

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 44D0315253	<b>(X3) Date Survey Completed</b> 08/27/2018
<b>Name of Provider or Supplier</b> Pediatrics East, Inc Germantown	<b>Street Address, City, State</b> 2002 Exeter Rd, Germantown, TN	
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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 recording testing personnel competency assessments, and interview with the laboratory coordinator, the laboratory failed to follow testing personnel policy for competency assessment in 2018. The findings include: 1. Review of the laboratory's policy for testing personnel revealed that competency assessments 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 recording 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 4:00 pm confirmed the laboratory failed to follow testing personnel policy for competency assessment when it did not include direct observations and blind testing as part of competency assessment in 2018.</p>
<b>D5291</b>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> 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 plan, the manufacturer package insert for quality control (QC) lot number L8127, the laboratory QC report for lot number L8127, the July 2018 quality assessment (QA) monitoring form, the January 2017 Cell-dyn Emerald maintenance log and patient number eleven test report, the January 2017 QA monitoring form, and interview with the laboratory coordinator, the laboratory's quality assessment plan was ineffective when it failed to detect problems with QC target entry in 2018 and untrained testing personnel in 2017.

1. Review of the laboratory's quality assessment 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 51.1% for lymphocyte %. 3. Review of the laboratory quality control report for lot number L8127 revealed a target value of 49.9% in use for the lymphocyte %. 4. Review of the July 2018 QA monitoring form 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 lymphocyte % for QC lot L8127.

Acceptable QC target limit entry was not included as part of QA on the QA monitoring form. 5. Review of the Cell-dyn Emerald complete blood count (CBC) instrument maintenance log for January 2017 and patient number eleven test report revealed maintenance and patient testing performed on 01.02.2017 by a testing personnel with no prior documented training. 7. Review of the January 2017 form used for recording quality assessment activities revealed the signatures of both the laboratory coordinator and the laboratory director/technical consultant with no documentation of corrective action for the person performing patient testing with no documented training. 8. Interview with the laboratory coordinator on August 27, 2018 at 4:00 pm confirmed the laboratory's quality assessment process was ineffective when it failed to detect problems with control limit entry in 2018 and untrained testing personnel in 2017.