Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2139218	01/15/2020
Name of Provider or Supplier	**Street Address, City, State**	
Oxford Clinical Laboratory	397 Haledon Avenue, Haledon, NJ	

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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the General Supervisor (GS), the Laboratory Director (LD) failed to have the Attestation Statements (AS) signed by the analyst and LD for all PT tests performed with the College of American Pathologists (CAP) for events in the calendar year 2019. The findings include: 1. The laboratory did not document handling, processing and each step in the testing and reporting of PT samples for: a. Urine Chemistry - event A b. Urine Drug Testing (Screen) - event C c. Hematology Auto Differential FH13 - event B d. Erythrocyte Sedimentation Rate (ESR) - event A & B e. Diagnostic Immunology - event B f. Viral Markers - event B 2. The GS confirmed on 1/15/20 at 1:15 pm that the laboratory did not maintain all records for PT.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons

	other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the General Supervisor (GS), the laboratory failed to undertake appropriate training and employ technical assistance necessary to correct problems associated with PT failures performed with the College of American Pathologists (CAP). The findings include: 1. There was no remedial action taken or documented for unacceptable International Normalized Ratio (INR) in the CGL-A 2019 Coagulation Limited event for samples CGL-01, CGL-03 and CGL-04. 2. The General Supervisor confirmed on 2 /4/20 at 10:55 am that corrective action was not documented for the unsatisfactory PT performance.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC), Reagent verification records and interview with the General Supervisor (GS), the laboratory failed to retain Manufactures Package Inserts (MPI) for QC and Reagent for Prothrombin Tests (PT) performed on the ACL-1000 Analyzer from 10/22/18 to 2/11/19. The findings include: 1. The MIP for Hemosil Controls 1 and 3 were not retained for the above mentioned time frame. 2. The MPI for Hemosil Throbin Time reagent with an International Sensitivity Index (ISI) value of 1.82 was not retained for the above mentioned time frame. 3. The GS confirmed on 1/15/20 at 10:00 am that MPI's were not retained.
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 surveyor review of the Proficiency Testing (PT) records and interview with the General Supervisor (GS), the laboratory failed to review and evaluate coded PT results obtained with the College of American Pathologists (CAP) in the calendar year 2019. The findings include: 1. The laboratory did not evaluate Code 26 (educational challenge) for Blood Cell Identification samples BCP-26 - BCP-30 in event C and Diagnostic Immunology samples RF 06, 07 and 09 in event B. 2. The laboratory did not evaluate Code 28 (response qualified with a greater or less than sign; unable to

	quantitative) for Diagnostic Immunology event S-B samples RF 08 and RF 10. 2. The GS confirmed on 1/15/20 at 1:30 pm that the laboratory failed to evaluate coded results for PT events.
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 surveyor review of the Proficiency Testing (PT) records and interview with the General Supervisor (GS), the laboratory failed to evaluate results when they received an unacceptable score in Hematology, Diagnostic Immunology and Urine Drug Screen tests performed with the the College of American Pathologists (CAP) and the American Proficiency Institute (API) in the calendar year 2019. The findings include: 1. The laboratory received "Unacceptable" results as stated below: a. International Normalized Ratio (INR) - CAP event A samples CGL-01, CGL-03 and CGL-04 b. Activated Partial Thromboplastin Time (aPTT) - API (off cycle) sample 65RCOA-03 c. Urine Drug Testing (Screen) CAP - event C sample UDS-15 d. Diagnostic Immunology CAP - event B Rheumatoid Factor Screening RF-09 and RF10. 2. There was no documented evidence that the laboratory investigated the failures. 3. The GS confirmed on 1/15/20 at 1:10 pm that the laboratory did not perform and document an evaluation of unacceptable PT results.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), calibration records and interview with the General Supervisor, the laboratory failed to follow their calibration procedure for Hematology tests performed on the Coulter LH 750 from July 2018 to the date of the survey. The findings include: 1. The PM stated calibration was to be performed every six months but calibration was performed once in 2018 and once in 2019 2. The GS confirmed on 1/14/20 at 11:30 am that the laboratory did not follow the PM. Note: This deficiency was previously cited. The Plan of Corrections stated: "A scheduled reminder has been set to notify the technical supervisor to perform the calibration every six months so we do not miss it in the future"
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

