

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D1084432	<b>(X3) Date Survey Completed</b>  10/27/2022
<b>Name of Provider or Supplier</b>  Affinity Physician	<b>Street Address, City, State</b>  3686 Grandview Parkway, Suite 820, Birmingham, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5805</b>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of a patient report and an interview with the Clinic Manager and the Testing Personnel, the laboratory failed to ensure one of five required parameters was included on a test report. The test report included the previous name of the facility, and the facility had failed to correct this deficiency since the previous survey on 11/20/2020. The findings include: 1. During the post analytical review on 10/27/2022 at 1:00 PM, the surveyor requested a patient test report. The laboratory provided one patient report printed from the Athena EMR (Electronic Health Record). However, the surveyor noted the name of the facility performing the test was incorrect. It did not match the name on the laboratory's CLIA Certificate, or the name of the practice in which the laboratory was located. The surveyor further noted the same problem was discussed during the previous survey on 11/20/2020, when the Clinic Manager stated the laboratory would fix it. 2. During an interview on 10/27/2022 at 1:15 PM, the Clinic Manager explained the name on the test report, "Medicine Montclair" was the previous name of the facility, and Athena was unable to change the name set up in the "corporate office table". The laboratory provided a letter dated December 22, 2020, mailed to the CLIA State Agency with the same information. The surveyor explained</p>

the name of the laboratory performing the test was required by CMS (Center for Medicare and Medicaid Services). If Athena was unable to change the name of the laboratory in the EHR, the laboratory must implement another mechanism to ensure the correct laboratory name was on the test report. SURVEYOR ID #32558 Licensure and Certification Surveyor