

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0863604	(X3) Date Survey Completed 08/24/2018
Name of Provider or Supplier Pediatrics East, Inc-Germantown	Street Address, City, State 7465 Poplar Ave Suite 201, Germantown, TN	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy for testing personnel, the form used for documenting testing personnel competency assessment and interview with the laboratory coordinator, the laboratory failed to follow policy for testing personnel competency assessment in 2018. The findings include: 1. Review of the laboratory's policy for testing personnel revealed that competency assessment would be performed using direct observation of patient testing, monitoring recording and reporting of test results, review of intermediate test results or worksheets, direct observation of instrument maintenance and function checks, blind testing and problem solving skills. 2. Review of the form used for documenting testing personnel competency assessment revealed that direct observations and blind testing was not included as part of the competency assessment for complete blood count, urine colony count, urine microscopy, and pinworm prep. 3. Interview with the laboratory coordinator on August 28, 2018 at 2pm confirmed the laboratory failed to follow the testing personnel policy for competency assessment when it did not include direct observation and blind testing as part of competency assessment in 2018.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231</p>

through 493.1236.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality assessment (QA) plan, the manufacturer package insert for quality control (QC) lot number L8127, the laboratory QC report for lot number L8127, the complete blood count (CBC) instrument maintenance log for June 2018, patient numbers one, two, and three test reports, and proficiency testing attestation statements for 2018 events one and two, the June 2018 quality assessment form and interview with the laboratory coordinator, the laboratory's quality assessment process was ineffective when it failed to detect problems with QC target assignment and personnel performing testing with no prior documented training in 2018. 1. Review of the laboratory's QA plan revealed the following definition: To monitor and evaluate the ongoing and overall quality of the total testing process by evaluating all established policies and procedures for their effectiveness, identifying and correcting problems, assuring accurate, reliable and prompt test reports and assuring adequacy and competency of the staff. This includes the entire testing process from patient preparation and specimen collection, test analysis and reporting of test results. To qualify as testing personnel a high school diploma and documented training is required. 2. Review of the manufacturer package insert for quality control lot number L8127 revealed an acceptable target value of 17.5% for the hematocrit analyte. 3. Review of the laboratory's QC report for lot number L8127 revealed a target value of 17.3% in use for the hematocrit analyte, and in use dates from 6.1.2018 to 8.24.2018. 4. Review of the Cell-dyn Emerald complete blood count (CBC) instrument maintenance log for June 2018, patient numbers one, two, and three test reports for pinworm prep and CBC performed in June 2018, and the laboratory's proficiency testing attestation statements for 2018 events one and two revealed maintenance, patient testing, and proficiency testing performed by multiple testing personnel with no prior documented training. 5. Review of the June 2018 form used for recording quality assessment activities revealed signatures of both the laboratory coordinator and the laboratory director/technical consultant with no documentation of corrective action for the unacceptable target limits for the hematocrit analyte for QC lot L8127 or for the persons performing instrument maintenance, patient testing, and proficiency testing with no prior documented training. Acceptable QC target limit entry was not included as part of QA on the QA monitoring form. 6. Interview with the laboratory coordinator on August 24, 2018 at 2:00 pm confirmed the laboratory's quality assessment process was ineffective when it failed to detect problems with control target entry and personnel performing testing with no prior documented training in 2018.