Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0227489	04/07/2022
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 PC on April 7, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The inspector noted that the laboratory performs SARS-CoV-2 (COVID-19) testing and is in compliance with the applicable COVID-19 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, lack of documentation, and an interview, the laboratory failed to verify twice annually accuracy of urinalysis sediment microscopy in calendar year 2021. Findings include: 1. Review of the laboratory's College of American Pathologists (CAP) Clinical Microscopy module PT records (five events reviewed: 2020 Events A-B, 2021 Events A-B, 2022 Event A) revealed the following unsatisfactory score: 2021 Event A - scored as Unacceptable 34% (USP-01, USP-03 scored as failed). The inspector requested to review documentation of corrective action for the microscopy unsatisfactory scores outlined above and additional accuracy checks for calendar year 2021. No documentation was available for review. 2. An interview with the lab supervisor on 4/7/22 at approximately 1:30 PM confirmed the above findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other

	supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a laboratory tour, review of manufacturer's user guide, lack of documentation, and interviews, the laboratory failed to follow their protocol to document opened-expiration dates to ensure the quality of three (3) opened hematology quality control (QC) vials stored in the refrigerator for use to evaluate the precision of Complete Blood Count (CBC) patient testing on the date of the inspection, April 7, 2022. Findings include: 1. During a laboratory tour at approximately 11:00 AM on 4/7/22, the inspector noted the following DxH 500 QC vials stored in the laboratory refrigerator opened for use: Low (Lot Number 352213511), Normal (Lot Number 362213512), and High (Lot Number 372213513). The inspector noted each vials' lower liquid volume indicated they were in use and that 3 of 3 did not have opened-expiration dates. The laboratory inspector inquired of the laboratory's protocol for labeling hematology QC for opened-expiration dates. The primary testing personnel stated at approximately 11:30 AM: "We usually write the dates that we open along with the new expiration dates". The lab supervisor stated: "It is our policy to write open/expiration dates on the vials. I intended to do this when they were opened." 2. A review of the procedure manual revealed a Beckman Coulter DxH 500 manufacturer's guide for the hematology QC that stated: "Control storage and stability: store DxH 500 controls upright at 2-8 C, unopened tubes are stable through the printed expiration date, open tubes are stable for 14 days, if they are handled properly. Label open vial stability to 14 days and discard once outdated". 3. An interview with the lab supervisor on 4/7/22 at approximately 1:30 PM confirmed the above findings.
D6055	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 whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), procedures, new analyzer installation validation records, manufacturer's users guide, laboratory personnel files, lack of documentation, and an interview, the technical consultant (TC) failed to document training /competency evaluation for one (1) of two (2) testing personnel after a hematology instrument change occurred in the laboratory on September 2, 2021. Findings include: 1. Review of the CMS 209 form revealed that the laboratory director (LD) also performs the duties of TC and that 2 testing personnel (TP A, TP B) were identified as responsible for hematology Complete Blood Count (CBC) testing during the twenty-four months reviewed. (See Personnel Code Sheet.) 2. Review of hematology procedures revealed the laboratory moved from a Beckman Coulter AcTdiff hematology analyzer to a Beckman Coulter DxH 500 for patient CBC testing on 9/2 /21. 3. Review of the laboratory's instrument validation records revealed the new analyzer installation was performed by a field service technical specialist on 9/1/21 - 9

	/2/21. The validation records included documentation of initial training by the field service representative for TP A. 4. Review of the DxH 500 User's Guide revealed manufacturer's instructions that the "DxH 500 Competency Training Checklist is to be completed prior to patient testing". 5. Review of the laboratory personnel files and installation records revealed that "TP B" lacked a DxH 500 Competency Training Checklist and evaluation. The inspector requested to review the training competency evaluation for TP B. No documentation was available for review. 6. An interview with the lab supervisor on 4/7/22 at approximately 1:30 PM confirmed the above findings.