Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0227489	04/08/2026
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, LLC on April 7, 2026 by the Virginia Department of Health's Office of Licensure and Certification. The survey concluded with an offsite interview with the primary testing personnel on 4/8/26.The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Glenside Medical Associates, LLC was not in compliance with applicable Standards and Conditions under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows and include the Conditions: D2000 - 42 CFR. 493.801 Enrollment Proficiency Testing Samples D5400 - 42 CFR 493.1250 Analytic Systems D6000 - 42 CFR 493.1403 Laboratory Director
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Application for Certification (CMS 116) form and CMS CLIA Survey Summary Report (CMS CASPER Report 0096D), tour, review of proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to enroll in a PT program for seven of seven regulated Complete Blood Count (CBC) analytes for calendar year 2026 while reporting 97 patient CBC results from January 1, 2026 to April 7, 2026. Findings: 1. Review of the laboratory's CMS 116 form revealed that the laboratory

	director identified non waived CBC testing by Beckman Coulter DxH. Review of CMS CASPER Report 0096D revealed the following seven regulated analytes under speciality 0760 Hematology were included for 2024 and 2025 PT Events 1-3: 0765 Cell ID, 0770 White Blood Cell (WBC) Differential, 0773 Red Blood Cell (RBC), 0785 Hematocrit (HCT), 0795 Hemoglobin (HGB), 0805 WBC, and 0815 Platelets (PLT). The inspector noted that the speciality 0760 Hematology result column for calendar year 2026 was blank. 2. A tour of the laboratory on 4/7/26 at 1:00 PM revealed one DxH 500 hematology analyzer (serial number 81176199) in use for CBC testing. 3. Review of the laboratory's PT binder revealed no documentation for calendar year 2026 year to date. The inspector noted that the 2026 College of American Pathologists (CAP) enrollment form was incomplete and had not been marked as submitted. The inspector requested to review 2026 hematology PT Event 1 documents. The records were not available for review. The laboratory tech stated on 4 /7/26 at 1:30 PM, "We have not enrolled for 2026. It was overlooked when the previous technical consultant left last year." 4. A phone call interview with CAP PT technical support specialist on 4/7/26 at 2:00 PM confirmed that the laboratory failed to enroll for the regulated CBC analytes: WBC, RBC, HCT, HGB, PLT, and WBC Differential -Automated for calendar year 2026 and had missed the first event's mailing deadline. The CAP Customer Contact Center representative assigned the CLIA inquiry as Case Number: 02753928. 5. Review of patient CBC test logs for timeframe of 1/1/26 - 4/7/26 revealed 97 CBC test panels had been resulted while failing to enroll in PT. 6. Interviews with the laboratory tech onsite 4/7/26 at 4:30 PM and offsite on 4/8/26 at 3 PM confirmed the above findings.
D2014	TESTING OF PROFICIENCY TESTING SAMPLES (b)(6) 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. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Application for Certification Form (CMS 116), CMS CLIA Survey Summary Report (CMS CASPER Report 0096D), proficiency testing (PT) records, lack of documentation, patient test logs, and interviews, the laboratory failed to retain participation documentation for five of six hematology Complete Blood Count (CBC) PT testing events while reporting 1,344 CBC panels during the 26 month timeframe of February 8, 2024 to April 7, 2026. **REPEAT DEFICIENCY Findings include: 1. Review of the CMS 116 and Casper Report 0096D forms revealed that the laboratory performed CBC with Automated Differential and participated in the College of American Pathologists (CAP) PT program in 2024 (Events 1-3) and 2025 (Events 1-3). 2. Review of the laboratory's CAP PT documentation for the survey timeframe of 2/8/24 to 4/7/26 revealed that the laboratory had not retained CAP PT forms, signed attestation statements by laboratory director or testing personnel, nor retained the hematology instrument printouts for the following five PT events: 2024 Hematology Auto Differential Module FH 16 for Events 1, 2, and 3; 2025 Hematology Auto Differential Module FH 16 for Events 2 and 3. The inspector requested to review the missing