	This STANDARD is not met as evidenced by: Based on surveyor review of the Manufacturers Package Insert (MPI) and interview with the General Supervisor (GS), the laboratory failed to follow the MPI for Coagulation testing performed on the ACL-1000 analyzer from 10/22/18 until 2/11 /19. The findings include: 1. The Hemosil Throbin Time MPI stated to establish a Normal Patient Mean (NPM) with each new lot of reagent but the laboratory did not establish a NPM with the lot used from 10/22/18 through 2/11/19. 2. Approximately 400 patients were run and reported. 4. The GS confirmed on 1/15/20 at 11:00 am that the MPI was not followed.
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 surveyor observation of reagents and interview with the General Supervisor (GS), the laboratory failed to discard expired reagents used for Urine Microscopy (UM) tests from 7/1/18 to the date of the survey. The finding includes: 1) Count-10tm Stain Lot # 810-601 used for UM expired 7/1/18. 2) Approximately 5,796 patients were run and reported. 3) The GS confirmed on 1/15/20 at 1:10 pm that the laboratory used an expired reagent.
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 surveyor review of the Quality Control (QC) records, Work Records (WR) and interview with General Supervisor (GS), the laboratory failed to perform and document two level of controls on each day of patient testing for Coagulation testing performed on the ACL - 1000 analyzer on 10/26/19 the finding includes: 1. Controls were not run on 10/26/19. 2. Eight patients were run and reported. 3. The GS confirmed on 1/15/20 at 1:00 pm that two levels of QC were not performed pm 10/26 /20.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for

	example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) records and interview with the General Supervisor (GS), the laboratory failed to verify QC material used for Hemoglobin A1C tests performed on the Premier 9210 and urinalysis tests performed on Clinitex Atlas analyzers from 6/6/2018 to the date of survey. The GS confirmed on 1/15/20 at 10:15 am that the assayed values of QC material were not verified before putting in use.
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 on surveyor review of the Final Report (FR) and interview with the General Supervisor (GS), the laboratory failed to identify problems on the FR from 6/6/18 to the date of the survey. . The findings include: 1. The Reference Range for Drug Screen test results contained both a cutoff value and "Negative". 2. The Glycohemoglobin result contained a diagnosis. 3. The GS confirmed on 1/15/20 at 1: 30 pm the laboratory did not identify problems on the FR.
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 an surveyors review of the laboratory's records, procedures and interview with the General Supervisor (GS), the Laboratory Director (LD) failed to provide overall management and direction to the laboratory to ensure that laboratory testing is performed satisfactorily and in compliance with the CLIA regulations from 6/6/18 to the date of the survey. 1. The LD failed to ensure Performance Specification procedures were adequate for all Chemistry and Endocrinology tests. Cross Refer to D6013. 2. The LD failed to ensure the establishment and maintenance of acceptable levels of analytical performance for coagulation tests. Cross Refer to D6023
D6013	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the General Supervisor (GS), the Laboratory Director (LD) failed to ensure that PS procedures for Chemistry and Endocrinology tests performed on the Beckman AU 480 and DXI 600 analyzers respectively were adequate from May 2019 to the date of survey. The findings include: 1. There was no documented evidence that PS procedures were performed on plasma Glucose. 2. The PS stated the random Error Budget (REB) for precision was 16-25% but a review of documentation revealed the REB for Progesterone and Vitamin B12 was 33.33% 3. The GS confirmed on 1/15/19 at 2:15 pm that PS records were not adequate.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on surveyor review of the Coagulation Records and interview with the General Supervisor (GS) the Laboratory Director (LD) failed to ensure the establishment and maintenance of acceptable levels of analytical performance for coagulation tests performed on the ACL-1000 from 10/22/18 until 6/6/19. The findings include: 1) The International Sensitivity Index (ISI) was changed to 1.82 on 10/22/18 with no evidence of a new calculated Normal Patient Mean (NPM). 2. A review of event CGL-A 2019 Coagulation Limitied Proficiency Testing records revealed the NPM used with an ISI of 1.82 was 12.0. 3) A calculation check on patient work records using an ISI of 1.82 and a NPM of 12 revealed that twenty out of twenty INR test results were calculated incorrectly from 10/22/18 through 6/6/19. 4) The laboratory ran and reported approximately 80 patient INR results incorrectly. 5) The GS confirmed on 1 /15/20 at 2:00 pm the LD failed to ensure the establishment and maintenance of acceptable levels of analytical performance for coagulation tests. 35471