Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2316151	06/02/2026
Name of Provider or Supplier	**Street Address, City, State**	
Atlantic Medical Group Dba Acoha	901 West Main St, Freehold, 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
D2005	ENROLLMENT CFR(s): 493.801(a)(4) (a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to authorize PT data for Hematology events performed with the American Proficiency Institute (API) to be released to the Centers for Medicare and Medicaid Services (CMS) in calendar years 2025 and 2026. The findings include: 1. The Hematology PT records from API state "CLIA No: Not on file." 2. All Hematology PT records performed with API in calendar years 2025 and 2026 stated the CLIA Number was "Not on file". 3. TP #1 as listed on the CMS-209 form confirmed the PT results performed with API were not being released to CMS.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records, Procedure Manual (PM) and interview with the Testing Personnel (TP) the laboratory failed to ensure

	that all Testing Personnel (TP) who performed Hematology testing participated in all PT events from the American Proficiency Institute (API) in all events of 2025 and the first event of 2026. The findings include: 1. Only one TP performed all Hematology PT events.. 2. TP#1 listed on CMS form 209 confirmed on 6/2/26 at 11:45 am that the laboratory failed to rotate all TP to participate in all Hematology PT events.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), and interview with the Testing Personnel (TP), the PM lacked a Quality Control Verification (QCV) procedure for new lots of Quality Control (QC) used for Hematology tests from 12/30 /24 to 6/2/26. The findings include: 1. The laboratory did not establish a detailed procedure for performing QCV on new lots of QC material that included frequency and acceptability criteria. 2. The laboratory performed QCV on new lots of QC, but did not have a detailed procedure. 3. TP #1 as listed on the CMS 209 form confirmed on 6/2/26 at 12:05 pm, the laboratory did not establish a QCV procedure.
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 surveyor review of the Performance Specification (PS) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that PS procedures performed on the Sysmex XN-L analyzer were adequate from 11/15/24 to 6/2/26. The finding includes: 1. There was no documented evidence that Precision and linearity were performed. 2.. TP#1 listed on CM form 209 confirmed on 6/2/26 at 11:20 am, the LD failed to ensure the PS were adequate before being used for patient testing.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on surveyor review of the Personnel Files (PF), Training Records (TR) and interview with Testing Personnel (TP), the Laboratory Director (LD) failed to have appropriate education records for two out of four TP performing patient testing on file

	from 12/30/24 to the date of the survey. The findings include: 1. There were no education records for TP #3 and TP #4 listed on CMS form 209. 3. TP #1 listed on CMS form 209 confirmed on 6/2/26 at 11:15 AM the above records were not on file.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based surveyor review of Personnel Files (PF) and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to specify in detail the duties and responsibilities the Techincal Consultant (TC) engaged in the performance of Hematology testing from 12/30/24 to 6/2/26. The finding includes: 1. The laboratory did not have documented detailed duties and responsibilities for the TC. 2. TP#1 listed on CMS form 209 confirmed on 6/2/26 at 12:15 am that the LD did not specify the duties and responsibilities of the TC.