	records outlined above. The records/documentation were not available for review. The testing personnel stated on 4/7/26 at 3 PM, "I am unable to locate those records. The previous technical consultant may have taken them offsite." 3. Review of CBC test logs for the review timeframe outlined (2/8/24 - 4/7/26) revealed that 1,344 patient CBC panels were reported by the laboratory while not maintaining PT records. 4. Interviews with the laboratory tech onsite 4/7/26 at 4:30 PM and offsite on 4/8/26 at 3 PM confirmed the above findings.
D2093	ROUTINE CHEMISTRY CFR(s): 493.841(d) (d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on a review of the Centers of Medicaid and Medicare Services CLIA Survey Summary Report (CMS CASPER Report 0096D), proficiency testing (PT) records, and interviews, the laboratory failed to submit chemistry PT results receiving unsatisfactory scores for one of six events reviewed (timeframe of review: February 8, 2024 to April 7, 2026). Findings include: 1. During a pre-survey review, the CMS CASPER Report 0096D revealed that the laboratory reported regulated analytes under speciality Chemistry for 2024 (Events 1-3) and 2025 (Events 1-3), a total of six events. The inspector noted that zero percent (0%) scores were reported on the 2025 Event 3 for the following speciality and three analytes: 0245 ROUTINE CHEMISTRY 0340 B NATRIURETIC PEPTIDE (BNP) 0395 CK, ISO (CKMB) 0500 TROPONIN I 2. A review of the laboratory's College of American Pathologists (CAP) PT records revealed that the laboratory failed to retain records for the event outlined above. 3. The inspector acquired an emailed copy of the laboratory's 2025 Event 3 submitted and scored results via CAP Customer Contact Center (Case Number: 02753928) on 4/7/26 at 2:00 PM. Review of the retrieved CAP PT report revealed the following unsatisfactory challenge scores: 2025 Cardiac Point of Care Event 3: Five of five PT challenge samples (PCAR-#11 - PCAR-15) received 0% scores for BNP, CK MB, and TROP. CAP reported "Results for this kit were not received, resulting in scores of zero". The inspector inquired regarding documentation and corrective action for the unsatisfactory scores outlined above.The testing personnel stated on 4/7/26 at 3 PM, "I am unable to locate those records. The previous technical consultant may have taken them offsite." 4. Interviews with the laboratory tech onsite 4/7/26 at 4:30 PM and offsite on 4/8/26 at 3 PM confirmed the above findings.
D2127	HEMATOLOGY CFR(s): 493.851(d) (d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on a review of the Centers of Medicaid and Medicare Services CLIA Survey Summary Report (CMS CASPER Report 0096D), proficiency testing (PT) records,

	lack of documentation, and interviews, the laboratory failed to submit hematology PT results receiving unsatisfactory scores for one of six events reviewed (timeframe of review: February 8, 2024 to April 7, 2026). Findings include: 1. During a pre-survey review, the CMS CASPER Report 0096D revealed the laboratory resulted regulated analytes under speciality Hematology for 2024 (Events 1-3) and 2025 (Events 1-3), a total of six events . The inspector noted that zero percent (0%) scores were reported on the 2025 Event 2 for the following speciality and six (6) analytes: 0760 HEMATOLOGY 0765 CELL ID- Automated Diff 0775 RBC - Red Blood Cell Count 0785 HCT - Hematocrit 0795 HGB - Hemoglobin 0805 WBC -White Blood Cell Count 0815 PLT - Platelets 2. A review of the laboratory's College of American Pathologists (CAP) PT records revealed that the laboratory failed to retain the event outlined above - Refer to D2014. 3. The inspector acquired an emailed copy of the laboratory's 2025 Event 2 submitted and scored results via CAP Customer Contact Center (Case Number: 02753928) on 4/7/26 at 2:00 PM. Review of the retrieved CAP PT report revealed the following unsatisfactory challenge scores: 2025 Hematology FH 16 Event 2: Five of five PT challenge samples (FH16-#06 - FH16-#10) received 0% scores for Cell Identification (Lymphocyte, Monocyte, Granulocyte), Red Blood Cell Count, White Blood Cell Count, Platelet Count, Hemoglobin, and Hematocrit. CAP reported "Results for this kit were not received, resulting in scores of zero". The inspector inquired regarding documentation and corrective action for the unsatisfactory scores outlined above. The testing personnel stated on 4/7/26 at 3 PM, "I am unable to locate those records. The previous technical consultant may have taken them offsite." 4. Interviews with the laboratory tech onsite 4/7/26 at 4:30 PM and offsite on 4/8/26 at 3 PM confirmed the above 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 a review of the Centers for Medicare and Medicaid Services Application for Certification Form (CMS 116), CMS CLIA Survey Summary Report (CMS CASPER Report 0096D), the laboratory's proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to review and evaluate 13 of 16 PT testing modules' event scores during the 26 month timeframe of February 8, 2024 to April 7, 2026. **REPEAT DEFICIENCY Findings include: 1. Review of the CMS 116 form revealed that the laboratory performed Complete Blood Count with Automated Differential, Clinical Microscopy (Urine Sediment and Wet Prep Potassium Hydroxide examination), and Chemistry Point of Care Cardiac testing to include B Natriuretic Peptide (BNP), CK Isoenzyme MB (CKMB), Troponin I (TROP), and Ddimer during the review timeframe of 2/8/24 to 4/7/26. 2. Review of the CASPER Report 0096D revealed that the laboratory participated in College of American Pathologists (CAP) PT program for Hematology regulated analytes Module 2024 (Events 1-3) and 2025 (Events 1-3); and Chemistry regulated analytes Module (BNP, CKMB, TROP) for 2024 (Events 1-3) and 2025 (Events 1-3). 3. Review of the laboratory's CAP PT binders for the survey timeframe of 2/8/24 to 4/7/26 revealed that the laboratory had retained only the 2025 Event 1 for each of the following three modules: Hematology Auto Differential, Clinical Microscopy, and Point of Care Cardiac Markers in the PT binder. The inspector noted that each of the three retained 2025 Event 1 PT modules were signed as reviewed by the laboratory director on 6/10

