Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2118440	(X3) Date Survey Completed 12/20/2018
Name of Provider or Supplier Lincoln Diagnostics, Llc	**Street Address, City, State** 1023 Commerce Ave, Union, 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
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 records and interview with the Testing Personnel (TP), the laboratory failed to evaluate coded results obtained for Hematology proficiency testing performed with the American Proficiency Institute (API) in the 2nd and 3rd 2018 events. The finding includes: 1. The laboratory did not evaluate code 6 "Not Graded" for Blood Cell Identification - Educational Challenge in event 2 & 3 2018. 2. The TP #3 listed on CMS form 209 confirmed on 12/20/18 at 10: 30 am that the laboratory failed to evaluate coded results.
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 Testing Personnel (TP), the laboratory failed to evaluate results when they received an unacceptable score in Hematology and Chemistry performed with the American Proficiency Institute (API) in the 1st and 3rd 2018 event . The findings include: 1. The laboratory received an unacceptable result for sample BCI-01 Blood Cell Identification in 1-2018. 2. The laboratory received an unacceptable result for Thyroid Stimulating Hormone on sample CH-13 in 3-2018. 3. The laboratory received an unacceptable result for Thyroid Uptake (%) on sample CH-12 in 3-2018. 4. There

	was no documented evidence that the laboratory investigated the failures. 5. The TP #3 listed on CMS form 209 confirmed on 12/20/18 at 10:20 am 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: a. Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to follow the procedure for flags on the Capillary 2 Sebia analyzer used for Hemoglobin A1C tests from 9/1/18 to the date of the survey. The findings include: 1. The PM stated samples flagged with the comment "Atypical Profile" required Action - confirmation with Hemoglobin Variant testing." 2. A review of results from 10/13/18 to 12/03/18 revealed 14 Atypicl Profile flags but there was no evidence of follow up testing. 3. The TP #3 listed on CMS form 209 confirmed on 12/18/18 at 12:10 pm that the PM was not followed. b. Based on surveyor review of the PM and interview with the TP, the laboratory failed to follow the procedure for verification of controls used on the Coulter LH 750 analyzer in the calendar year 2018. The findings include: 1. The PM stated to verify the assay value of Quality Control (QC) material prior to it being placed into use. 2. QC verification was not performed prior to use as follows: a. Lot 1001892K expired 9/9/18 - new lot verified 9/10/18. b. Lot 1001885K expired 7/22/18 - new lot verified 8/1/18. c. Lot 1001885K was not verified. d. Lot 1001873 expired 4/22/18 - new lot verified 4/25 /18. e. Lot 1001859 expired 2/5/18 - new lot verified 3/22/18. f. Lot 1001859 expired 2 /5/18 -verified 2/5/18. g. Lot 1001852K expired 12/10/18 verified 12/10/18. h. Reticulocyte Lot 317402 expired 4/7/18 - new lot verified 4/9/18. i. Reticulocyte Lot 427402 expired 4/8/18 - new lot verified 4/7/18. j. Reticulocyte Lot 319002 expired 7 /27/18 - new lot verified 8/1/18. 3. The TP #3 listed on CMS form 209 confirmed on 12/18/18 at 2:10 pm that the PM was not followed.
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 Manufacturer's Package Insert (MPI), observation of Quality Control (QC) material, and interview with the Testing Personnel (TP), the laboratory failed to follow the manufacturer's instruction for Biorad Lyphochek Immunoassay Plus and Liquid Assay Multiqual 1,2, and 3 controls on the date of survey. The findings include: 1. A review of the freezer revealed Biorad QC frozen with an expiration date of one month. 2. The MPI was not followed as stated below: a. The MPI stated frozen Liquid Assay Multiqual 1, 2, and 3 were stable for 14 days

