

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D2076401	<b>(X3) Date Survey Completed</b>  12/15/2022
<b>Name of Provider or Supplier</b>  Eastside Family Care Llc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D6045</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(7)</p> <p>(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;</p> <p>This STANDARD is not met as evidenced by: Based on reviews of personnel files, and an interview with the Testing Personnel #1 (also the Laboratory Supervisor), the Technical Consultant failed to ensure training was performed and documented before testing personnel began patient testing. This affected two of two new testing personnel listed on the Form CMS-209 (Laboratory Personnel Report). The findings include: 1. A review of personnel files revealed the following: A) Testing Personnel #5: The Basic Training Checklist for the Cell Dyn Emerald (for moderate complexity CBC [Complete Blood Count] testing) was dated 8/17/2022, however her job description was signed 8/3/2021, and the record included five patient CBC's performed on 8/9/2021 and 11/3/2021. B) Testing Personnel #6: The Basic Training Checklist for the Cell Dyn Emerald (for moderate complexity CBC [Complete Blood Count] testing) was dated 8/30/2022, and her job description was signed 8/30/2022, however the record included five patient CBC's performed 10/25/2021 through 11/1/2021. 2. During an interview on 12/15/2022 at 12:37 PM (with the Clinic Manager present), Testing Personnel #1 confirmed new testing personnel documented their training by performing five CBC's. The surveyor reviewed the additional elements CLIA required during initial training for moderate-complexity testing which can be found on the BASIC TRAINING CHECKLIST for the Cell Dyn Emerald, however completion of the training should be dated before the testing personnel performed patient testing independently. .</p>
<b>D6046</b>	<b>TECHNICAL CONSULTANT RESPONSIBILITIES</b>

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 (also the Laboratory Supervisor), the Technical Consultant failed to implement a mechanism to assess and document the competency of moderate-complexity testing personnel which included all six of the minimal regulatory requirements. This was noted in the semi-annual and annual competency evaluations for six of six testing personnel listed on the Form CMS-209 (Laboratory Personnel Report). This is a repeat deficiency. The findings include: 1. A review of employee files revealed the laboratory had implemented additional semi-annual and annual competency assessment procedures for the testing personnel since the previous survey. However, a review of the new forms revealed the laboratory failed to ensure all six of the minimal regulatory requirements for assessing competency were included on each, as follows: A) The semi-annual competency evaluations for Testing Personnel #3 thru #6 failed to include criteria "d", "e", and "f" (see criteria listed below in the interview). B) The annual competency evaluations (when attached to the Cell Dyn Basic Training Checklist) for Testing Personnel #1 thru #6 failed to include criteria "e", "Assessment of test performance through ...internal blind testing samples ... or proficiency testing ...". 2. During an interview on 12/15/2022 at 12:37 PM (with the Clinic Manager present), the surveyor provided another copy of 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, as follows: a) "Direct observation of routine patient test performance" b) "Monitoring the recording and reporting of test results" c) "Review of ... quality control records, proficiency testing results, and preventive maintenance records" d) "Direct observation ... of instrument maintenance ..." e) "Assessment of test performance through ...internal blind testing samples ... or proficiency testing ..." f) "Assessment of problem solving skills" Testing Personnel #1 confirmed the laboratory competencies still did not include all the above requirements. SURVEYOR ID#32558 Licensure and Certification Surveyor