	/25. 4. The inspector contacted CAP Customer Contact Center (Case Number: 02753928) on 4/7/26 at 2:00 PM and acquired emailed copies of the laboratory's missing PT results as following: 2024 Hematology Auto Differential Event 1 2024 Hematology Auto Differential Event 2 2024 Hematology Auto Differential Event 3 2024 Clinical Microscopy Module Event 1 2024 Clinical Microscopy Module Event 2 2024 Cardiac Point of Care Event 1 2024 Cardiac Point of Care Event 2 2024 Cardiac Point of Care Event 3 2025 Hematology Auto Differential Event 2 2025 Hematology Auto Differential Event 3 2025 Clinical Microscopy Module Event 2 2025 Cardiac Point of Care Event 2 2025 Cardiac Point of Care Event 3 The inspector requested to review evaluation assessments for the laboratory's performance on the 13 PT modules outlined above. No records were available in the laboratory. 5. Interviews with the laboratory tech onsite 4/7/26 at 4:30 PM and offsite on 4/8/26 at 3 PM confirmed the above 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 a review of manufacturer's operations manual, hematology analyzer maintenance records, hematology calibration records, lack of documentation, quality control procedures, and interviews, the laboratory failed to: 1. document required annual Beckman DxH 500 hematology analyzer preventative maintenance for 24 of the 26 months reviewed (timeframe: February 8, 2024 to April 7, 2026) - Refer to D5429; 2. document Beckman DxH 500 calibration procedures for Complete Blood Count testing every six months according to policy for 24 of 26 months reviewed (timeframe 2/8/24 - 4/7/26) - Refer to D5437. ** Condition is a REPEAT DEFICIENCY
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of manufacturer's operations manual, hematology analyzer maintenance records, lack of documentation, and interview, the laboratory failed to document performance of required annual Beckman DxH 500 instrument preventative maintenance for 24 of the 26 months reviewed (timeframe: February 8, 2024 to April 7, 2026). Findings include: 1. Review of the Beckman DxH 500 Operations Manual revealed manufacturer's instructions "perform Lubricating Pistons maintenance procedure at least annually" requirement for the hematology analyzer (under heading: Preventative Maintenance). 2. Review of the laboratory's available Beckman DxH 500 hematology maintenance logs from February 2024 to the date of the inspection on 4/7

