

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0227489	(X3) Date Survey Completed 09/25/2019
Name of Provider or Supplier Glenside Medical Associates Llc	Street Address, City, State 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 September 25, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiency is as follows:
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a tour, review of manufacturer's reference guide, daily temperature logs, and an interview with Testing Personnel A (TP A), the laboratory failed to monitor the daily relative humidity percent (RH%) to ensure manufacturer's operating requirements were followed for the Beckman Coulter AcT diff analyzer utilized in patient hematology testing from February 2018 to September 2019. Findings include: 1. During a tour of the laboratory, the surveyor noted a Beckman Coulter AcT diff hematology analyzer in use for patient hematology Complete Blood Count (CBC) testing. 2. Review of the manufacturer's reference guide for instrument specifications revealed the Beckman Coulter AcT diff humidity requirement was 20% to 85% without condensation. 3. Review of the daily temperature logs from 02/01/18 to 09/25/19, revealed no record of laboratory humidity monitoring for twenty (20) of the 20 months reviewed. The surveyor requested documentation of the laboratory humidity from 02/01/19 to 09/25/19. The laboratory provided no documentation to review. 4. In</p>

an exit interview with TP A at approximately 12:00 PM, the above findings were confirmed.