

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0646585	(X3) Date Survey Completed 08/15/2018
Name of Provider or Supplier Unilab, Inc	Street Address, City, State 418 N Austin Blvd, Oak Park, IL	
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, procedure manuals, and interview with technical supervisor # 2; 1 of 4 testing personnel who perform routine Human Immunodeficiency Virus (HIV) testing of patient specimens failed to perform Proficiency Testing (PT). Findings include: 1. Review of laboratory personnel report (Form CMS 209) revealed that there were 4 persons listed as High Complexity Testing Personnel in the laboratory. 2. Review of PT records from the American Association of Bioanalysts revealed that 1 of 4 testing personnel (listed on Form CMS 209 and given the # 4 by the surveyor) did not perform PT for HIV testing in 2016, 2017, or the 1st and 2nd quarters of 2018. 3. At 10:30 AM on 08/14/18, technical supervisor #2 confirmed the surveyor's findings.</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's user guide, Prothrombin Time records, and interview with technical supervisor #2; the laboratory failed to retain printouts of</p>

analytic system activities of its Prothrombin Time activities as specified below for two of two Thromboplastin reagent lots reviewed. Findings include: 1. At 3:00 PM on 08/14/18, the surveyor reviewed the manufacturer's users guide for the Coaga Mate XM. On page 4.23 there are instructions that describe the process for printing test results. These instructions were also included at the end of other sections that give instructions for performing other tests that may be performed on the Coaga Mate XM. 2. At 3:30 PM on 08/14/18, the surveyor requested documentation showing how the laboratory determined the Normal Patient Mean Value of Thromboplastin Reagent lot J187730 and lot G098514. The surveyor was handed a handwritten log of 20 Protimes results. There was no record of the date and time the 20 Protimes were tested nor any printout of actual test results. When the surveyor asked technical supervisor #2 to show her the actual printouts of data, technical supervisor #2 told the surveyor that he didn't know he had to keep the printouts. 3. At 4:00 PM on 08/14/18, technical supervisor # 2 confirmed the surveyor's findings.

D5201

CONFIDENTIALITY OF PATIENT INFORMATION
CFR(s): 493.1231

The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control.

This STANDARD is not met as evidenced by:
Based on observation, record review and interview with technical supervisor #2; the laboratory failed to ensure confidentiality of patient information throughout all phases of the total testing process that were under the laboratory's control. Findings include: 1. At 9:30 AM on 08/15/18, during the review of quality control (QC) records, the surveyor observed that there were old log sheets, which included patients' names; accession numbers; and names of tests orders, that were used as scratch paper for jotting down notes in the QC records. 2. At 10:00 AM on 08/15/18, technical supervisor # 2 confirmed the surveyor's findings.

D5400

ANALYTIC SYSTEMS
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
Based on observations, review of the laboratory's procedures manual, manufacturer's instructions, quality control (QC) records, test data worksheets, laboratory test records, reports, and interview with technical supervisor #2; the laboratory failed to meet the requirements specified in 493.1251 through 493.1283, and monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. Findings include: 1. For International Normalized Ratio (INR) calculations, the laboratory failed to ensure that it established a Normal Patient Mean Value with each new thromboplastin lot number according to the manufacturer's instructions and its

own procedures manual when it performed Coagulation testing. See D5411 2. The laboratory failed to ensure that control materials used for testing did not exceed their expiration date. See D5417 3. The laboratory failed to perform and document calibration verification procedures on its Cell Dyne analyzer using the criteria established by the laboratory when it performed Complete Blood Count testing. See D5439 4. The laboratory failed to perform and document control procedures that produce graded and/or titered results for Syphilis Serology and Rubella tests. See D5451 5. The laboratory failed to report test results consistently across testing records and patient test reports did not include titers and/or numerical results. See D5805 Repeat deficiency from 2016

