Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0257797	12/10/2019
Name of Provider or Supplier	**Street Address, City, State**	
Anglyn Family Medical Center Llc	55 Sims Street, Mcdonough, GA	

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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on December 10, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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 review of American Academy of Family Physicians (AAFP) proficiency testing (PT) documents and staff interview, the laboratory failed to review and evaluate all results obtained on PT evaluations in 2018 and 2019. Findings include: 1. Review of 2018 & 2019 PT result documents reveals the lab director (LD) did not review the PT results for 2018 events A or B; 2019 events A, B, or C. 2. Interview with staff #4 (CMS 209 form) on 12/10/19 at approximately 11:00 am in the breakroom, confirmed the LD did not review all of the PT results received.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of American Academy of Family Physicians (AAFP) proficiency testing (PT) documents and staff interview, the laboratory failed to verify the accuracy

	of test procedures twice annually for all non-waived tests performed in 2018 and 2019. Findings include: 1. Review of 2018 & 2019 PT documents reveals the lab did not participate in PT or verify test accuracy twice annually for urine microscopics in 2018 and 2019. 2. Interview with staff #4 (CMS 209 form) on 12/10/19 at approximately 10:55 AM in the breakroom, confirmed the lab did not verify the accuracy of test procedures twice annually for all non-waived tests performed
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of American Academy of Family Physicians (AAFP) proficiency testing (PT) documents and staff interview, the laboratory failed to document corrective actions for unsatisfactory/unsuccessful scores obtained on PT evaluations in 2018. Findings include: 1. Review of 2018 PT result documents reveals the lab did not document corrective actions for PT results for 2018 event A: red blood cell (RBC), hemoglobin (HGB), and hematocrit (HCT) scores of 60% each; or 2018 event B: red blood cell (RBC), hemoglobin (HGB), and hematocrit (HCT) scores of 80% each. 2. Interview with staff #4 (CMS 209 form) on 12/10/19 at approximately 11:00 am in the breakroom, confirmed the lab did not document corrective actions for the aforementioned PT results received.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on procedure manual (SOP) review and staff interview, the lab failed to include all required elements for corrective actions or panic/critical values. Findings include: 1. SOP review reveals the lack of required elements in written lab procedures for the documentation of corrective actions or the definition and proper reporting of critical /panic values. 2. Interview with staff #4 (CMS 209 form) on 12/10/19 in the

	breakroom at approximately 1200 Noon, confirmed the lack of the aforementioned procedure elements.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on procedure manual (SOP) review and staff interview, the lab failed to have procedures for all maintenance required on the eyewash or the microscope. Findings include: 1. SOP review reveals the lack of operators guide, package insert, or written lab procedure for the maintenance required on the Sieler West microscope or the lab eyewash. 2. Interview with staff #4 (CMS 209 form) on 12/10/19 in the breakroom at approximately 1200 Noon, confirmed the lack of the aforementioned procedures.
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 observation, document review, and staff interview, the lab failed to perform annual Preventative Maintenance (PM) on the microscope used for urine microscopic exams or document maintenance as required for the Sysmex XP-300 hematology analyzer. Findings include: 1. Observation during the lab tour revealed the Sieler West microscope did not have documented PM(s). 2. Review of maintenance documents reveals the lack of PM performed on the lab microscope. 3. Review of the Sysmex XP-300 maintenance logs reveals the weekly maintenance was not performed per manufacturer in: November 2018 or April 2019. Monthly maintenance was not performed per manufacturer in 2018: April, September, November, December; in 2019: January, March, April, May, June, or July. 4. Interview with staff #4 (CMS 209 form) on 12/10/19 in the lab at 11:58 AM, confirmed the missing aforementioned maintenance.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the

	laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and staff interview, the lab failed to document corrective actions when QC exceeded acceptable limits. Findings include: 1. Review of QC records: October 2018 to October 2019 reveals the lack of corrective actions when 1 or more analytes are out of acceptable range. 2. Interview with staff#4 (CMS 209 form) on 12/10/19 at 11:08 AM in the breakroom, confirmed the corrective actions were not documented.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on lab report reviews and staff interview, the laboratory failed to include all the required information on the in-house laboratory test reports. Findings include: 1. Review of in-house lab reports #9046548750 and #903134444 reveals the lack of the laboratory Name and address where the test are performed. 2. Interview with staff #4 (CMS 209 form) on 12/10/19 at approximately 1 PM in the breakroom, confirmed the lack of the Laboratory name and address on in-house reports.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory director (LD) failed to specify, in writing the duties and responsibilities of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of laboratory testing. Findings include: 1. SOP review reveals the LD failed to specify in writing the duties and responsibilities of

	each person engaged in the performance of all phases of laboratory testing. 2. An interview with Staff #4 (CMS 209) in the breakroom on 12/10/19 at approximately 12 Noon, confirmed the SOP did not contain a duties and responsibilities policy and procedure.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) documents and staff interview, the technical consultant (TC) failed to perform semiannual competency on all testing personnel. Findings include: 1. Review of personnel competency documents revealed the TC (the lab director) failed to perform semiannual competency on staff #5 and #6 (CMS 209 form). 2. Interview with staff #4 (CMS 209 form) on 12/10/19 at approximately 11:00 am in the breakroom, confirmed the semiannual competency was not performed by the TC on the aforementioned staff.