

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0863604	(X3) Date Survey Completed 12/07/2021
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
D6042	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4)</p> <p>(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;</p> <p>This STANDARD is not met as evidenced by: Based on observations of the laboratory, record review and staff interview, the technical consultant failed to review and approve quality assessment/quality control records in 2019, 2020 and 2021. The findings include: 1. Observations of the laboratory on 12.7.21 at approximately 9:20 am revealed moderately complex patient testing was being performed as follows: microscope for pinworm and urine microscopy, Cell DYN Emerald (serial number 7302) for complete blood count (CBC) and incubator for urine colony counts. 2. Review of monthly quality assurance /quality control records revealed no review by the previous technical consultant from June 2019 through July 2021. 3. Interview with lead TP on 12.7.21 at approximately 4: 20 pm confirmed the previous technical consultant failed to review and approve quality assurance/quality controls records from June 2019 through July 2021.</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 test procedures and report test results promptly, accurately and proficiently.</p>

This STANDARD is not met as evidenced by:

Based on observations of the laboratory, review of the Department of Health and Human Services Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), review of testing personnel competency records and staff interview, the previous technical consultant failed to evaluate the competency for eight of eight testing personnel (TP) in 2020 and 2021. The findings include: 1. Observations of the laboratory on 12.7.21 at approximately 9:20 am revealed moderately complex patient testing was being performed for pinworm and urine microscopy, complete blood count (CBC), and urine colony counts. 2. Review of the Form CMS-209 revealed eight TP performed moderately complex testing. 3. Review of competency assessment records revealed eight of eight TP annual competencies were not performed and reviewed by the previous technical consultant in 2020 and 2021. 4. Interview with lead TP on 12.7.21 at approximately 4:20 pm confirmed the previous technical consultant failed to perform and review competency assessment for eight of eight TP in 2020 and 2021.