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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 49D0226406 | (X3) Date Survey Completed 09/10/2019 |
| Name of Provider or Supplier Pediatric And Adolescent Health | Street Address, City, State 13821 Village Mill Drive - Suite A, Midlothian, 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 Health on September 10, 2019 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: |
| D3031 | <p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records, lack of documentation, and interview with the primary testing personnel (TP), the laboratory failed to retain the "Cell Dyn 18 Plus control" manufacturer's assay information inserts documenting Complete Blood Cell (CBC) count QC acceptable ranges for five (5) of 5 lot numbers utilized from January 1, 2018 through December 31, 2018. Findings include: 1. Review of the laboratory's end of the QC lot instrument printouts from January 1, 2018 through December 31, 2018 revealed the laboratory received and utilized 5 lot numbers of the "Cell Dyn 18 Plus control". The following QC lot numbers lacked documentation of acceptable ranges or manufacturer's package inserts: 7324, 8043, 8127, 8211, and 8295. 2. An interview with the primary TP at approximately 4:00 PM confirmed the findings.</p> |
| D6046 | <p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(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</p> |

test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on the review of Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, lack of documentation, and interview with the primary TP and the technical consultant (TC), the TC failed to perform and document review of the annual competency assessments for twelve (12) of 12 TP in 2019. Findings include: 1. Review of the CMS-209 form revealed that the lab director also performs the duties of technical consultant and that there were a total of 12 TP performing patient testing in 2019. See attached TP code sheet. 2. Review of the TP records revealed lack of documentation by the TC of performance and review of the annual competency assessments for all 12 of the TP: Testing Personnel A- July 18, 2019 Testing Personnel B- July 19, 2019 Testing Personnel C- July 19, 2019 Testing Personnel D- July 18, 2019 Testing Personnel E- July 17, 2019 Testing Personnel F- July 18, 2019 Testing Personnel G- July 19, 2019 Testing Personnel H- July 19, 2019 Testing Personnel I- July 18, 2019 Testing Personnel J- July 19, 2019 Testing Personnel K- July 17, 2019 Testing personnel L- July 19, 2019 3. An interview with the primary TP and TC at approximately 4:00 PM confirmed the findings.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on the review of Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, lack of documentation, and interview with the primary TP and the technical consultant (TC), the TC failed to perform and document review of the semi-annual competency assessments for four (4) of 4 new TP in 2018 and 2019. Findings include: 1. Review of the CMS-209 form revealed that the lab director also performs the duties of TC and that there were 4 new TP performing patient testing in 2018 and 2019. See attached TP code sheet. 2. Review of the TP records revealed lack of documentation by the TC of the performance and review of the semi-annual competency assessments for the following: TP H (semi-annual April 12, 2018), TP I (semi-annual April 12, 2018), TP K (semi-annual April 25, 2019) and TP L (semi-annual April 25, 2019). 3. An interview with the primary TP and TC at approximately 4:00 PM confirmed the findings.