Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0177137	09/11/2025
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 lack of documentation and interview with the Technical Consultant (TC), the laboratory failed to establish and follow procedures to assess the competency of 1 of 1 TC for their supervisory responsibilities performed from 01/22/2025 to the date of the survey. Findings Include: 1. On the day of survey, 09/11/2025 at 10:24 am, the laboratory could not provide a procedure for assessing the competency of the laboratory's personnel for their supervisory responsibilities when overseeing potassium hydroxide (KOH) prep and wet mount microscopic examinations performed from 01/22/2025 to 09/11/2025. 2. The laboratory could not provide competency assessment records for 1 of 1 TC (CMS 209 personnel #6, dated 09/10 /2025) for their supervisory responsibilities performed from 01/22/2025 to 09/11 /2025. 3. The TC confirmed the findings above on 09/11/2025 at 11:03 am.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) 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. This STANDARD is not met as evidenced by:

	Based on review of the laboratory's procedure manual, proficiency testing records, lack of documentation and interview with the Technical Consultant (TC), the laboratory failed to provide 1 of 1 written procedure for testing personnel to follow when performing proficiency testing for Potassium Hydroxide (KOH) prep and wet mount microscopic examinations from 01/22/2025 to the day of survey. Findings include: 1. On the day of survey, 09/11/2025 at 10:24 am, review of the laboratory procedure manual and proficiency testing records revealed the laboratory did not establish a written procedure for testing personnel to follow when performing proficiency testing from 01/22/2025 to 09/11/2025 for KOH prep and wet mount microscopic examinations. 2. The laboratory reported 74 KOH prep and wet mount microscopic examinations performed in 2025 (CMS 116 estimated annual volume, dated 09/10/25). 3. The TC confirmed the findings above on 09/11/2025 at 11:03 am.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment (QA) policy, lack of documentation and interview with the Technical Consultant (TC), the Laboratory Director (LD) failed to ensure established QA programs were maintained and documented to assure the quality of laboratory services provided for 8 of 8 months from 01/22/2025 to the day of survey. Findings Include: 1. The laboratory's Quality Improvement/QA Plan states, "The Risk Manager will maintain a log of QI/QA activities. Risk Assessments will be conducted quarterly. Review and analysis of incident/injury reports, patient complaints, infection control data, and lab quality control will contribute to the assessment of Risk Prevention activities." 2. On the day of survey 09/11/2025 at 10:24 am, the laboratory could not provide site specific QA documentation of the periodic evaluation used to assess its pre-analytical, analytical, and post-analytical processes to assure the quality of laboratory services provided for 8 of 8 months from 01/22/2025 to 09/11/2025. 3. The TC confirmed the findings above on 09/11/2025 at 11:03 am.