

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D0239062	<b>(X3) Date Survey Completed</b>  12/17/2025
<b>Name of Provider or Supplier</b>  Guilford Medical Associates, Pa	<b>Street Address, City, State</b>  2703 Henry Street, Greensboro, NC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5423</b>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of verification of performance records for the Beckman DXH 900 hematology analyzer and the Beckman DXI 600 analyzer, lack of documentation, review of laboratory procedure manual, review of patient test reports and interview with technical consultant (TC) 12/17/25, the laboratory failed to establish reference ranges (normal values) for the testing performed on the Beckman DXH 900 hematology analyzer and failed to establish reference ranges (normal values) for the testing performed on the Beckman DXI 600 analyzer. 1. The laboratory failed to establish reference ranges (normal values) for the testing performed on the Beckman DXH 900 hematology analyzer. Findings: Review of verification of performance records for the Beckman DXH 900 revealed the verification was performed in November of 2024. The records failed to include the reference ranges (normal values) established for the hematology testing performed. Review of laboratory procedure manual revealed hematology reference ranges (normal values) established and signed by the laboratory director in January 2019. Review of patient test reports, Patient # 70895 (Male) and Patient # 51997 (Female), revealed reference ranges (normal</p>

values) were not the same ranges as established and signed by the LD in January 2019. For example: a. White Blood Cell (WBC) - established range is 4.0 - 11.0, test report range is 4.10 - 10.90. b. Red Blood Cell (RBC) - established range is 4.20 - 5.80, test report range is 4.2 - 6.3. c. Hemoglobin (HGB) - established range is 13.0 - 17.0, test report range is 12.0 - 18.0. d. Hematocrit (HCT) - established range is 39.0 - 52.0, test report range is 37.0 - 51.0. e. Platelet (PLT) - established range is 150 - 400, test report range is 140 - 440. Interview with TC at approximately 2:30 p.m. confirmed the reference ranges (normal values) established in 2019 by the LD were not the same ranges as the ranges on the patient's test reports. She also confirmed the verification records for the Beckman DXH 900 failed to include documentation of established reference ranges. She stated she did not realize the values on the test report were not the same as the values established in 2019. 2. The laboratory failed to establish reference ranges (normal values) for the testing performed on the Beckman DXI 600. Findings: Review of verification of performance records for the Beckman DXI 600 revealed the verification was performed in October of 2025. The records failed to include the reference ranges (normal values) established for the testing performed on the Beckman DXI 600. Review of laboratory procedure manual revealed no documentation of the reference ranges (normal values) established for the testing performed on the Beckman DXI 600. Interview with TC at approximately 2:30 p.m. confirmed the verification of performance records and the procedure manual failed to include the reference ranges (normal values) established for the testing performed on the Beckman DXI 600.

**D5433**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(b)(1)

(b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section.

This STANDARD is not met as evidenced by:  
Based on review of Beckman Coulter's on-line operator's manual for the DXH 900 hematology analyzer, review of a DXH 900 maintenance log, review of laboratory procedures, lack of documentation and interview with technical consultant (TC) 12/17/25, the laboratory failed to establish a maintenance protocol and failed to document the maintenance and/or function checks for the testing performed on the DXH 900 hematology analyzer since testing began in November of 2024, a period of approximately 13 months. Findings: Review of Beckman Coulter DXH 900 operator's manual reviewed the following maintenance and/or function checks; a. Daily - Performance of Shutdown and "Daily Checks". b. Monthly or sooner if needed - Cleaning the BSV Externally. c. Every 6 months or as needed - Cleaning the STM. d. As needed - Cleaning the Air Mix Temperature Control (AMTC) Module. Review of maintenance log, "UniCel DXH 900 Maintenance Log", presented at time of survey, revealed the following maintenance and/or function checks: a. Daily - Perform Shutdown, Perform Daily Checks - Verify that all results are within limits, Run Controls/approve/comment. b. Weekly - Clean the BSV Externally, Clean the STM, Clean the AMTC Module. c. Monthly - Clean the Pneumatic Supply Module Fan Filter. Review of laboratory procedures for the documentation of maintenance on the Beckman Coulter DXH 900 revealed no documentation of an established procedure. Review of laboratory records for the documentation of maintenance performed on the Beckman Coulter DXH 900 revealed no documentation. Interview with TC at 11:25

confirmed the laboratory has no documentation of maintenance performed on the Beckman Coulter DXH 900. She stated she does not know how to pull up a maintenance report from the analyzer.

**D5801**

**TEST REPORT**

CFR(s): 493.1291(a)

(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

Based on review of verification of performance records for the Beckman AU 700, lack of procedure, and interview with the Technical Consultant (TC) 12/17/25, the laboratory failed to verify accuracy of the calculated eGFR (estimated glomerular filtration rate) transmitted from the LabDAQ Laboratory Information System (LIS) to the Electronic Health Record (EHR). Findings: Review of verification of performance records for the Beckman AU 700 revealed the verification was performed in November of 2024. The records failed to include documentation of an LIS verification to verify the accuracy of the calculated eGFR. Review of the laboratories procedure manual revealed the absence of an LIS procedure to ensure calculated data transmitted from the LIS to the EHR is accurate and reliable. During an interview at approximately 3:05 p.m., the TC confirmed the absence of a procedure to determine the accuracy of calculated data transmitted to final reports. The TC also verified that calculation verification has not been performed in 2024 or 2025.

**D5807**

**TEST REPORT**

CFR(s): 493.1291(d)

(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on review of verification of performance records for the Beckman AU 700 chemistry analyzer, review of laboratory procedure manual, review of patient test reports and interview with technical consultant (TC) 12/17/25, the laboratory failed to ensure patient test reports were updated to reflect the new reference ranges (normal values) established by the laboratory upon the installation of the Beckman AU700 in November of 2024. Findings: Review of verification of performance records for the Beckman AU 700 chemistry analyzer revealed the verification was performed in November of 2024. Review of laboratory procedure manual revealed new reference ranges (normal values) were established in November of 2024 to reflect the normal values established by the manufacturer. The new values and the old values were listed side by side in the "Normal Patient Ranges for Beckman AU vs (Abbott Architect)" policy. Review of patient test reports, Patient # 70895 (Male) and Patient # 51997

(Female), revealed the reference ranges (normal values) established in November of 2024 were not updated in the laboratory's information system (LIS), hence the patient test reports were also not updated with the new reference ranges (normal values). Interview with TC at approximately 2:30 p.m. confirmed the new reference ranges had not been updated in the LIS. They also confirmed the patient test reports did not reflect the new values. They stated that the providers were given the "Normal Patient Ranges for Beckman AU vs (Abbott Architect) policy so they could compare the previous values with the current values.

**D6020**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:  
Based on deficiencies cited at time of survey, review of verification of performance records for the Beckman AU 700, Beckman DXI 600 and Beckman DXH 900 analyzers, review of laboratory procedure manual, review of patient test reports and lack of documentation 12/17/25, the laboratory director failed to establish a quality assessment policy to ensure the laboratory's information system (LIS), LabDAQ, was monitored periodically to ensure accurate transmission of all test results and pertinent information, including the established normal ranges and calculations, into the patients' final test reports. Findings: See D5423, D5801 and D5807.