Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2139218	06/06/2018
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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on surveyor review of the Laboratory Procedures and interview with the Laboratory President (LP), the laboratory failed to be in compliance with the State of New Jersey (NJ) requirements to report communicable diseases as required by the NJ Administrative Code Title 8, Chapters 57 and 58 from October 2017 to the date of the survey. The finding includes: 1. On 1/27/18, accession # 1801270011 Rapid Plasma Reagin (RPR) test result was positive but it was not reported to the State of New Jersey. 2. The LP stated on 6/6/18 at 1:00 pm that the laboratory was not in compliance with the State of New Jersey.
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 Quality Control (QC) records, and interview with the Testing Personnel (TP), the laboratory failed to retain all QC records for Urinalysis performed on the Clinitek Atlas analyzer from 10/4/17 to 5/12/18. The finding

	includes; 1) The laboratory did not retain repeat QC printouts. 2) The TP # 2 listed on CMS form 209 confirmed on 6/6/18 at 1:10 pm that all QC printouts were not retained.
D5018	URINALYSIS CFR(s): 493.1211 If the laboratory provides services in the subspecialty of Urinalysis, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of the Urinalysis Procedure Manual (UPM) and Work Records, lack of the Quality Control (QC) records and interview with the Technical Supervisor (TS), the laboratory failed to meet the requirements of pre analytic, analytic and post analytic Urinalysis test procedures. The findings include: 1. The laboratory did not retain repeat QC printouts. Refer to D 3031 2. The laboratory did not follow UPM procedures. Refer to D 5401 3. The laboratory did not follow manufacturer's procedure. Refer to D 5411 4. The laboratory did not perform maintenance on the certrifuge. Refer to D 5432 5. The laboratory did not run QC. Refer to D 5449 6. The laboratory did not report results accurately. Refer to D 5801 & D 5805
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: a) Based on surveyor review of the Procedure Manual and interview with the Laboratory President (LP), the laboratory failed to establish a policy to report communicable diseases test results to The State of New Jersey from October 2107 to the date of survey. The LP confirmed on 6/6/18 at 1:00 pm that the laboratory did not establish a policy. b) Based on surveyor review of the Procedure Manual (PM), observation of centrifuge and interview with the Technical Supervisor (TS), the laboratory failed to follow Microscopic Examination (ME) procedure from October 2017 to the date of survey. The finding includes: 1. The ME procedure stated to "Spin urine specimen approximately 2000 RPM" but the laboratory's centrifuge spun at 3406 RPM and was not adjustable. 2. The TS confirmed on 6/6/18 at 1:30 pm that the laboratory did not follow the PM instructions. c) Based on surveyor review of the PM, review of Hematology test results and interview with the TS, the laboratory failed to follow the flag and repeat procedure for Hematology tests performed on the Coulter LH 750 Analyzer from May 2018 to the date of the survey. The findings include: 1. A review of 5 patient results with flags revealed a manual differential was not performed when results were abnormal. 2. A review of the 2 patient results requiring repeats revealed the samples were not repeated. 3. The TS confirmed on 6/6/18 at 11:45 am the PM was not followed. d) Based on surveyor review of the PM, review of Hematology test results and interview with the TS, the laboratory failed to have a procedure for Cold Agglutinin tests from October 2017 to the date of the survey. The

	TS confirmed on 6/6/18 at 11:00 am the laboratory did not have a Cold Agglutinin procedure. e) Based on surveyor review of the PM, Quality Control (QC) records and interview with the TS, the laboratory failed to follow the QC verification procedure for QC used on the Coulter LH 750 and Premier Trinity Biotech 9210 from October 2017 to the date of the survey. The finding includes: 1. The PM stated new QC must be run over 3 days before using but the laboratory did not run Hematology or Hemoglobin A1C QC before putting it into use. 2. The TS confirmed on 6/6/18 at 11: 55 am that the laboratory did not follow the PM. f) Based on surveyor review of the PM, calibration records and interview with the TS, the laboratory failed to follow their calibration procedure for Hematology tests performed on the Coulter LH 750 from October 2017 to the date of the survey. The finding includes: 1. The PM stated calibration was to be performed every six months but there was no documented evidence that calibration was performed after 11/19/16. 2. The TS confirmed on 6/6 /18 at 11:30 am that the laboratory did not follow the PM.
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 Clinitek Atlas Reagent Package Insert (RPI) and interview with the Laboratory President (LP), the laboratory failed to follow RPI instructions for specimen integrity from October 2017 to the date of survey. The finding includes: 1. The RPI stated "If testing cannot be performed within an hour after voiding, refrigerate the specimen immediately" but the laboratory did not ensure that urinalysis specimens were refrigerated immediately. 2. The LP confirmed on 6/6 /18 at 1:30 pm that RPI was not followed.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation of the Quality Control (QC) material and interview with the Testing Personnel (TP), the laboratory failed to put open and new expiration dates on Hematology, Routine Chemistry, Special Chemistry and Endocrinology QC material at the time of survey. The findings include. 1) The expiration date of control material shortens once opened. 2) The laboratory did not put new expiration dates on Bio-Rad Liquichek Immunoassay Plus Control Lot# 40360, Bio-Rad Lymphochek Assayed Chemistry Control Lot# 26440, and Bio-Rad Liquicheck Specialty Immunoassay Control Lot# 60200 in use. 3) The laboratory did not put open and new expiration date on Coulter QC in use. 4) The TP #2 listed on CMS form 209

