

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D1063708	(X3) Date Survey Completed 03/31/2021
Name of Provider or Supplier Lexington Clinic - Paa East	Street Address, City, State 171 N Eagle Creek Dr, Suite 100, Lexington, 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
D2025	<p>BACTERIOLOGY CFR(s): 493.823(c)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and record review on 03/31/2021, the laboratory failed to submit proficiency testing results to the American Proficiency Institute (API) for the third (3rd) Microbiology event of 2019. Findings include: 1. Staff acknowledged that the proficiency testing samples for microbiology were not tested or submitted to API for the third (3rd) event of 2019. 2. Record review on 03/31/2021 revealed that no corrective action, self evaluation or investigation was conducted or documented.</p>
D2127	<p>HEMATOLOGY CFR(s): 493.851(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and record review on 03/31/2021, the laboratory failed to submit proficiency testing results to the American Proficiency Institute (API) for the third (3rd) Hematology event of 2019. Findings include: 1. Staff acknowledged that the proficiency testing samples for hematology were not tested or submitted to API for the third (3rd) event of 2019. 2. Record review on 03/31/2021 revealed that no corrective action, self evaluation or investigation was conducted or documented.</p>

D5445

CONTROL PROCEDURES

CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and staff interview on 03/31/2021, the laboratory failed to perform at least two levels of quality control samples on two of five days of Complete Blood Count (CBC) testing reviewed on the Sysmex Pochi Hematology instrument. Findings include: 1. One patient CBC was tested on 01/21/2020. Review of quality control data failed to reveal quality control results. 2. One patient CBC was tested on 03/24/2020. Review of quality control data failed to reveal quality control results. 3. Interview with the staff at 9:00 AM on 03/31/2021, revealed the facility failed to have a system in place to ensure at least two levels of quality control samples were tested prior to testing patient samples.