

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D0177137	<b>(X3) Date Survey Completed</b> 12/08/2021
<b>Name of Provider or Supplier</b> East Liberty Family Health Care Center	<b>Street Address, City, State</b> 7157 Mary Peck Bond Place, Pittsburgh, PA	
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>D5291</b>	<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 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and interview with the Director of Nursing, the laboratory failed to follow their quality assurance (QA) policy for 3 of 12 months in 2020 and 9 of 12 months in 2021. Findings Include: 1. The Quality Assurance Program Management and implementation states, " The QA committee shall convene monthly or more often if need to assess urgent concern". 2. On the day of survey, 10 /08/2021 at 03:30 p.m. , review of QA documentation revealed, the laboratory did not documented QA activities for the following: - 2020: January, February and March. - 2021: March, April, May, June, July, August, September, October, and November. 3. The Director of nursing confirmed the findings above on 10/08/2021 around 04:50 p. m..</p>
<b>D5429</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on observation of microscopes during the laboratory tour, review of</p>

maintenance records, and interview with the Director of Nursing, the laboratory failed to document maintenance for the microscope from September 7, 2019 to the date of survey. Findings include: 1. The Laboratory could not provide microscope maintenance records for the microscope used for microscopic urinalysis, wet mounts, and potassium hydroxide (KOH) microscopic examinations. 2. The maintenance sticker observed at the time of survey, indicated that the microscope was last maintenance on 09/07/2019 and was due 09/07/2020. 2. The Director of Nursing confirmed the findings above on 12/08/2021 around 03:30 p.m. \* Repeated Deficiency

**D5449**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on lack of Quality Control (QC) records and interview with the Director of Nursing, the laboratory failed to performed quality control (QC) each day of patient testing for potassium hydroxide (KOH), wet mount, and urine microscopic examinations performed in 2020 and 2021 Findings include: 1. On the day of survey, 12/08/2021, the Director of Nursing could not provide QC records for KOH, wet mount, and urine microscopic examination in 2020 and 2021. 2. The following microscopic examinations were performed: - 2020: KOH: 10 Wet mount: 22 Urine Microscopic: 3 -2021: KOH: 48 Wet Mount: 52 Urine Microscopic: 6 3. the Director of Nursing confirmed the finding above on 12/08/2021 at 03:30 pm. \* Repeated deficiency.

**D6019**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(iv)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:  
Based on review of American Academy of Family Physicians (AAFP) Proficiency Testing (PT) records and interview with the Director of Nursing, the laboratory director did not ensure that an approved, effective corrective action plan was documented for the unsatisfactory results for 1 of 2 events urine sediment identification in 2021. Findings include: 1. On the day of survey, 12/08/2021, review of AAFP PT records revealed, the laboratory did not document a correction plan for the 2021 event B Urine Sediment with score of 50%. 2. 6 Urine sediment microscopic were performed in 2021 . 3. The Director of Nursing confirmed the finding above on 12/08/2021 at 02:40 p.m.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)

(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.

This STANDARD is not met as evidenced by:

Based on lack of competency assessment (CA) records and interview with the Director of Nursing, the technical consultant failed to assess the competency of 6 of 7 Testing Personnel (TP) for potassium hydroxide (KOH), Wet Mounts, and urine microscopic examinations in 2020 and 2021. Finding Include: 1. On the day of survey, 12/08/2021 at 01:05 p.m., The Director of Nursing could not provide CA records for 6 of 7 TP performing KOH, Wet Mounts, and Urine Microscopic examinations in 2020 and 2021. 2. The following microscopic examinations were performed: - 2020: KOH: 10 Wet mount: 22 Urine Microscopic: 3 -2021: KOH: 48 Wet Mount: 52 Urine Microscopic: 6 3. The Director of Nursing confirmed the findings above on 12/08/2021 at 03:00 p.m. \* Repeated deficiency