/2018. 4. Review of

the QC and instrument maintenance records revealed that: TP D performed QC procedures on 10/24/17, 12/22/17, 12/26/17 and 12/27/17, 01/05/18, 10/17/18, 02/16/18, 03/02/18, 04/04/18, 05/01/18 and 5/15/18. TP D performed instrument maintenance procedures on 01/04/18, 01/05/18, 01/16/18, 02/16/18, 03/16/18, and 04/20/18. TP C performed QC procedures on 06/15/18 and 06/22/18. 5. Review of the personnel records revealed no training or competency assessments for TP C and TP D. Records were not available upon request. 6. An interview with the laboratory director at approximately 2:00 PM confirmed the above-listed findings.