

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0952711	(X3) Date Survey Completed 09/21/2023
Name of Provider or Supplier Greater Louisville Internal Medicine Norwood	Street Address, City, State 7410 New Lagrange Rd #120, Louisville, 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
D0000	A Recertification Survey was conducted on 09/21/2023. The laboratory was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the facility's procedure manual and documents, and interview, the laboratory failed to monitor the performance of the complete blood count (CBC) quality controls for the Cell-Dyn Emerald analyzer for thirteen (13) (September 2022 to September 2023) of thirteen (13) months reviewed. The findings include: Review of the facility's procedure manual signed by the Laboratory Director (LD) on 05/04 /2022, revealed a section titled, "Routine QC" (quality control)," which stated, "On at least weekly bases [sic], the controls for all tests will be looked at to check for shifts and/or trends." A review of the section titled, "QC Verification," the policy stated, "Review the Levey-Jennings (QC) graphs. Are there shifts or trends occurring? If yes, the instrument may need to be calibrated." Review of the facility's, "Cell-Dyn Emerald Maintenance Log" for the time period September 2022 to September 2023,</p>

revealed the section used to note the performance of the "Weekly Levy-Jennings Review" was blank. In an interview on 09/21/2023 at 1:00 PM, Testing Personnel (TP) #1 and TP #2 were shown the "Cell-Dyn Emerald Maintenance Log" and asked why the weekly review of the Levey-Jennings charts was not being performed as required by the laboratory procedure. TP #1 and TP #2 responded they did not know how to access that data in the analyzer.

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 policy review, document review, and interview, it was determined the Laboratory Director (LD)/Technical Consultant (TC) failed to evaluate and perform competency of 3 of 6 testing personnel (TP) listed on the Form CMS-209 for 2 of 2 years reviewed (2022 and 2023). The findings include: Review of the laboratory's CMS-209 revealed that the LD also served as the TC. The laboratory's "Delegation of Duties" policy, signed by the LD/TC on 05/22/2023, stated "Purpose: While the Laboratory Medical Director maintains ultimate responsibility for Laboratory's performance, certain tasks are delegated to other members of the laboratory team. The purpose of this policy is to define which responsibilities are delegated to whom." Per the policy, the responsibility of "Employee Evaluation" was authorized to be performed by the "Lab [Laboratory] Director." Review of the following competency assessments revealed that the assessments were signed by TP #2 instead of the LD /TC: a. "Competency Assessment" for TP #1 dated 02/15/2023 and 07/05/2023 b. "Competency Assessment" for TP #4 dated 04/20/2022 and 04/20/2023 c. "Competency Assessment" for TP#5 dated 04/22/2022 and 04/21/2023 During an interview on 09/21/2023 at 12:30 PM, with the LD, Office Manager, and TP #2, it was acknowledged that the competency assessments were not signed by the LD/TC as required.