

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2309027	(X3) Date Survey Completed 03/13/2025
Name of Provider or Supplier Lmg Cancer & Infusion Center	Street Address, City, State 1860 Town Center Drive, #120, Reston, VA	
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	An announced CLIA initial survey was conducted at LMG Cancer & Infusion Center on March 13, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows and includes the Conditions under 42 CFR part 493 CLIA Regulation: D5400 -42 CFR. 493.1250 Analytic Systems D6000 -42 CFR. 493.1403 Laboratory Director
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on a tour, review of policies and procedures, instrument performance verification records, manufacturer's instructions for use, daily humidity logs, lack of documentation and interviews, the laboratory failed to: 1. follow their established policy to evaluate/verify the accuracy, precision, reportable range and normal range after installing and initiating patient Complete Blood Count (CBC) testing on the newly installed Sysmex PocH-100i hematology analyzer on November 26, 2024 up to the date of the survey on March 13, 2025. See D5421. 2. document corrective actions taken on the dates the laboratory's relative humidity (RH%) was outside of the manufacturer's criteria on twenty-six (26) of thirty (30) patient testing days from November 26, 2024 to the date of the survey on March 13, 2025. See D5785.</p>
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(1)

(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 a tour, review of the laboratory's policies and procedures, instrument performance verification records, lack of documentation, and interviews, the laboratory failed to follow their established policy and evaluate/verify the accuracy, precision, reportable range and normal range after installing and initiating patient Complete Blood Count (CBC) testing on the newly installed Sysmex pocH-100i hematology analyzer on November 26, 2024 up to the date of the survey on March 13, 2025. The findings include: 1. In an entrance interview on March 13, 2025 at 9:00 AM, the Laboratory Manager (LM) stated the laboratory performs Complete Blood Cell testing on the Sysmex pocH-100i. They stated the instrument was installed on October 30, 2024 and began testing on November 26, 2024. In a tour of the laboratory on March 13, 2025 at 9:10 AM, the surveyor noted a Sysmex pocH-100i (serial number G5505). The surveyor inquired when the validation/verification of the instrument was performed. The LM stated calibration and patient comparison samples were run on November 13, 2024. 2. Review of the laboratory's policies and procedures revealed a policy, "Method Validation", with the statement, "All tests /methods/instrumentation will be validated prior to implementation and reporting of patient results...The validation will include accuracy, precision, method comparison, and analytical sensitivity (linearity)...Once the validation is complete, a validation report must be prepared and approved by the laboratory director." 3. Review of the laboratory's instrument validation records for the Sysmex pocH-100i revealed documentation of an instrument calibration on November 13, 2024, and forty patient sample instrument printouts for the PocH 100i and a Sysmex XN-450. No further validation documentation was noted. The surveyor requested to review documentation of the pocH-100i's precision, accuracy, reportable range and normal range verification. The laboratory provided no further documentation for review. In an interview with the LM on March 13, 2025 at 10:15 AM, the LM stated they performed the calibration and ran the specimens but did not realize the patient comparison should be evaluated or reviewed by the Laboratory Director prior to patient testing. 4. Review of patient test logs revealed that the laboratory reported one-hundred ten (110) patient CBC results from the Sysmex pocH-100i analyzer (G5505) beginning November 26, 2024 to date of the survey on March 13, 2025. 5. In an exit interview with the LM on March 13, 2025 at 12:00 PM, the above findings were confirmed.

D5785

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(3)

(b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:
 Based on a laboratory tour, a review of the Sysmex pocH-100i's Instructions for Use, daily humidity logs, lack of documentation, and an interview, the laboratory failed to document corrective actions taken on the dates the laboratory's relative humidity (RH%) was outside of the manufacturer's criteria on twenty-six (26) of thirty (30) patient testing days from November 26, 2024 to the date of the survey on March 13, 2025. The findings include: 1. In an entrance interview on March 13, 2025 at 9:00 AM, the Laboratory Manager (LM) stated the laboratory performs Complete Blood Cell (CBC) testing on the Sysmex PocH-100i hematology analyzer. They stated the instrument was installed on October 30, 2024 and began testing on November 26, 2024. In a tour of the laboratory on March 13, 2025 at 9:10 AM, the surveyor noted a Sysmex pocH-100i (serial number G5505). 2. Review of the Sysmex pocH-100i's Instructions for Use revealed the performance characteristic-specifications for the analyzer for relative humidity (RH%) was "30%-85%". 3. Review of the laboratory's daily RH% from November 2024 until the date of the survey on March 13, 2025 revealed the laboratory's recorded RH% exceeded the above Sysmex pocH-100i operating RH% on the following days: 11/26/2024, 12/3/2024, 12/05/2024, 12/12/2024, 12/19/2024, 12/31/2024, 01/02/2025, 01/07/2025, 01/09/2025, 01/14/2025, 01/16/2025, 01/21/2025, 01/23/2025, 01/28/2025, 01/30/2025, 02/06/2025, 02/11/2025, 02/13/2025, 02/18/2025, 02/20/2025, 02/25/2025, 02/27/2025, 03/04/2025, 03/06/2025, 03/11/2025, and 03/13/2025. A total of 26 patient testing days. Review of the laboratory's humidity logs from November 2024 until March 2025 revealed a lack of documentation of the corrective actions taken when the laboratory's RH% exceeded the performance specifications for the Sysmex pocH-100i hematology analyzer. 4. In an exit interview with the LM on March 13, 2025 at 12:00 PM, the above findings were confirmed.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
 CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
 Based on a tour of the laboratory, review of instrument performance verification records, patient test results, Sysmex pocH-100i Instructions for Use, daily humidity logs, lack of documentation, and interviews, the laboratory director failed to ensure: 1. verification of the accuracy, precision, reportable range and the normal (reference) ranges for the Sysmex pocH-100i hematology analyzer prior to patient testing on November 26, 2024. Refer to D6013. 2. maintenance of the laboratory's relative humidity (RH%) and documentation of corrective actions taken when the laboratory's RH% was outside of the manufacturer's performance characteristic-specifications. See D6023.

D6013

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(3)(ii)

(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

This STANDARD is not met as evidenced by:
Based on a tour of the laboratory, instrument performance verification records, review of patient test results, lack of documentation, and interviews, the laboratory director failed to ensure the verification of the accuracy, precision, reportable range and the normal (reference) ranges for the Sysmex pocH-100i hematology analyzer prior to patient testing on November 26, 2024. Refer to D5421.

D6023

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(6)

(e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

This STANDARD is not met as evidenced by:
Based on a tour of the laboratory, a review of the Sysmex pocH-100i Instructions for Use, daily humidity logs, lack of documentation, and an interview, the laboratory director failed to ensure the maintenance of the laboratory's RH% and documentation of corrective actions taken when the laboratory's relative humidity (RH%) was outside the manufacturer's performance characteristic-specifications. See D5785.