Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2271660	08/07/2024
Name of Provider or Supplier	**Street Address, City, State**	
American Medical Laboratory	14221-A Willard Rd, Suite 200, Chantilly, 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 unannounced onsite Clinical Laboratory Improvement Amendments (CLIA) complaint investigation (Complaint # VA00061410) was conducted at American Medical Laboratory (AML) on August 6-7, 2024, by Medical Facilities Inspectors from the Virginia Department of Health, Office of Licensure and Certification. The investigation included a tour, review of documents and interviews with the laboratory owner. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiency cited is as follows:
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a tour of the laboratory, review of the facility's Centers for Medicare and Medicaid Services Application for Certification (CMS 116) form, patient test requisitions, American Medical Laboratory (AML) patient reports, corresponding reference laboratory reports and interviews, the laboratory failed to ensure two of two patient reports correctly identified the reference laboratory name and address where testing was performed from March 2024 until the date of the complaint investigation on August 7, 2024. The findings include: 1. During a tour of the laboratory with the laboratory owner on August 7, 2024 at 8:30 AM, the inspectors observed the laboratory was not performing patient testing. The inspectors inquired with the

	laboratory owner concerning the lack of patient testing. The laboratory owner stated, "We are not performing patient testing yet. We are working on the instrument validations. Since March 2024, patient specimens are collected at the provider's office and then we send the specimens to the reference laboratories for testing. The reference laboratories we use are [reference (ref) lab #1] and [ref lab #2]. Once the results are completed by the reference laboratories, I access the results from the reference laboratories portal and then manually enter the patient results into our laboratory computer system." 2. Review of the facilities CMS 116 form revealed a laboratory name and facility physical location address as: American Medical Laboratory 14221-A Willard Rd. Suite 200 Chantilly, VA 20151 3. The inspectors randomly selected 2 patient reports from the reference laboratory requisition records for review. Review of order number 1923000001's reference laboratory's report revealed the testing laboratory name and location of [ref lab #1]. Review of order number 1825000020's reference laboratory's report revealed the testing laboratory name and location of [ref lab #2]. 4. Review of the two corresponding AML medical record patient reports (Order numbers 192300000 and 1825000020) revealed the following the testing location: American Medical Laboratory 14221-A Williard Rd, Suite 200 Chantilly, VA 20151 5. In an exit interview with the laboratory owner on August 7, 2024, at 10: 30 AM, the above findings were confirmed. The laboratory owner stated, "I will add the reference laboratory location as a comment to the patient reports."