	/26, revealed no documentation of the required annual maintenance outlined above in calendar years 2024 and 2025. The inspector requested to review documentation of the piston maintenance in calendar year 2024 and 2025. No records were available. 3. Interview with the laboratory tech on 4/7/26 at 4:30 PM confirmed the above findings.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) (a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a review of the laboratory's hematology calibration records, quality control (QC) procedures, lack of documentation, and interviews, the laboratory failed to document calibration procedures for Complete Blood Count (CBC) testing every six months according to policy for 24 of 26 months reviewed (timeframe 2/8/24 - 4/7/26). Findings include: 1. Review of the laboratory's 2024 and 2025 calibration records for the Beckman DxH 500 hematology analyzer revealed no CBC calibration documentation. The inspector inquired regarding the laboratory's policy for calibration of the analyzer. The testing personnel stated on 4/7/26 at 4:00 PM, "The protocol is to calibrate every six months and whenever we have troubleshooting problems. I calibrated last month when I had QC problems." 2. The inspector requested 2024 and 2025 calibration records for the analyzer outlined above. No calibration documentation was available for the two calendar years requested. 3. Review of the laboratory's hematology QC policy revealed instructions stating, "calibration is required every 6 months". 4. Interview with the laboratory tech on 4/7/26 at 4:30 PM confirmed the above findings.
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 review of hematology quality control (QC) monthly reports, procedures, lack of documentation, and interviews, the laboratory failed to retain documentation of monthly Complete Blood Count (CBC) QC statistics' review/evaluation for 23 of 26 months reviewed (survey timeframe February 8, 2024 to April 7, 2026). Findings include: 1. Review of the laboratory's monthly QC Levey Jennings (LJ) statistics reports revealed that the laboratory retained printed Beckman DxH 500 monthly

	Levey Jennings reports for year-to-date 2026 but failed to retain records for the following months in calendar years 2024 and 2025: 2024: February, March, April, May, June, July, August, September, October, November, December; 2025: January, February, March, April, May, June, July, August, September, October, November, December. 2. The inspector requested to review hematology LJ reports for the 23 months outlined above. The records were not available for review. 3. The inspector inquired regarding the laboratory's protocol for monitoring CBC QC shifts/trends, documentation of assessments and corrections with the DxH 500 analyzer. The testing personnel stated on 4/7/26 at 3:30 PM, "I review the QC daily and can look at the monthly QC graphs. The previous technical consultant reviewed the monthly QC prior and we have not been able to locate them." 4. Interviews with the laboratory tech onsite 4/7/26 at 4:30 PM and offsite on 4/8/26 at 3 PM confirmed the above findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of laboratory records, Centers of Medicaid and Medicare Services (CMS) CLIA Survey Summary Report, CMS Application for Certification Form, proficiency testing (PT) records, hematology quality control (QC) monthly reports, procedures, lack of documentation, and interviews, the laboratory director failed to: 1. ensure laboratory proficiency testing enrollment for Complete Blood Count (CBC) regulated analytes for calendar year 2026 - Refer to D6015; 2. ensure that the laboratory submitted chemistry and hematology PT results for one of six events for each speciality (timeframe: February 8, 2024 to April 7, 2026) - Refer to D6017; 3. ensure that 13 of 16 PT modules' scores were evaluated and corrective action was documented during the 26-month timeframe outlined above - Refer to D6018; 4. ensure that the laboratory retained documentation of CBC QC statistics' review /evaluation for acceptibility during 23 of 26 months reviewed - Refer to D6023.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that-- This STANDARD is not met as evidenced by: Based on a review of laboratory records, lack of documentation, and interview, the laboratory director failed to ensure proficiency testing enrollment for Complete Blood Count regulated analytes by Beckman hematology instrument for calendar year 2026 - Refer to D2000.
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) (e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program;

	This STANDARD is not met as evidenced by: Based on a review of the Centers of Medicaid and Medicare Services CLIA Survey Summary Report, proficiency testing (PT) records, and interviews, the laboratory director failed to ensure that the laboratory submitted chemistry and hematology PT results for one of six events for each speciality (timeframe of review: February 8, 2024 to April 7, 2026). Refer to D2093 and D2127.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services (CMS) Application for Certification Form, CMS CLIA Survey Summary Report, proficiency testing (PT) records, lack of documentation, and interviews, the laboratory director failed to ensure that 13 of 16 PT modules' scores were evaluated and corrective action was documented during the 26 month timeframe of February 8, 2024 to April 7, 2026. Refer to D5211. **REPEAT DEFICIENCY
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on review of hematology quality control (QC) monthly reports, procedures, lack of documentation, and interviews, the laboratory director failed to ensure that the laboratory retained documentation of Complete Blood Count QC statistics' review /evaluation for acceptability during 23 of 26 months reviewed (survey timeframe February 8, 2024 to April 7, 2026). Refer to D5791.