	(with exceptions) after it's thawed and opened. and remaining material must be discarded after use. b. The MPI stated Lyphochek Immunoassay Plus can be frozen for 28 days and remaining material must be discarded after each use. c. TP #3 stated at the time of the survey Biorad QC material was reconstituted, frozen, thawed and refrozen after use for 30 days. 3. The TP #3 listed on CMS form 209 confirmed on 12 /20/18 at 1:40 pm that the laboratory did not follow the MPI.
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: a. Based on surveyor observation of reagents and interview with the Testing Personnel (TP), the laboratory failed to put expiration dates on working reagents for Hemoglobin A1C tests performed on the Capillary 2 Sebia analyzer at the time of the survey. The findings include: 1) The expiration date of reagents change once put on the analyzer.\ 2) The laboratory did not put new expiration dates on the Hemolysis Reagent and Working Wash in use. 3) The TP #3 listed on CMS form 209 confirmed on 12/18/18 at 11:50 am the laboratory failed to put new expiration dates on reagents in use on the Sebia. b) Based on surveyor observation of Quality Control (QC) material, Glucose Calibrators (GC) and interview with the TP, the laboratory failed to label QC and GC used in Hematology, Chemistry and Endocrinology tests correctly at the time of the survey. The findings include: 1. The expiration date of control and calibrator material shortens once opened. 2. The laboratory did not put open and new expiration dates on Hematology QC in use. 3. The GC expired seven days after opening but the bottle had a 30 day expiration date. 4. Glucose and Potassium QC expired 14 days after opening but the vial had a 30 day expiration date. 5. Prostate Specific Antigen QC expired 3 days after opening but the vial had a 7 day expiration date. 6. The TP #3 confirmed on 12/20/18 at 10:35 am reagents were not labeled correctly.
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 test reports, procedure manual and interview with the Testing Personnel (TP), the laboratory failed to report patient test results accurately when results were above the linearity for Hemoglobin A1C (HbA1C) tests performed

	on the Capillary 2 Sebia analyzer from 9/1/2018 to the date of the survey. The finding includes: 1. The laboratory's lower limit of linearity was 5.30 but a review of results revealed ten patients were resulted below the linearity limit. 2. The TP # 3 listed on the CMS form 209 stated on 12/18/18 at 11:40 am that the laboratory reported HbA1C results below the linearity limit.
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 surveyor review of the Maintenance Record (MR) and interview with the Testing Personnel (TP), the laboratory failed to perform and document Maintenance as specified by the manufacturer on the Coulter LH 750 analyzer used in Hematology Testing the calendar year 2018. The findings include: 1. A review of the MR revealed there was no documented evidence of monthly maintenance performed in January thru November. 2. Approximately 15 - 20 patient were tested each day. 3. The TP #3 listed on CMS form 209 confirmed on 12/18/18 at 1:20 pm that maintenance as specified by the manufacturer was not performed.
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 (FR) and interview with the Testing Personnel (TP), the laboratory failed to identify the source of the Reference Intervals (RI) used for Hemoglobin A1C tests from 9/1/18 to the date of survey. The TP #3 listed on CMS form 209 confirmed on 12/18/18 at 11:00 am that the source of the RI was unknown
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on surveyor review of Final Reports, observation of Luminex Printouts (LP), Procedure Manual (PM) and interview with the Director of Molecular Testing (DMT),

	the laboratory failed to report patient result accurately in December 2018. The findings include: 1. On 12/13/18, LP had a positive result for Rhinovirus/Enterovirus for accession #1812130001 but the laboratory reported Not Detected on FR for Respiratory Pathogen Panel. 2. The PM stated "if the values of the positive results are close to threshold values, reporting will be done with the discretion of supervisor /director" but a. The procedure did not define what was close to threshold value. b. Threshold was 40 and calculated signal was 67 for Rhinovirus/Enterovirus. c. On 12 /18/18 at 11:00 am the DMT stated that as Influenza B and Coronavirus 229E results were positive she decided to report Rhinovirus/Enterovirus result as Not detected. 3. The DMT stated on 12/18/18 at 11:30 am that on her discretion she decided to report positive result as Not Detected.
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 Quality Control (QC) records and interview with the Testing Personnel (TP), the TP failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for Hematology, Chemistry and Endocrinology tests performed on the Coulter LH 750, Olympus BK-2 and the Unicell DX I 800 respectively in the calendar year 2018. The findings include: 1. The TP did not document review of Levy Jennings (LJ) charts for shift and trends for any instrument listed above. 2. There was no documented corrective action taken when LJ charts showed Alanine transaminase (ALT) and Rheumatoid Factor (RF) QC below the mean from 11/20/18 to 12/20/18. 3. The TP #3 listed on the CMS form 209 confirmed on 12/20/18 at 11:55 am that trends and shifts were not reviewed.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Administrative Manager (AM), the Laboratory Director failed to include all six elements in the Competency Assessment (CA) procedure from 7/12/17 to the date of survey. The AM confirmed on 12/20/18 at 1:00 pm that all six elements were not in the procedure.