

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0679593	(X3) Date Survey Completed 11/02/2022
Name of Provider or Supplier Atlantic Medical Group	Street Address, City, State 261 James St Suite 1a, Morristown, NJ	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of Competency Assessment (CA) records and interview with the Office Manager (OM), the laboratory failed to perform a CA on one out of one testing personnel for the calendar years 2021 and 2022. The OM confirmed on 10/2/22 at 11:30 am that the CA was not performed as stated above.</p>
D5787	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Accession Log (AL), Test Report (TR) and interview with the Office Manager (OM), the laboratory failed to maintain an accurate information system for Cytology tests from on the date of survey. The findings</p>

include: 1. Review of the AL and revealed: a. one out of ten TR were not logged in the AL. 2. The OM confirmed at 11:30 am on 10/2/22 the laboratory did not maintain an accurate information system.

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 surveyor review of the Final Report (FR) and interview with the Office Manager (OM), the laboratory failed to ensure that the FR included all the required information on the date of survey. The finding include: 1. A review of ten FR revealed that the name and address of the laboratory performing the Professional Component for Cytology testing was not on FR. 2. The OM confirmed on 11/2/22 at 11:45 am that FR did not have all the required information.