

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2141626	(X3) Date Survey Completed 10/10/2019
Name of Provider or Supplier Pediatrics East, Inc - Arlington	Street Address, City, State 5580 Airline Rd, Arlington, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Citation number one: Based on observation of the laboratory, review of the laboratory procedure and interview with testing personnel number one, the laboratory failed to follow the urine culture colony count inoculation procedure, in 2019. The findings include: 1) Observation on October 10, 2019 at 2:05 p.m. of the laboratory revealed non-sterile transfer pipettes in the laboratory. 2) Review of the Uri-Check laboratory procedure revealed, "Immerse the slide into freshly voided urine so that the agar surfaces become totally immersed. If the specimen is of insufficient volume, pour the urine over the surface of both media." 3) Interview on October 10, 2019 at 2:05 p.m. with testing personnel number one confirmed that if a urine sample is insufficient to immerse the slide, the non-sterile transfer pipette be placed in the sterile container, remove the urine sample, and cover the Uri-Check media surface with the urine sample. Citation number two: Based on review of the laboratory procedure, the urine colony count patient log, patient number one final colony count report, and interview with testing personnel number one, the laboratory failed to follow the incubation procedure in 2019. The findings include: 1) Review of the Uri-Check laboratory procedure revealed, "Incubate at 35*-37* for 18-24 hours and read/document results at 18-24 hours." 2) Review of the August 2019 urine colony count patient log revealed on August 9, 2019 patient number one had a urine colony count placed in the incubator at 3:00 p.m. "not picked up for weekend read at 72 hours 0-1000 Dr (name redacted) informed" 3) Review of patient number one final colony count report revealed, "08-12-19 urine culture 0-1,000 culture not picked up at 24 hours. dr (name</p>

redacted) informed and no further action required" 4) Interview on October 10, 2019 at 1:45 p.m. with testing personnel number one confirmed patient number one urine colony count culture was not picked up for delivery to a sister laboratory for Saturday reading. The urine colony count was reported on Monday at 72 hours of incubation.

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on review of patient numbers two, three and four final reports and interview with the laboratory coordinator, the laboratory final reports failed to include the appropriate units of measurement for the pinworm, urine microscopic analysis and the urine culture colony counts, in 2018 and 2019. The findings include: 1) Review of patient numbers two, three and four final reports revealed the following: 04-23-18 patient number two reported a pinworm with no units of measurement 05-31-19 patient number three reported a urine microscopic analysis with no units of measurement 03-14-19 patient number four reported a urine culture colony count with no units of measurement 2) Interview on October 10, 2019 at 1:25 p.m. with the laboratory coordinator confirmed the unit of measurements were not included in the microscopic results for pinworm and urine, nor for the urine colony count, in 2018 and 2019.

D6054

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 annually, after the first year.

This STANDARD is not met as evidenced by:
Based on review of the spread sheet for testing personnel, the personnel records, and interview with the laboratory consultant, the technical consultant failed to evaluate and document the annual competency for the nurse manager, in 2019. The finding include: 1) Review of the personnel spreadsheet for laboratory testing revealed on March 28, 2019, the nurse manager performed one patient CBC. 2) Review of the personnel records revealed the nurse manager competency was documented in 2015, none in 2019. 3) Interview on October 11, 2019 at 12:30 p.m. with the laboratory coordinator confirmed the nurse manager performed CBC testing on March 28, 2019 and there is no competency documented in 2019.