Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0908618	(X3) Date Survey Completed 01/17/2023
Name of Provider or Supplier Erlanger Health	**Street Address, City, State** 1720 Gunbarrel Rd, Suite 110, 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
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 review of the CMS Laboratory Personnel Report (CLIA) (CMS 209), laboratory quality assurance plan, testing personnel (TP) records, and interview with the office manager, the laboratory failed to follow the quality assurance plan for personnel training/competency assessment for five of five testing personnel in 2021 and 2022 The findings include: 1. Review of CMS 209 report revealed five testing personnel performing moderately complex patient testing for complete blood count. Testing personnel one, two, three and five were established and testing personnel four a new testing personnel since last survey with documented hire date of 02.07.2022). 2. Review of the laboratory's quality assurance plan "Personnel" section, revealed, "competency will be evaluated initially, at 6 months and annually thereafter". 3. Review of testing personnel competency assessments revealed no annual competency assessments for testing personnel one, two, three, and five in 2021 and 2022. 4. Review of testing personnel training/competency assessments revealed no initial training and no 6 month competency assessment performed on testing personnel four since documented hire date of 02.07.2022. 5. Interview with the office manager on 01.17.2023 at 12:00 pm confirmed the laboratory failed to follow the quality assurance plan for personnel training/competency assessment in 2021 and 2022.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test

	procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and interview with the office manager, the laboratory's procedure for the Beckman Coulter DxH 520 instrument for Complete Blood Count testing did not include control procedures. The findings include: 1. Review of the procedure for the Beckman Coulter DxH 520 instrument used for performing patient testing for complete blood count revealed the procedure did not include control procedures to include the following; type of control, identity, number and frequency of testing controls, control limits, and criteria to determine acceptable control results. 2. Interview with the office manager on 01.17.2023 at 12: 00 pm confirmed the procedure for the Beckman Coulter DxH520 instrument did not include control procedures (type of control, identity, number and frequency of testing controls, control limits, and criteria to determine acceptable control results).
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of CMS Laboratory Personnel Report (CLIA) "CMS 209", testing personnel records and interview with the office manager, the laboratory director failed to perform initial training/verification of accurate test performance for one of one new testing personnel since last survey. The findings include: 1. Review of the CMS 209 report revealed one new testing personnel (testing personnel number four) since last survey performing moderately complex patient testing for complete blood count. 2. Review of testing personnel records revealed initial training and verification that the testing personnel were performing the testing accurately was not performed/verified

	by the laboratory director for one of one new testing personnel. (Refer to D5209) 3. Interview with the office manager on 01.17.2023 at 11:30 am confirmed the laboratory director failed to perform initial training/verification of accurate test performance for one of one new testing personnel.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) 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 review of CMS Laboratory Personnel Report (CLIA) "CMS 209", testing personnel (TP) records and interview with the office manager, the laboratory director failed to perform annual competency assessments for four of five established testing personnel in 2021 and 2022. The findings include: 1. Review of the CMS 209 report revealed five testing personnel performing moderately complex patient testing for complete blood count. 2. Review of competency assessment records revealed no annual competency assessments performed by the lab director/technical consultant for established testing personnel numbers one, two, three, and five (four of five) for 2021 and 2022. (Refer to D5209) 3. Interview with the office manager on 01.17.2023 at 11: 30 am confirmed testing personnel competency assessments for established testing personnel one, two, three, and five listed on the CMS 209 report were not performed by the lab director/technical consultant in 2021 and 2022.