

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  18D0938133	<b>(X3) Date Survey Completed</b>  05/25/2021
<b>Name of Provider or Supplier</b>  U Of L Physicians Primary Care Associates	<b>Street Address, City, State</b>  6801 Dixie Highway, Suite 133, Louisville, KY	
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>D6018</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(iii)</p> <p>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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and record review of the hematology proficiency testing results from the American Proficiency Institute (API) testing agency on 05/25/2021 at 10:50 AM, the laboratory director failed to review the proficiency testing results from 05/24/2019 through 05/24/2021. Findings Include: At the time of the survey on 05/25/2021, the final results of the hematology proficiency for three (3) events in 2019, three (3) events in 2020, and one (1) event in 2021 were not reviewed by the medical director or testing staff. The staff acknowledged in an interview on 05/25/2021 at 10:50 AM that the laboratory did not have a system to ensure that the hematology proficiency testing results were reviewed and documented by the medical director and testing personnel from 05/24/2019 through 05/24/2021.</p>
<b>D6046</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)</p> <p>(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.</p>

This STANDARD is not met as evidenced by:

Based on staff interview and record review on 05/25/2021 at 10:41 AM, the Technical Consultant failed to perform and document annual competency using the six (6) mandated competency assessment requirements for testing personnel. The laboratory failed to perform competency assessment using six (6) methods of assessment for four (4) out of four (4) employees from 05/24/2019 through 05/24/2021. Findings include:

1. Record review on 05/25/2021 revealed there were no documented competency assessments between 05/24/2019 and 05/24/2021 for four (4) employee that included the following: competency assessments failed to include direct observation of routine patient test performance, direct observation of the performance of instrument maintenance function checks and calibration, monitoring the recording and reporting of test results, review of worksheets, review of quality control records, review of proficiency test results, review of maintenance records, assessment of testing external proficiency testing samples and problem-solving skills.
2. The staff acknowledged in an interview on 05/25/2021 at 10:41 AM, that the laboratory did not have a system in place to document competency assessment using the six (6) mandated competency assessment requirements from 05/24/2019 through 05/24/2021.