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 review of manufacturer's assay information sheet, laboratory procedure manuals, quality control (QC) records, patient test records, and interview with technical supervisor #2; the laboratory failed to perform and document all the Normal Patient Mean Value studies when it performed Prothrombin Times (PT) using the Coaga Mate XM analyzer for two of four lots of Thromboplastin reagent reviewed and failed to correctly calculate the Normal Patient Mean Value for one of four lots of Thromboplastin reagent reviewed. Findings include: 1. The manufacturer's assay information sheet explains what the International Normalized Ratio (INR) is; and how it is calculated. The procedures state, "The INR provides a standardized scale for monitoring patients who are under stable oral anticoagulant therapy.... The INR value corresponds to the value of the ratio of the patients Prothrombin Time (PT) to that of the standard PT raised to the International Sensitivity Index (ISI) power of the thromboplastin used." Then the procedures illustrate how to calculate the INR using the Normal Patient Mean Value established by the laboratory. 2. Review of the laboratory's procedures manual revealed that there was a procedure, as well as a worksheet to use when the laboratory determined the Normal Patient Mean Value of the Prothrombin Time for its lot of Thromboplastin Reagent. The procedure was as follows: "The Normal Mean Value of the patient will be determined from a group of at least 20 patients for each lot number." 3. At 3:00 PM on 08/14/18, review of patient test records and their corresponding QC records revealed that there was no documentation to show that the Normal Patient Mean Value was determined for lots of thromboplastin (127908 and H008861) used in patient testing for the following patients whose PT results were reported: a.10 /13/17 - Patient 405101 and 11/02/17 - Patient 405539 - There was no documentation to show that the Normal Patient Mean Value was determined for the lot of thromboplastin used (Lot 127908; expiration 03 /31/2020). b.12/28/17 - Patient 406727; 01/09/18- Patient 406924; and 02/06/18- Patient 407526 - There was no documentation to show that the Normal Patient Mean Value was determined for the lot of thromboplastin used (Lot H008861; expiration 06 /16/2018). 4. Review of the Normal Patient Mean Value study for lot number J187730 (expiration 12/29/19) revealed that the Normal Patient Mean Value was recorded as 12.0 seconds. When the surveyor calculated the mean of the 20 patients PT (11.7; 11.2; 11.5; 11.5; 12.0; 12.7; 11.4; 11.8; 11.0; 11.8; 12.4; 12.6; 12.5; 11.0; 12.3; 11.7;

11.8; 12.7; 12.0; and 11.5), she calculated the Normal Patient Mean Value as 11.9 seconds. 4. Review of the CLIA test volume worksheets revealed that the laboratory performed 200 PT INRs from June 2017 through June 2018. 5. At 3:30 PM on 08/14/18, technical supervisor #2 confirmed the surveyor's findings. Repeat deficiency from 2016

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 review of patient test requisitions, patient test reports, laboratory records, quality control (QC) records, and interview with technical consultant #2; the laboratory used control materials when they had exceeded their expiration date when it performed Complete Blood Count (CBC) testing from 07/04/2017 until the date of survey. Findings include: 1. At 2:00 PM on 08/14/18, the surveyor requested 4 patient test requisitions where CBC testing was ordered. The following patient requisitions were selected: a. Patient # 400252 tested on 03/17/17 b. Patient # 402304 tested on 06/08/17 c. Patient # 404262 tested on 09/09/17 d. Patient # 404838 tested on 10/02/17 2. Review of corresponding quality control records show that CBC test results were reported for 2 of 4 patients when QC material had expired for the following patient list above: a. Patient # 404262 tested on 09/09/17 b. Patient # 404838 tested on 10/02/17 The expired QC lots were as follows: a. Control L; Lot 63610422; expiration 2017-07-03 b. Control N; Lot 63610423; expiration 2017-07-03 c. Control H; Lot 63610424; expiration 2017-07-03 3. Manufacturer's product information sheets note that QC open-vial stability is 30 days. QC records show that the above Lot of QC material was currently being used on 08/14/18. When the surveyor asked technical supervisor #2 which lot of QC material he currently uses for CBC testing, technical supervisor # 2 went to the refrigerator to retrieve the manufacturer's product information sheet. The surveyor asked him why was the lot number different from the one recorded on the QC printouts. Technical supervisor # 2 told the surveyor that he has not changed the lot numbers on the QC records. He stated that he copied the same lot again and again. 4. Review of the CLIA test volume worksheets revealed that the laboratory performed 16, 800 CBCs from June 2017 through June 2018. Repeat deficiency from 2016

