Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2163585	08/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
Erlanger Health	1635 Gunbarrel Rd Ste 400, Chattanooga, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the Department of Health and Human Services Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), College of American Pathologists (CAP) proficiency testing (PT) records, and staff interviews, the laboratory failed to ensure that one of the two total testing personnel (TP) who performed patient testing for KOH preps and scabies examinations also tested PT samples in 2023, 2024, and 2025. The findings include: 1. A review of Form CMS-209 revealed two TP who performed patient testing. 2. A review of the laboratory's CAP PT records for 2023, 2024, and 2025 revealed that five of five events reviewed were performed by TP1, resulting in one TP who did not participate in PT events: 2023: CM-A and CM-B 2024: CM-A and CM-B 2025: CM-A 3. The laboratory director confirmed the survey findings during an interview on 08/12/2025 at 12:45 p.m. .
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) 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.

	This STANDARD is not met as evidenced by: Based on a review of the laboratory procedure manual, lack of documentation, and staff interview, the laboratory failed to establish a written policy or procedure defining quality activities to monitor, assess, and correct problems in the laboratory's testing systems for 2023, 2024, and 2025. The findings include: 1. A review of the laboratory procedure manual revealed the following Quality Assurance statement that failed to define quality assessment activities to monitor, assess, and correct problems in the laboratory's testing systems on the day of the survey, 08/12/2025: "The lab director will monitor all aspects of the laboratory and make certain that all testing complies with the individual testing policy and procedure protocols." 2. There were no quality assessment records or documentation available. 3. The laboratory director confirmed that the laboratory did not have written quality assessment policies for monitoring and evaluating the pre-analytical, analytical, and post-analytical phases of the testing process in an interview on 08/12/2025 at 12:45 p.m. .
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of the laboratory policy and procedure manual and staff interview, the laboratory failed to define criteria for essential laboratory conditions when it did not have an approved policy or procedure for temperature and humidity monitoring available on the day of the survey, 08/12/2025. The findings include: 1. A review of the laboratory's policy and procedure manuals revealed no policy defining the laboratory's temperature and humidity monitoring criteria. 2. The laboratory director confirmed the survey findings in an interview on 08/12/2025 at 12:45 p.m. .
D5485	CONTROL PROCEDURES CFR(s): 493.1256(h) (h) If control materials are not available, the laboratory must have an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be documented. (a) The laboratory must check the following for positive and negative reactivity using control organisms: This STANDARD is not met as evidenced by: Based on a review of laboratory policies and procedures, patient testing logs, lack of documentation, and staff interviews, the laboratory failed to define or document alternative control procedures for potassium hydroxide (KOH) testing and scabies examinations in 2023, 2024, and 2025, with 74 patients tested in 2023, 39 patients tested in 2024, and 23 patients tested in 2025. The findings include: 1. A review of the

	laboratory's Provider Performed Microscopy (PPM) policies and procedures revealed a policy that contained no QC requirements for KOH testing or scabies examinations. 2. A review of patient testing logs revealed that the laboratory tested 74 patients in 2023, 39 patients in 2024, and 23 patients in 2025. 3. No QC documentation for KOH testing or scabies examinations was available for review on the day of the survey, 08 /12/2025. 4. The laboratory director confirmed the survey findings during an interview on 08/12/25 at 12:45 p.m. .
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on a review of laboratory policies and procedures and staff interviews, the laboratory director failed to have a personnel policy for competency assessment for testing personnel performing grossing procedures on patient tissue samples removed during Mohs surgical procedures in 2025. The findings include: 1. A review of the laboratory policies and procedures revealed that the laboratory did not have a personnel competency policy available on the day of the survey, 08/12/2025. 2. The laboratory director confirmed the survey findings during an interview on 08/12/25 at 12:45 p.m.