Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0227489	02/07/2024
Name of Provider or Supplier	**Street Address, City, State**	
Glenside Medical Associates Llc	4000 A Glenside Drive, Richmond, 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 Recertification survey was conducted at Glenside Medical Associates on 02/07/24 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D5400 - 42 C.F. R. 493-1250 Condition: Analytic Systems.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on the review of proficiency testing (PT) records, lack of documentation, and an interview, the lab director and testing personnel (TP) failed to review and sign one of three attestation statements reviewed for calendar year 2023. Findings include: 1. Review of the three 2023 College of American Pathologists (CAP) hematology PT records revealed lack of documentation for the following: 2023 FH16 C Hematology event- Attestation statement- no signature by the lab director and testing personnel. 2. An exit interview with testing personnel and lab consultant on 02/07/24 at 1700 confirmed the findings.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the

	proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on the review of Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), CASPER Survey Summary (Report 0096D), proficiency testing (PT) records, lack of documentation, and an interview, the laboratory failed to retain documentation of participation for two of two 2022 hematology events reviewed. Findings include: 1. Review of the CMS 116 form, the CASPER Report 0096D, and the College of American Pathologists (CAP) 2023 PT records revealed the laboratory performs Complete Blood Count with automated White Blood Cell differential (CBC with WBC Diff) patient testing and participates in the CAP PT program. In addition, the CASPER Report 0096D revealed scores submitted to CMS for events B and C in 2022. 2. Review of the laboratory's available CAP PT records revealed lack of documentation of participation in the CAP FH16 B and C events in 2022 to include the PT program report forms, instrument printouts, attestation statements and result reviews for the two events. The inspector requested to review the documents. The laboratory could not locate the documents for review. 3. An exit interview with the testing personnel and lab consultant on 02/07/24 at 1700 confirmed the findings.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on the review of proficiency testing (PT) records, lack of documentation, and an interview, the laboratory failed to review and evaluate one of two urinalysis sediment microscopy events in calendar year 2023. Findings include: 1. Review of the College of American Pathologists (CAP) PT records revealed the laboratory participates in the CAP Clinical Microscopy PT module. The review revealed participation and review of results for the first event in 2023, CMA- A and CAP PT report forms for the second event in 2023, CMA-B. In addition, the review revealed lack of documentation of results from CAP PT program for CMA-B and the laboratory's review or assessment of the second event. 2. The inspector requested to review the CAP PT CMA-B event results and laboratory's assessment for the event. The documentation was not available for review. 3. An exit interview with testing personnel and lab consultant on 02/07/24 at 1700 confirmed the findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 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. This CONDITION is not met as evidenced by: Based on the review of manufacturer storage requirements, temperature records, calibration verification records, available quality control (QC) records, electronic medical records (EMR), lack of documentation, and an interview, the laboratory failed to: 1. Ensure the freezer temperatures were within manufacturer's acceptable range for the Triage Total 5 quality control materials for 26 of 62 days reviewed. Refer to D5413. 2. Perform and assess the accuracy, precision and reference range of the creatine kinase-myocardial band (CK-MB), myoglobin, troponin I and D-Dimer analytes assayed on the Quidel Triage MeterPro. Refer to D5421.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on the review of manufacturer storage requirements, temperature records, and an interview, the laboratory failed to ensure the freezer temperatures were within manufacturer's acceptable range for the Triage Total 5 quality control materials for 26 of 62 days reviewed (December 2023 and January 2024). Findings include: 1. Review of manufacturer storage requirements for the Triage Total 5 quality control materials revealed the materials must be stored at freezer temperatures of equal to or less than -20 degrees Celsius. 2. Review of daily freezer temperature logs for December 2023 and January 2024 revealed that the freezer temperature recorded as warmer than -20 degrees Celsius for: 11 days in December 2023 and 15 days in January 2024. 3. An exit interview with testing personnel and lab consultant on 02/07/24 at 1700 confirmed the findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 the review of calibration verification records, available quality control (QC) records, electronic medical records (EMR), lack of documentation, and an interview, the laboratory failed to perform and assess the accuracy, precision and reference range of the creatine kinase-myocardial band (CK-MB), myoglobin, troponin I and D-Dimer analytes assayed on the Quidel Triage MeterPro prior to reporting patients at the date of the survey on 02/07/24. Finding include: 1. Review of available calibration verification records revealed procedures performed on 11/10/23 for the CK-MB, myoglobin, troponin I and D-Dimer analytes using the Quidel Triage MeterPro. In addition, testing of levels 1 and 2 of the Triage Total 5 QC materials were performed on 11/10/23 and 12/05/23. The documentation lacked review by the lab director. 2. An interview with testing personnel #1 and the lab consultant on 02/07/24 at 1543 revealed the lab began patient testing for the above-specified analytes 01/04/24. Review of patient test data in the Athena EMR revealed one patient assayed and reported for the CK-MB, myoglobin, and troponin I analytes on 01/12/24. 3. The inspector requested to review the assessment, review and approval of the accuracy, precision and reference ranges for the above-specified analytes by testing personnel and lab director prior to testing patients. No additional documentation was available for review. 4. An exit interview with testing personnel and lab consultant on 02/07/24 at 1700 confirmed the findings.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on the review of calibration verification records, available quality control (QC) records, electronic medical records (EMR), lack of documentation, and an interview, the laboratory director failed to ensure the accuracy, precision and reference range verification was performed and approved prior to resulting patients for the creatine kinase-myocardial band (CK-MB), myoglobin, troponin I and D-Dimer analytes at the date of the survey on 02/07/24. Cross Reference D5421.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on the review of Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, policy and procedures (P&P), lack of documentation, and an interview, the technical consultant failed to provide documentation of annual

	competency assessments for two of two TP performing patient testing in the calendar year 2022. Findings include: 1. Review of the CLIA CMS 209 Form revealed the lab director performs the duties of technical consultant and three TP. 2. Review of TP records and an interview with TP #1 and the lab consultant on 02/07/24 at 1543 revealed that TP #2 and #3 performed patient testing up to November 1, 2023. The inspector requested to review documentation of competency assessments performed in 2022 for TP #2 and #3. The documentation was not available for review. 3. Review of the P&P revealed a quality assurance (QA) program that included the following statements, "Personnel Assessment- The laboratory uses a lab personnel evaluation form to document performance of all lab personnel annually and whenever there is a problem with competency." "Quality Assurance Reviews- the lab retains all quality assurance records for two years." 4. An exit interview with testing personnel and lab consultant on 02/07/24 at 1700 confirmed the findings.