	confirmed on 6/6/18 at 11:00 am the laboratory failed to put open and new expiration dates on the control material b) Based on surveyor observation of the Manual Differential (MD) reagents and interview with the Technical Supervisor (TS), the laboratory failed to label the reagents used to perform staining with pertinent information required for proper use on the date of the survey. The finding includes: 1. The laboratory had three plastic pour off containers that were not labeled as to their identification,storage requirements, preparation and expiration date. 2. The TS confirmed on 6/6/18 at 1:05 pm reagents did not have all the pertinent information on the label.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the Technical Supervisor (TS), the laboratory failed to verify Reference Interval (RI) for Endocrinology, Special Chemistry and Routine Chemistry testing performed on the VITROS 5600 analyzer from October 2017 to the date of survey. The finding includes; 1) The laboratory failed to verify RI for Creatine Kinase, C-Reactive Protein, Chloride, Ferritin, Parathyroid Hormone, Microalbumin, Progesterone, Prolactin, Testosterone, Vitamin D. 2) The TS confirmed on 6/6/18 at 2:00 pm that the laboratory did not perform RI PS.
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 on surveyor review of the Maintenance Records (MR), observation of Centrifuge and interview with the Technical Supervisor (TS), the laboratory failed to perform and document maintenance on the Hamilton Bell/Van Guard V6500 centrifuge used for spinning blood and urine samples from October 2017 to the date of the survey. The findings include: 1. The observation of maintenance sticker on centrifuge had due date of April 2018 but there were no records to substantiate that it was performed. 2. The TS confirmed on 6/6/18 at 1:45 pm that the laboratory did not perform maintenance on the centrifuge.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of the Quality Control records and interview with the Technical Supervisor (TS), the laboratory failed to perform and document quality control for Urine Microscopic test from October 2017 to the date of the survey. The finding includes: 1. The laboratory did not perform and document QC on each day of patient testing. 2. The laboratory ran and reported around 25 patient results a month. 3. The TS confirmed on 6/6/18 at 1:15 pm that the laboratory did not perform and document quality control on each day of patient testing.
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 the Quality Control (QC) records and interview with the Technical Supervisor (TS) the laboratory failed to verify that the assayed QC materials were within the acceptable ranges before they were put into use for analytes performed on the VITROS 5600 analyzer from May 2018 to the date of survey. The TS confirmed on 6/6/18 at 2:30 pm that the laboratory did not verify QC materials for analytes performed on VITROS 5600 analyzer.
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: a) Based on surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory did not document corrective action taken when Endocrinology, Special Chemistry and routine Chemistry controls were out of range on the Vitros 5600 from October 2017 to the date of survey. The TP #2 on CMS form 209 confirmed on 6/6/18 at 1:00 pm that corrective action was not documented on out of range controls. b) Based on surveyor review of the Hematology records and interview with the Technical Supervisor (TS), the laboratory did not perform corrective action when the daily startup failed for Hematology tests performed on the Coulter LH 750 from February to March 2018. The findings include: 1. The LH 750 daily startup report revealed the laboartory used expired reagents: a. Complete Blood Cell (CBC) Lyse from 2/24/18 to 3/5/18. b. CBC Cleaner Pack from 2/5/18 to 3/5/18. 2. The TS confirmed on 6/6/18 at 2:10 pm that corrective action was not performed.
D5801	TEST REPORT CFR(s): 493.1291(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 surveyor review of the Work Records, Final Report (FR) and interview with the Laboratory President (LP), the laboratory failed to ensure that test results were accurately transcribed on the FR from October 2017 to the date of survey. The findings include: 1. A review of the Urine Microscopic Examination Log (UMEL) revealed on 12/27/17, accession # 1712290003 had Urine White Blood Cell results of 5-10 but the laboratory reported 50-100. 2. There were no bacteria seen recorded on UMEL but the FR had Many. 3. A manual differential performed 2/18/18 on Patient 1802180001 reported one Eosinophil (Eos) and no Basophils (Baso) but the FR reported three Eos and one Baso. 4. The LP confirmed on 6/6/18 at 1:30 pm that the laboratory did not transcribe results accurately.
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: a) Based on surveyor review of the Final Report (FR) and interview with the Laboratory President (LP), the laboratory failed to ensure that the Test Report Date (TRD) was accurate on the FR from October 2017 to the date of survey. The finding includes: 1. The TRD changed to the report printed date when the FR was reprinted. 2. The LP confirmed on 6/6/18 at 11:30 am that the TRD did change when FR was reprinted. b) Based on review of FR and interview with the LP, the laboratory failed to report Urinalysis test results accurately from October 2017 to the date of survey. The findings include: 1. The laboratory reported units of measurement for qualitative Urine Glucose, Ketone and Protein tests. 2. The LP confirmed on 6/6/18 at 1:45 pm that test results were not reported accurately.
D5807	TEST REPORT CFR(s): 493.1291(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 surveyor review of the Final Report and interview with the Technical Supervisor (TC), the laboratory failed to identify the source of the Reference Intervals (RI) used for testosterone tests from October 2017 to the date of survey. The findings include; 1) The TS stated the laboratory used the RI provided by the manufacturer. 2) The RI on the FR for testosterone was 241-827 ng/dL but the manufacturer RI for testosterone was 132-813 ng/dL. 3) The TS confirmed on 6/6/18 at 11:30 am that the source of the RI was not known.
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 surveyor review of the Laboratory Work Records and interview with the Technical Supervisor (TS), the Laboratory Director failed to provide overall management and direction to the laboratory for performing Urinalysis tests from October 2017 to the date of survey.
D6074	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(5) Each individual performing moderate complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director.

	This STANDARD is not met as evidenced by: Based on surveyor review of the Levy Jennings (LJ) records and interview with the Technical Supervisor (TS), the Testing Personnel (TP) failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for Hemoglobin A1C tests performed on the Premier Trinity Biotech 9210 analyzer from October 2017 to the date of the survey. The TS confirmed on 6/6/18 at 1:45 pm that trends and shifts were not reviewed.