Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2125579	11/29/2018
Name of Provider or Supplier	**Street Address, City, State**	
Oxford Mediplex Laboratory	1400 Highway Drive, Oxford, AL	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of CAP (College of American Pathologists) proficiency testing records (2017 and 2018) for CLIA identification #01D0641705, an interview with the hospital's laboratory manager, telephone interviews with the Technical Consultant (also the Point-of-Care Coordinator for the system's clinics), and a CAP employee, and a lack of documentation, the surveyor determined the laboratory failed to enroll in proficiency testing for creatinine (a moderate-complex test) performed on the EPOC. The findings include: 1. On 11/04/2018 an onsite visit was made to the laboratory to conduct an initial certification survey. 2. A review of CAP proficiency testing records, provided by the laboratory, for 2017 and 2018, were identified by the hospital's name and CLIA identification number (01D0641705), not the laboratory's CLIA number (01D2125579). 3. At 11:30 AM on 11/14/2018, the surveyor asked the hospital's laboratory manager why the identifying number on the CAP reports differed from the CLIA number for the laboratory. The manager called the hospital to inquire if the number was for the hospital, and confirmed it was. The manager further explained the clinic was performing the creatinine test from the proficiency testing kit assigned to the hospital. The manager further stated the kit was shared between the laboratories, and confirmed this by a telephone call to the Technical Consultant. 4. On 11/15/2018,

	the surveyor conducted a telephone interview with a CAP employee of the proficiency testing division. The CAP employee searched the proficiency testing system for the laboratory's CLIA number, and was not able to locate the CLIA number for the laboratory as an enrollee. The surveyor asked if laboratories shared proficiency testing kits, would each laboratory be considered enrolled in proficiency testing. The CAP employee stated each laboratory had to enroll and perform proficiency testing, using its own identifying number. 5. In a telephone interview on 11/29/2018 at 1:30 PM, after receiving numerous documents via mail to review, the surveyor asked the Technical Consultant to clarify proficiency testing enrollment for the laboratory (01D2125579). The Technical Consultant stated the proficiency testing kits were being split for the ICU (Intensive Care Unit) at the hospital and the Mediplex (different location), with the Mediplex laboratory performing the creatinine for each kit. The Technical Consultant stated since the survey on 11/14/18, she now understands the requirement for each CLIA laboratory to enroll in proficiency testing.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of policies and procedures (a lack of documentation); a review of quality control records; an interview with the hospital's laboratory manager, on the day of the survey; a review of the mailed IQCP (Individualized Quality Control Plan), which was received on November 19, 2018; and a telephone interview with the Technical Consultant (TC), the surveyor determined the laboratory failed to establish a complete and approved IQCP, prior to reducing the frequency of testing quality control for Creatinine to less than the CLIA standard of at least two levels of external quality control on each day of patient testing. This affected the only test performed at the laboratory. The findings include: 1. On 11/14/2018, an initial certification survey was conducted at the laboratory with CLIA identification number, 01D2125579. 2. At 10:35 AM, testing personnel #3 stated the quality controls were run once per week, usually on a Thursday. However, patient testing occurred more than once per week. 3. At 12:15 PM, the surveyor inquired of the quality control testing for Creatinine of the hospital's laboratory manager. The laboratory manager stated the laboratory staff tested two levels of liquid controls once per week. The surveyor inquired of an IQCP for the Creatinine testing, performed on the EPOC. The laboratory manager stated the laboratory used a system-wide (hospital) IQCP for the clinic. However, the IQCP was not available on-site at the laboratory to review, nor were the quality control records made available to review. 4. The IQCP plan, as well as the quality control records were mailed to the CLIA State Agency and received on 11/19/18. 5. A review of the quality control documentation, provided by the laboratory, revealed once a month testing of two levels of quality control. (See the interview at paragraph 6) Further review of the documents, revealed an incomplete IQCP. The plan failed to include a QCP (Quality Control Plan) and a QA (Quality Assurance plan). The plan failed to