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless

the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on review of manufacturer's procedures, laboratory procedures manual, laboratory records, patient test records and interview with technical supervisor #2; the laboratory failed to perform and document calibration verification procedures at least once every 6 months of its Cell Dyne 1600 Complete Blood Count (CBC) analyzer in 2017. Findings include: 1. Manufacturer's procedures instructed the laboratory as follows: "Calibration should be confirmed on a regular basis according to the requirements governing quality control in your laboratory." 2. The laboratory's procedures manual did not specify the frequency with which the laboratory performs calibration verification procedures on its CBC analyzer. 3. At 2:00PM on 08/14/18, the surveyor asked technical supervisor #2 how often the laboratory performed calibration on their CBC analyzer. Technical Supervisor #2 told the surveyor that the laboratory performs Calibration every 6 months. 4. At 2:00 PM on 08/14/18, review of calibration records revealed that there was no documentation to show the 6 month calibration of the CBC analyzer between 12/21/16 through 11/20/17. 5. Review of the CLIA test volume worksheets revealed that the laboratory performed 16, 800 CBCs from June 2017 through June 2018. 6. At 2:30 PM on 08/14/18, technical supervisor #2 confirmed the surveyor's findings.

D5451

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(iii)(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-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of manufacturer's instructions, patient test records, test volumes, quality control (QC) records, and interview with technical supervisor #2; the laboratory failed to perform and document control procedures that produce graded and /or titered results for Syphilis Serology and Rubella tests. Findings: 1. Manufacturer inserts from test kits for RPR and Rubella described the process for performing serial dilutions when performing titers. 2 Review of patient test records revealed that Titers were ordered on the following patients: a. 04/02/18 - Patient 408609 Titer was ordered. The requisition did not specify which analyte(s) titer (s) were ordered. There was no documentation of titers performed. b. 05/05/18 - Patient 409290 MMR Titers was ordered. There was no documentation of titers performed. 3. At 8:30 AM on 08/15 /18, review of QC records for RPR and Rubella testing revealed that there was no

documentation to show that the laboratory titered QC material. 4. At 9:00 AM on 08/15/18, surveyor requested documentation of titer results. Technical supervisor #2 stated that titer results were performed but not recorded for quality control or patients. 5. Review of the CLIA test volume worksheets revealed that the laboratory performed 400 Syphilis Serology tests and 2325 General Immunology tests from June 2017 through June 2018.

