Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0239062	09/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
Guilford Medical Associates, Pa	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
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 review of the laboratory's policies and procedures, random review of 2021, 2022, and 2023 Architect quality control records, and interview with the TC (technical consultant) 9/14/23, the laboratory failed to follow their quality assessment plan and used expired reagent for patient testing. Findings: Review of the laboratory's "QUALITY ASSESSMENT PLAN" revealed "... QUALITY ASSURANCE ACTIVITIES ... Expired reagents will be discarded. ... ANALYTICAL MONITORING ... After problem has been identified, corrective action must follow. Documentation of error and the recommended remedial action is necessary. ... QC review by the consultant should be used as a tool to flag problems involving accuracy of results. ..." Random review of 2021, 2022, and 2023 Architect quality control records revealed the laboratory used expired reagent (lot #63263UQ12) for ALT (alanine transaminase) testing performed 4/5/23-4/11/23. There was no documentation that the laboratory director performed a review of patients tested 4/5/23-4/11/23 to determine whether any remedial action was needed. During interview at approximately 1:30 p.m., the TC stated that approximately 45 patients were tested during this time.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document 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 review of the laboratory's policies and procedures, review of 2021, 2022, and 2023 Architect maintenance logs and review of 2021, 2022 and 2023 Cell Dyn Ruby maintenance logs, the laboratory failed to perform and document maintenance as required. Findings: Review of the laboratory's "QUALITY ASSESSMENT PLAN" revealed "MAINTENANCE LOGS: All instrument, action, and maintenance, and temp logs are maintained according to manufacturer's instructions. Each log is maintained by testing personnel and is reviewed by the technical consultant. ... These logs include, temperature and humidity logs, hematology instrument maintenance logs, and all general and immunochemistry maintenance logs, etc. ..." A. Review of the laboratory's Architect maintenance logs revealed the following items to be performed quarterly: 1. Change Lamp 2. Sample Syringe Maintenance 3. Wash Syringe Maintenance 4. Reagent Syringe Maintenance 5. Change 1 ml Syringe 6. Change ICT Asp Check Valve 7. Check ICT Ref Check Value Review of the laboratory's 2021, 2022, and 2023 Architect maintenance logs revealed quarterly maintenance was not documented on a quarterly basis. 1. 2021 - There was no documentation of quarterly maintenance from January to September (9 months). In addition, there were no maintenance records available for review for October, November, and December. 2. 2022 - Quarterly maintenance was performed in June and October, but not quarterly as required. B. Review of the laboratory's Cell Dyn Ruby maintenance logs revealed the following items to be performed monthly: 1. Extended Auto Clean 2. Replace Dil/Shealth Filter Review of the laboratory's 2021, 2022 and 2023 Cell Dyn Ruby maintenance logs revealed monthly maintenance was not documented on a monthly basis. 1. 2021 - There was no documentation of the performance of an extended auto clean in September and November. 2. 2022 - There was no documentation of the performance of an extended auto clean in March. Also, there was no documentation of the replacement of the dil/shealth filter in January.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based upon review of the laboratory's policies and procedures, the absence of 2021, 2022 and 2023 maintenance records and interview with the TC (Technical Consultant) on 9/14/2023, the laboratory failed to perform a function check on the centrifuge used to prepare urine sediment for microscopy. Findings: Review of the laboratory's "Microscopic Examination of Urine Sediment" policy revealed "Procedure: Centrifuge the specimen for 5 minutes at 2000 rpms, decant supernatant, and mix sediment in bottom of tube." There were no 2021, 2022, or 2023 maintenance records to document the performance of function checks on the centrifuge used to prepare urine sediment for microscopy. During interview at approximately 2:05 p.m., the TC confirmed the laboratory had not checked the rpms (revolutions per minute) of the centrifuge.

