Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2076401	(X3) Date Survey Completed 04/15/2021
Name of Provider or Supplier Eastside Family Care Llc	Street Address, City, State 14 Mitylene Park Lane, Montgomery, AL	

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
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 a review of personnel files and an interview with Testing Personnel #1, the Technical Consultant failed to implement a mechanism to assess and document the competency of moderate-complexity testing personnel in all six of the minimal regulatory requirements. This was noted in the semi-annual and annual competency evaluations for four of five testing personnel listed on the Form CMS-209 Laboratory Personnel Report. The findings include: 1. A review of employee files for Testing Personnel #1 thru #4, revealed semi-annual and annual competency was documented by running one CBC (Complete Blood Count); the patient identification number was recorded on the form, and employee was instructed to give the CBC results to the supervisor. 2. During an interview on 4/15/2021 at 11:15 AM, Testing Personnel #1 confirmed competency was assessed by running one CBC, usually with the physician observing the process. 3. As the interview continued, the surveyor provided the CMS booklet, "What Do I Need to Do to Assess Personnel Competency?", and reviewed the six minimal regulatory requirements for assessing the competency of the laboratory testing personnel. The surveyor explained the laboratory currently only assessed the first criteria, "Direct observation of routine patient test performance". However, the Technical Consultant should also insure competencies included: a) "Monitoring the recording and reporting of test results" b) "Review of ... quality control records, proficiency testing results, and preventive maintenance records" c) "Direct observation ... of instrument maintenance ..." d) "Assessment of test

	performance through ...internal blind testing samples ... or proficiency testing ..." e) "Assessment of problem solving skill" Testing Personnel #1 confirmed the laboratory competencies did not include all the above requirements. .
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of personnel files and an interview with Testing Personnel #1, the Technical Consultant failed to evaluate and document the semiannual competency for one of five testing personnel listed on the Form CMS-209 Laboratory Personnel Report. The findings include: 1. A review of personnel files revealed Testing Personnel #3 was trained in the performance of CBC (Complete Blood Count) testing in September 2019, however there was no documentation of a semiannual competency in early 2020. 2. During an interview and review of employee records on 4/15/2021 at 11:15 AM, Testing Personnel #1 confirmed the above noted findings. .
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of personnel files and an interview with Testing Personnel (TP) #1, the Technical Consultant failed to evaluate and document the annual competency for three of five testing personnel listed on the Form CMS-209 Laboratory Personnel Report. The findings include: 1. A review of personnel files revealed the following: A) TP #1 had annual evaluations in September 2018 and 2019, however there was no documentation of competency assessment in 2020. B) TP #2 had an annual evaluations on 3/2/2018; there were no other annual evaluations until 3/2/2021. C) TP #3 was trained in the performance of CBC (Complete Blood Count) testing in September 2019, however there was no documentation of an annual competency assessment in late 2020. [The test documented as the 2020 competency was actually performed on 9/6/2019.] 2. During an interview and review of employee records on 4 /15/2021 at 11:15 AM, TP #1 confirmed she had been on sick leave March-October 2020, and had not been working in September 2020 when the evaluation was due. When asked if she had performed patient testing when she returned to work, TP #1 confirmed she had, and further confirmed no one had performed the annual competency in October 2020 when she returned to work. 3. As the interview continued on 4/15/2021, TP #1 stated TP #2 had an annual on 3/2/2018, and then was no longer employed by this provider in 2019 and early 2020, however she returned in June 2020. There was no documentation of re-training when the employee was re-hired, and an "annual" competency evaluation was not performed until 3/2/2021. TP #1 further confirmed TP #3 had not had an evaluation since her training. .

D6067	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Each individual performing moderate complexity testing must have training to ensure that the individual has-- (A) the skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (B) the skills required for implementing all standard laboratory procedures; (C) the skills required for performing each test method and for proper instrument use; (D) the skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed; (E) a working knowledge of reagent stability and storage; (F) the skills required to implement the quality control policies and procedures of the laboratory; (G) an awareness of the factors that influence test results; and (H) the skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a review of personnel files and an interview with Testing Personnel #1, the laboratory failed to ensure records of new personnel who performed moderate complexity CBC (Complete Blood Count) testing included documentation of training in all elements of test performance and use of the Abbott Cell Dyn Emerald. This was noted on three of three new testing personnel. The findings include: 1. A review of training records for Testing Personnel #3, #4, and #5 revealed a form documenting the patient identification number for five patients on whom the employee had run CBC's. According to instructions on the form, the employees were to give the CBC results to the supervisor. The records failed to include documentation of training on start-up, shut-down, and preventive maintenance procedures, how to change reagents and on-board stability, quality control policies and procedures, the significance of error codes and other problems that can affect test results, and final reporting of patient results. There was also no indication of who had trained the employees. 2. During an interview on 4/15/2021 at 11:15 AM, Testing Personnel #1 confirmed new testing personnel document their training by performing five CBC's. The surveyor reviewed the additional elements CLIA required during initial training for moderate-complexity testing, and explained the current records only document the testing personnel's test performance skills. Testing Personnel #1 stated the testing personnel are trained in the above listed aspects of test performance and use of the Abbott Cell Dyn Emerald, however they have not documented this. SURVEYOR ID#32558 Licensure and Certification Surveyor