	include the signature (notation of approval) of the laboratory director. Please see the regulation at 493.1256 for guidance of IQCP development. 6. In a telephone interview on 11/29/18 at 1:30 - 1:50 PM, the TC stated she had followed the example of the former point-of-care coordinator to develop the IQCP for the Creatinine testing on the EPOC. The surveyor discussed the requirements of a completely developed IQCP. The TC confirmed the plan did not include the QCP and QA portions. When asked about the frequency of quality control testing, the TC verified the quality control testing was done once per week. However, the number of documents were too great to send.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of policies and procedures (a lack of documentation), a review of quality control records, and interviews with Testing Personnel (TP) #3, the Technical Consultant (TC), and the hospital's laboratory manager, the surveyor determined the laboratory failed to perform at least two levels of quality control each day of patient testing for Creatinine, in the absence of an acceptable and approved IQCP (Individualized Quality Control Plan). This affected the only test performed at the laboratory. The findings include: 1. The laboratory did not have a policy and procedure for quality control testing of Creatinine to include the following: a) Type of Control b) Identity (e.g. levels) c) Number and frequency of testing of controls d) Control limits e) Criteria to determine acceptable control results 2. In an interview on 11/14/18 at 10:35 AM, TP #3 (a part-time employee) stated two levels of liquid quality controls for Creatinine (tested on the EPOC) were run once a week, usually every Thursday. 3. At 12:15 PM on 11/14/18, the hospital laboratory manager stated the quality controls were run once per week and were retained in the electronic data management system, as the results were transmitted via interface to the laboratory information system. At this time, due to the records not being available to review at the time of the survey, the surveyor requested random quality control documents be sent to CLIA for review by November 16, 2018. The laboratory manager also stated the laboratory utilized an IQCP plan (system-wide). 4. Along with other documents, examples of quality control testing were received by CLIA, State Agency on 11/19 /18. A review of these records revealed results of quality control testing for two levels each month, from May 2017 - November 2018. 5. On 11/14/18 at 1:30 - 1:50 PM, during a telephone interview, the Technical Consultant stated two liquid levels of quality control were tested each week; however there were too many documents to send. At this time, the TC and the surveyor discussed the IQCP, which was also mailed to CLIA, along with the other documents. The IQCP did not include a quality control plan nor a quality assessment plan. At this time, no additional written policy /procedure has been provided to specify quality control testing of Creatinine. 6. In the absence of an acceptable and approved IQCP, the laboratory failed to test at least two levels of quality control on each day of patient testing. Patient testing of Creatinine occurred more frequently than once per week.

D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of proficiency testing and quality control records, a review of a partially developed IQCP (Individualized Quality Control Plan), a review of personnel records, and interviews with the testing personnel, hospital laboratory manager, and the technical consultant, the surveyor determined the laboratory director failed to: 1) Ensure testing personnel presented with the appropriate educational credentials to perform moderate-complexity testing, prior to performing testing on patient specimens; 2) Ensure the laboratory enrolled in proficiency testing, utilizing the laboratory's CLIA identification number; and report the results to CMS. 3) Ensure the laboratory performed quality control at the frequency specified by the CLIA guidelines, in the absence of an approved IQCP. 4) Ensure the laboratory developed a complete, acceptable and approved IQCP, prior to reducing the frequency to testing quality control to less than that required by the CLIA standard for Chemistry (Creatinine) testing. The findings include: 1. Refer to D6029. 2. Refer to D6020 (See also D5447). 3. Refer to D6020 (See also D5445). 4. Refer to D6015 (See also D2000).
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on a review of CAP (College of American Pathologists) proficiency testing records (2017 and 2018) for CLIA identification #01D0641705, an interview with the hospital's laboratory manager, telephone interviews with the Technical Consultant (also the Point-of-Care Coordinator for the system's clinics), and a CAP employee, and a lack of documentation, the surveyor determined the laboratory director failed to ensure the laboratory enrolled in proficiency testing for creatinine (a moderate-complex test) performed on the EPOC. The findings include: 1. Refer to D2000.
D6020	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 the quality control program is established and

	maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of policies and procedures (a lack of documentation), a review of quality control records, and interviews with Testing Personnel (TP) #3, the Technical Consultant (TC), and the hospital's laboratory manager, the surveyor determined the laboratory director failed to ensure the laboratory staff performed at least two levels of quality control each day of patient testing for Creatinine, in the absence of an acceptable and approved IQCP (Individualized Quality Control Plan). The laboratory director further failed to ensure the laboratory developed an acceptable IQCP to reduce the frequency of testing the quality control to at least once per week. This affected the only test performed at the laboratory. The findings include: 1. Refer to D5447. 2. Refer to D5445.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of personnel records, interviews with the Technical Consultant and the hospital's laboratory manager, and a lack of documentation, the surveyor determined the Laboratory Director failed to ensure all testing personnel of moderate complexity testing presented with the appropriate educational credentials, prior to allowing the personnel to perform testing on patient specimens. This affected three of four testing personnel. The findings include: 1. An on-site review of the personnel records revealed no educational credentials for four of four testing personnel (TP) of creatinine, using the EPOC instrument. 2. Upon exit on 11/14/18, the surveyor requested of the laboratory manager to send the documents by 11/16/2018, along with other documents requested for review [The laboratory was not prepared for the survey. Most of the necessary documents necessary for review were not on-site, at the time of the survey]. Numerous documents from the laboratory were received by mail by the CLIA, State Agency on 11/19/18; however the documents failed to include the educational credentials of the testing personnel. 3. During a telephone interview on 11 /29/18 at 1:30 - 1:50 PM, the Technical Consultant stated she thought the educational credentials for TP #2 were included with the documents. However, these documents were not included with the mailed documents. She further stated those were assessable and she would send them. The Technical Consultant further stated the laboratory did not have the educational credentials for the other three testing personnel. 4. The laboratory listed these four testing personnel on the CMS Personnel Form #209, as personnel who tested patient specimens for creatinine levels. Patricia Watson, BS, MT (ASCP) Licensure and Certification Supervisor