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 upon review of the laboratory's policies and procedures, review of the laboratory's 2021, 2022 and 2023 Cell Dyn hematology calibration records and interview with the TC (Technical Consultant) on 9/14/203, the laboratory failed to calibrate its hematology instrument at least every six months. Findings: Review of the laboratory's "Cell Dyn Ruby" policy revealed "Calibration: Calibration is done at least every six months or other times as stated in Section 6 of the Ruby Operating Manual." Review of the laboratory's 2021, 2022 and 2023 Cell Dyn Ruby calibration records revealed that the instrument was calibrated during the following months: May 2021, April 2022, December 2022, February 2023, and May 2023. There was no documentation of the performance of a calibration between May 2021 and April 2022, a period of approximately eleven months. During interview at approximately 10:05 a.m., the TC confirmed the laboratory missed performing a calibration between the months of May 2021 and April 2022.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of 2020, 2021, 2022, and 2023 calibration verification records 9/14/23, the laboratory failed to perform calibration verification at least once every six months. Findings: Review of the laboratory's "Architect Chemistry Analyzer" procedure revealed "... Calibration verifications are performed every 6 months on all analytes." Review of 2020, 2021, 2022, and 2023 calibration verification records revealed: 1. The laboratory performed calibration verifications in September 2020, March 2021, October 2021, August 2022, and February-March 2023. There was no documentation of calibration verification between October 2021 and August 2022, a period of approximately 10 months. 2. The laboratory failed to perform calibration for all analytes each time calibration verification was performed. a. September 2020 - no calibration verification for ferritin. b. March 2021 - no calibration verification for cholesterol. c. October 2021 - no calibration verification for HDL (high density lipoprotein). d. August 2022 - no calibration verification for sodium and ferritin. e. February-March 2023 - no calibration verification for glucose, PSA (prostate specific antigen), and ferritin.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based upon review of the laboratory's policies and procedures, the absence of 2021, 2022 and 2023 quality assessment records and interview with the TC (Technical Consultant) on 9/14/2023, the laboratory failed to check the accuracy of calculations performed by its LIS (laboratory information system). Findings: Review of the laboratory's "Quality Assessment" plan revealed "Post Analytical Monitoring: Process audits to review all systems between pre-analytical, analytical, and post analytical are performed at least once per year. The process of laboratory testing is followed from order entry into the EMR all the way through the Reporting Process or lab report." The laboratory's LIS performs the following calculations: 1. GFR (glomerular filtration rate) 2. LDL/HDL (low density lipoprotein/ high density lipoprotein) ratio 3. CHOL/HDL (cholesterol/high density lipoprotein) ratio There were no records to document that the laboratory verified the accuracy of calculations performed by the LIS in 2021, 2022, or 2023. During interview at approximately 2:15 p.m., the TC confirmed the laboratory does not verify the accuracy of calculations performed by the LIS once per year.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2021, 2022, and 2023 API (American Proficiency Institute) proficiency testing records, and interview with the TC (technical consultant) 9/14/23, the laboratory director failed to ensure an approved corrective action plan was followed for unacceptable proficiency testing results. Findings: Review of the laboratory's "QUALITY ASSESSMENT PLAN" revealed "... POLICY: ... All efforts to explain incorrect results must be made, including control value checks, maintenance record checks, transcription error checks, pipetting error checks and any other checks felt necessary by the consultant or laboratory manager. After all checks and reviews have been made, thorough documentation must follow and all efforts to identify the problem and correct the mistake to avoid further errors must be done. ... Results of Proficiency testing will be monitored as a part of Quality Assurance. ..." Review of API proficiency testing records revealed the laboratory provided incorrect results for 1/2 Vitamin D samples and 2/2 PSA (prostate specific antigen) samples on the 2021 Chemistry Core 2nd test event. On the "PERFORMANCE REVIEW AND CORRECTIVE ACTION" form, the TC had noted the following corrective action: "unsuccessful for Vit D - missed one this time. - Repeat; then send out 10 vit D's to (an outside laboratory) Missed both PSAs - missed both (slightly low) Repeat both". There was no documentation that testing of the samples was repeated and no documentation that the laboratory sent any samples to an outside laboratory. During interview at approximately 10:30 a.m., the TC confirmed that the specified corrective actions were not performed by the laboratory.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment plan 9/14/23 and the deficiencies cited at D5417, D5891, and D6019, the laboratory director failed to ensure the quality assessment program was maintained to identify and correct problems and prevent recurrence, and to assure the quality of laboratory services offered. Findings: Review of the laboratory's "QUALITY ASSESSMENT PLAN" revealed "... RESPONSIBILITY The lab service is under the jurisdiction of the Lab Director. It is the responsibility of the Technical Consultant to implement the plan. The Laboratory Director and Technical Consultant will be responsible either directly or by delegation for the following: ... resolution of any problem not immediately addressed by the personnel. ... Implementing actions to improve service. Follow-up reviews to show proof of improved service. ..." 1. The laboratory director failed to ensure remedial action was taken and documented for patients tested using expired reagents - see D5417. 2. The laboratory director failed to ensure process audits to review all pre-analytic, analytic, and post-analytic systems were performed at least

	once per year - see D5891. 3. The laboratory director failed to ensure corrective actions were performed for proficiency testing failures as specified by the TC - see D6019.