Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0227489	01/23/2018
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 January 23, 2018 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:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(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 a review of proficiency testing records, the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), and an interview, the laboratory failed to rotate hematology proficiency testing among all personnel performing patient testing in calendar year 2016. Findings include: 1. Review of the laboratory's College of American Pathologists (CAP) 2016 and 2017 hematology proficiency testing (PT) records, a total of six (6) events, revealed: Testing Personnel A performed testing and signed attestation for the following five (5) events: 2016 Hematology Event A, 2016 Hematology Event B, 2016 Hematology Event C, 2017 Hematology Event B, 2017 Hematology Event C, and Testing Personnel B performed and signed the attestation for 2017 Hematology Event A. (See attached Testing Personnel Code Sheet) 2. Review of the CMS 209: laboratory personnel form revealed a total of three (3) laboratory testing personnel performing patient testing during the timeframe of the PT events reviewed. 3. In an interview with the general supervisor at approximately 1:30 PM on January 23, 2018, it was confirmed that the laboratory failed to rotate hematology proficiency testing among all personnel performing patient testing in calendar year 2016.

D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on a laboratory tour, review of the laboratory policies and procedure manual, patient test logs, and interviews, the laboratory did not follow their written policy that defined specimen identification/labeling criteria for all specimens collected and submitted for laboratory testing during calendar year 2016 up to the date of survey on 1/23/18. Findings include: 1. During a laboratory tour with the general supervisor at approximately 11:30 AM on January 23, 2018, the inspector noted patient urine specimen cups in a bin located on the laboratory test bench. Each of the specimen cups had been labeled by a handwritten patient last name. No other patient identifiers were found on the patient specimens. The general supervisor stated that the laboratory did accept and routinely process samples labeled with last name only. The inspector inquired if the laboratory had a protocol in place to distinguish specimens in the event that the staff had collected multiple samples with the same last name simultaneously. The general supervisor indicated that the lab did not have a protocol in place. 2. Review of the laboratory procedure manual revealed a written policy which defined specimen identification/labeling criteria for specimens collected and submitted for laboratory testing. The policy states: "Label sample with patients full name, ID number, and date." 3. Review of the patient test logs revealed that the laboratory and nursing staff had collected, tested, and resulted: One thousand six hundred ninety-four (1,694) urinalysis/microscopy tests in calendar year 2016, One thousand one hundred fifty-five (1,155) urinalysis/microscopy tests from 01/3/17 to the date of the survey, for a total of two thousand eight hundred forty-nine (2,849) patient samples. 4. In an interview with the general supervisor at approximately 1:30 PM on 1/23/18, it was confirmed that the laboratory did not follow their written policy of specimen identification/labeling criteria for specimens collected and resulted for urinalysis /microscopy in 2016, and 2017 up to the date of the survey.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (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 (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (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 review of the laboratory's calibration records, quality control (QC) policy, patient test logs, and an interviews, the laboratory failed to document calibration procedures for Complete Blood Count (CBC) testing according to the laboratory's written policy from September 28, 2017 through October 25, 2017 while reporting eighty-five (85) patient CBC test results. Findings include: 1. Review of the laboratory's 2016 and 2017 calibration records for the Beckman Coulter AcTdiff hematology analyzer revealed CBC calibration documentation on the following dates: 3/21/16, 9/14/16, 3/28/17, and 10/25/17. The lab inspector requested calibration records for the time period of September 28, 2017. No calibration documentation was available for the timeframe requested. The general supervisor stated that the six (6) month calibration was missed on 9/28/17 due to short staffing issues and analyzer issues. 2. Review of the laboratory's hematology QC policy revealed instructions stating "calibration is required every 6 months". 3. Review of the laboratory's patient test log revealed eighty-five (85) patient CBC test results were reported during the timeframe of the calibration lapse outlined above. 4. In an interview with the general supervisor at approximately 1:30 PM it was confirmed that the laboratory failed to document calibration procedures for CBC testing on the Beckman Coulter AcTdiff analyzer according to the QC policy in 2017.