

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D1012009	(X3) Date Survey Completed 06/03/2021
Name of Provider or Supplier Lewis Family Care	Street Address, City, State 6628 Us 60, Ashland, KY	
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	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and record review on 06/03/2021, the Laboratory Director failed to perform and document annual competency using the 6 mandated competency assessment requirements for testing personel. Competency assessment was not performed using six (6) methods of assessment for testing personnel from 04/09/2019 though 06/02/2021. Findings include: 1. Record review on 06/03/2021 revealed there was no documented competency assessments for Hematology or Chemistry specialties from 04/09/2019 through 06/02/2021, for testing personnel. Competency assessments failed to include direct observation of routine patient test performance, direct observation of 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 maintence records, assessment of testing external proficiency testing samples and problem solving skills. An interview with the staff on 06/03/2021 at 10:00AM revealed the facility failed to have a system in place between 04/09/2019 through 06/02/2021 to ensure competency was performed using all six (6) mandated competency assessment requirements.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems</p>

identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on staff interview and record review, it was determined the laboratory failed to perform quality assessment from 09/10/2019 through 06/02/2021. Findings include: 1. Record review revealed there was not documented evidence of quality assessment performed from 09/10/2019 through 06/02/2021. 3. An interview on staff on 06/03/2021 at 1:00PM indicated that the facility has a quality assessment plan in place but was not followed from 09/10/2019 through 06/02/2021.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on record review and staff interview on 06/03/2021, the laboratory failed to verify the performance specifications established by the manufacturer prior to reporting patient test results when the Beckman Coulter Access 2 and Alpha Wasserman ACE AXCEL analyzers were moved to a new location on 12/01/2019. Findings include: 1. Review of records revealed that the laboratory failed to assess the accuracy of test systems prior to reporting patient results after analyzer was moved 12/01/2019. 2. Review of records revealed that the laboratory failed to assess day-to-day, run-to-run, and with-in run precision to ensure reproducibility prior to reporting patient results after analyzer was moved 12/01/2019. 3. Interview with staff at 1:00 PM on 06/03/2021 revealed the laboratory failed to have a system in place to ensure accuracy and precision performance specifications were verified after analyzers were moved.