Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0177137	12/06/2023
Name of Provider or Supplier	**Street Address, City, State**	
East Liberty Family Health Care Center	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on a lack of the laboratory ' s competency assessment records and interview with the Technical Consultant (TC) #2 (CMS 209), the laboratory failed to establish a competency assessment procedure to assess the competency of 1 of 2 technical consultant (TC) and 18 of 19 Testing Personnel (TP) for their supervisory and testing responsibilities performed in mycology, parasitology, and urinalysis in 2022 and 2023. Findings include: 1. On the day of the survey, 12/06/2023 at 10:12 am, the laboratory could not provide a competency assessment procedure to assess TC and TP for their supervisory and testing responsibilities. 2. The laboratory failed to provide competency assessment records for 1 of 2 TC #2 (CMS 209) for their supervisory responsibilities performed in 2022 and 2023. 3. The laboratory failed to provide competency assessments records for 18 of 19 TP (CMS 209 TP #2, #3, #4, #5, #6, #7, #8, #9, #10, #11, #12, #13, #14, #15, #16, #17, #18, and #19) who performed Potassium Hydroxide (KOH), wet mount, and urinalysis testing in 2022 and 2023. 4. The TC #2 confirmed the findings above on 12/06/2023 at 02:00 pm.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by:

	Based on review of the American Academy of Family Physicians (AAFP) proficiency testing (PT) records, and interview with Technical Consultant (TC) #2 (CMS 209), the laboratory failed to document the evaluation and verification activities for PT testing performed in chemistry, hematology, and urinalysis in 2022. Findings include: 1. On the day of survey, 12/07/2023, review of laboratory's AAFP PT records revealed that the laboratory did not document the review and corrective action taken for the following 2 of 3 PT events in 2022 that received an unsatisfactory score: - AAFP PT 2022-A Glycohemoglobin - AAFP PT 2022-A Urine Sediment ID - AAFP PT 2022-C Hemoglobin Waived 2. TC #2 confirmed the findings above on 12/07/2023 at 02:00 pm.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) 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. This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the Technical Consultant (TC) #2 (CMS 209), the laboratory failed to perform and document maintenance on the 1 of 1 thermometer for room temperature and humidity in laboratory in 2022 and 2023. Findings Include: 1. On the day of survey, 12/07/2023 at 01:35 pm, during observation of the lab the surveyor discovered the following thermometer with no expiration date. -1 of 1 Acurite Model 00826HDA2 2. The laboratory could not provide a maintenance procedure and documentation for the thermometer. 3. The following reagents were found to be stored in the laboratory with a storage temperature requirement of 15 to 30 degree Celsius. - Siemens Multistix 10SG- 2 of 2 bottles. 4. TC #2 confirmed the findings above on 12/07/2023 at 02:00 pm.
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 a lack of quality control (QC) records and interview with Technical Consultant (TC) #2 (CMS 209), the laboratory failed to document a negative and positive control material each day of patient testing for mycology and parasitology microscopic examinations performed in 2022 and 2023. Findings Include: 1. On the day of the survey, 12/07/2023 at 12:02 am, the laboratory failed to provide a QC procedure for KOH prep and Wet mount testing. 2. The laboratory failed to provide documents of KOH (Potassium Hydroxide) and Wet mount negative and positive QC each day of patient testing performed in 2022 and 2023. 3. The laboratory performed 3 KOH and 1 wet mount testing in 2023. 4. TC #2 confirmed the findings above on 12 /07/2023 at 02:00 pm.

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 test reports and interview with Technical Consultant (TC) #2 (CMS 209), the laboratory failed to include pertinent reference intervals/normal values on patient test reports for chemistry, mycology, and parasitology test performed in 2022 and 2023. Findings Include: 1. On the day of the survey, 12/07 /2023 at 01:00 pm, review of patient reports revealed that the laboratory failed to include pertinent reference intervals/normal values on the final reports for the following testing performed in 2022 and 2023. -Potassium Hydroxide (KOH) prep - Wet (saline) mount - Urinalysis, Dipstick 2. TC #2 confirmed the findings above on 12 /07/2023 at 02:00 pm.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a lack of Laboratory's Quality Assurance (QA) Program policy and interview with Technical Consultant (TC) #2 (CMS 209), the Laboratory Director (LD) failed to establish and maintain a QA program to ensure the quality of services provided by the laboratory from 12/08/2021 to date of survey. Findings include: 1. On the day of survey 12/07/2023 at 12:45 pm, the laboratory failed to provide a QA procedure. 2. The laboratory could not provide documentation of the periodic QA activities to assess the laboratory's pre-analytical, analytical, and post-analytical processes for 2022 and 2023. 3. TC#2 confirmed the above findings on 12/07/2023 at 02:00 pm.