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 review of laboratory procedure manuals, patient test records, patient test reports, and interview with technical supervisor #2; the laboratory failed to report test results consistently across testing records for five of five patients reviewed and patient test reports did not include titers and/or numerical results for two of five patients reviewed. Findings include: 1. Review of procedure manuals revealed that there were no instructions that described the laboratory's process for interpreting and reporting results for Rubella and RPR testing. 2. The package inserts for RPR and Rubella were reviewed. a. The RPR package insert states "Results for the ASI RPR Card test should be reported only as reactive or nonreactive" b. The Rubella package insert states under Interpretation of the Results "POSITIVE REACTIONS 3+ Large clumping with clear background 2+ Moderate clumping with fluid slightly opaque in background 1+ Small clumping with opaque fluid in background NEGATIVE REACTIONS No visible clumping, uniform suspension" 3. Review of RPR testing records for four of five patients reviewed (409290, 405052, 404801, 407624) revealed the following: a. Results for quality control are recorded as R, WR, NR on the "RPR Serology Log and Quality Control Form" and Immune, Weakly Immune, and Nonimmune on "RPR_Forms1" b. Patient results are logged as neg on the "RPR_Forms1". Patient final reports are resulted as Nonreactive. 4. Review of Rubella testing records for two of five patients reviewed (408609 and 409290) revealed the following: a. Results for quality control are recorded as Immune and Non Immune on "RPR_Forms2" b. Patient results are logged as Immune and Negative. 5. At 3:00 PM on 08/15/18 review of patient test reports revealed that the following patient test results were reported on the final reports as follows: a. 04/06/2018 Patient 408609 - Rubella IgG result "IMMUNE" Reference Values (IMMUNE 1:32) b. 05/08/2018 Patient 409290 - Rubella IgG result "IMMUNE"; RPR result "NON REACTIVE" Reference (NON REACTIVE); HEPATITIS BsAb "NEGATIVE" Reference (NEGATIVE [0.0 - 0.5]) The detection of BsAg, BsAb [≥ 0.2] or POSITIVE is indicative of a prior immunologic exposure to the antigen or vaccine.; VZV IgG Ab "IMMUNE" Reference Values (IMMUNE 1:32); Mumps Antibody, IgG "IMMUNE" Reference Values (IMMUNE 1:32); and Rubeola [Measles] IgG "IMMUNE" Reference (IMMUNE 1:32) 5. Reference range for Rubella is Immune 1:32. No evidence of titers performed for patient or quality control for patient 408609 and 409290. 6.

	<p>Hepatitis BsAB reference values is listed as Negative (0.0-0.5) with comment "The detection of BsAg, BsAb [=>0.2] or POSITIVE is indicative of a prior immunologic exposure to the antigen or vaccine." The result for 409290 is listed as Negative. No numerical value is given. 7. Review of the CLIA test volume worksheets revealed that the laboratory performed 2325 Immunology tests from June 2017 through June 2018. 8. At 3:30 PM on 08/15/18, technical supervisor #2 confirmed the surveyor's findings.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on observations, review of manufacturer's and laboratory's procedure manuals, quality control records, testing data, final reports, the CLIA test volume worksheets, and interview with technical supervisor #2; the laboratory director (LD) failed to provide overall management and direction in accordance with 493.1445 of this subpart. Findings include: 1. The LD failed to ensure that testing personnel are performing test method as required for accurate and reliable results. See D6087 2. The LD failed to ensure that test reports of test results include pertinent information required for interpretation. See D6098 Repeat deficiency from 2016</p>
<p>D6087</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii)</p> <p>The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of manufacturer's instructions, laboratory procedure manuals, quality control records, testing logs, data, CLIA test volume worksheet, and interview with technical supervisor #2; the laboratory director (LD) failed to ensure that laboratory personnel are performing test methods as required for accurate and reliable results. Findings include: 1. The LD failed to ensure that testing personnel were performing the required procedures for Coagulation testing. See D5411 2. The LD failed to ensure that testing personnel were not using expired quality control. See D5417 3. The LD failed to ensure that calibration verification was performed according to the laboratory's protocols when it performed Complete Blood Count tests. See D5439 4. The LD failed to ensure that testing personnel documented the reactions and graded reactions when it interpreted results for quality control material and patient tests. See D5451 and D5805 Repeat deficiency from 2016</p>
<p>D6098</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8)</p> <p>The laboratory director must ensure that reports of test results include pertinent information required for interpretation.</p>

This STANDARD is not met as evidenced by:

Based on review of test reports and interview with technical supervisor #2; the laboratory director (LD) failed to ensure that reports of test results includes pertinent information required for interpretation. Findings include: 1. The LD failed to ensure that proper test results are recorded in the test report for the test being performed. The laboratory reported the interpretation of the test on the final report of patients' testing, and not the actual results. See D5805