

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2016520	(X3) Date Survey Completed 01/15/2025
Name of Provider or Supplier Bio-Labs Usa, Inc	Street Address, City, State 1026 West Elizabeth Avenue, Linden, 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
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Laboratory Consultant (LC), the laboratory failed to review coded results for Hematology and Chemistry Testing performed with the American Proficiency Institute (API) in the second and third event of 2024. The findings include: 1. The laboratory received a coded result (Not Graded 2 -No Consensus) "See Data Summary" for Urinalysis Urobilinogen 2nd event 2024 sample UA-4. 2. The laboratory received a coded result (Not Graded 6 -Educational sample) "See Data Summary" for Educational Blood Cell Identification RBC morphology (DIF) 2nd event 2024 sample DIF-02. 3. The laboratory received a coded result (Not Graded 6 -Educational sample) "See Data Summary" for Educational Blood Cell Identification RBC morphology (DIF) 3rd event 2024 sample DIF-03. 4. The laboratory received a coded result (Not Graded 9) for Chemistry total Iron 3rd event 2024 samples CH-8 and CH-10. 5. There was no documented evidence that coded PT results was reviewed. 6. The LC confirmed on 1/14/25 at 11:15 am that the laboratory did not review coded PT results.</p>
D5313	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b)</p> <p>(b) The laboratory must document the date and time it receives a specimen.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Test Requisitions (TR), Final Reports (FR) and</p>

interview with Laboratory Consultant (LC), the laboratory failed to record specimen collection times and dates from 10/11/18 to 1/15/25. The findings include: 1. Review of TR revealed six out of six TR had no time, date the specimens were collected. 2. The LC confirmed on 1/14/25 at 11:40 am, the laboratory failed to ensure that specimen collection time and date were recorded on the TR.

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

(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 the surveyor review of the Procedure Manual and interview with the Laboratory Consultant (LC), the Laboratory failed to follow their procedure for 10/11/18 to 11/6/24. The findings include: 1) The laboratory did not follow their procedure "17. Daily Surveillance of Laboratory Results" the procedure stated as follows: a) "Levy Jennings charts will be printed monthly by QA manager, reviewed and signed. Director will discuss and review QC with QA manager on a monthly basis." 2) There was no documented evidence the above mentioned procedure was performed. 3) The LC confirmed on 1/15/25 at 11:00 am that the laboratory did not follow the aforementioned procedure. B) Based on the surveyor review of the Procedure Manual (PM) and interview with the LC, the Laboratory failed to have a procedure for the preparation of Quality Control (QC) material used for Unsaturated Iron Binding Capacity (UIBC) testing from 10/11/18 to 11/6/24. The findings include: 1) The laboratory uses Sekure UIBC tri level calibration/linearity material for their high and low controls. 2) The laboratory dilutes the calibration material to obtain acceptable High and Low QC values. 3) The laboratory does not have a written procedure for this process. 4) The LC confirmed on 1/15/25 at 11:00 am that the laboratory did not have the aforementioned procedure. C) Based on the surveyor review of the PM and interview with the LC, the Laboratory failed to have cutoff values for buprenorphine and Ecstasy testing performed on the Cobas AU480 analyzer from May 2022 to the date of survey. The LC confirmed on 1/15/25 at 11:00 am that the laboratory did not have the aforementioned cutoff values in the PM. D) Based on the surveyor review of the PM, interview with the LC, the Laboratory failed to have Specimen rejection, Specimen storage and turn around time procedures for toxicology tests performed on the Cobas AU480 analyzer from May 2022 to the date of survey. The LC confirmed on 1/15/25 at 11:00 am that the laboratory did not have the aforementioned procedures. 48354 E) Based on surveyor review of the Procedure Manual (PM), Patient Test Reports (PTR) and interview with the Laboratory Consultant (LC), Testing Personnel (TP) failed to follow the PM for Urine Microscopic Examination from 1/29/24 to the date of the survey. The findings include: 1. The PM states "correlate microscopic findings with chemical analysis as follows: c) Presence of RBC's- usually indicated by positive BLOOD." "If the microscopic and chemical tests correlate, then the chemical test may be omitted. If the microscopic and chemical tests do not correlate, recheck the chemical test." 2. Samples 2412200005, 241220005 and 2412190013 had urine chemistry results for Blood reported under abnormal for small detected. 3. The above mentioned samples did not have urine microscopic results for the presence of blood to correlate the chemistry results. 4. The LC confirmed on 1/15/25 at 1:25 pm, TP did not follow the PM.

D5403

PROCEDURE MANUAL

CFR(s): 493.1251(b)

(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual (PM) and interview with the Laboratory Consultant (LC), the laboratory lacked a source for Reference Intervals (RI) for Manual Urinalysis Microscopic (MUM) tests performed from 8/17/22 to 1/15/25. The findings include: 1. The laboratory lacked a source for RI for MUM tests in the PM. 2. The LC confirmed on 1/15/25 at 12:00 pm, there was no source for reference intervals for MUM tests in the PM.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(d)

(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 review of the Quality Control (QC) Records and interview with the Laboratory Consultant (LC), the laboratory used expired QC material for Toxicology testing from 10/31/24 to 1/14/25. The findings include: 1. Medtox Toxicology QC lot # CCO1651 expired 10/31/24. 2. The LC confirmed on 1/15/25 at 11:00 am that the laboratory used expired QC material.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(1)

(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)

(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 Performance Specification (PS) records and interview with the Laboratory Consultant (LC), the laboratory failed to ensure that all PS records were adequate for all analytes run on the Cobas AU480 Analyzer from May 2022 to 1/15/25. The findings include: 1. There was no Normal Patient Range study. 2. The LC confirmed on 2/15/25 at 11:30 am that the laboratory failed to ensure that all PS records were adequate.

D5469

CONTROL PROCEDURES

CFR(s): 493.1256(d)(10)(g)

(d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(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. (d)(10)(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. (d)(10)(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.

This STANDARD is not met as evidenced by:

Based on surveyor review of Quality Control Verification (QCV) records, Procedure Manual (PM) and interview with the Laboratory Consultant (TC), the laboratory failed to establish criteria for acceptability for Bio-Rad Quality Control (QC) materials used in Urinalysis testing from 8/17/22 to 1/15/25. The findings include. 1. The Clinitek Advantus PM stated "The manufacturer ranges are verified by repetitive testing before the new lot of quality control is placed into service." 2. The procedure did not define the number of times the Bio-Rad QC material must be tested to establish statistical limits. 3. The procedure did not define the acceptability or rejection criteria before a new lot of QC material is placed into use. 4. The LC 1/15/25 at 12:45 pm, the laboratory lacked established criteria for QCV for urinalysis testing.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(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 analytic systems specified in 493.1251 through 493.1283.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual and interview with Laboratory Consultant (LC) the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems from 10/11/18 to 1/15/25. The finding includes: 1. The laboratory failed to have a procedure to verify new lots of controls

before they were put in use on the Cobas AU480 analyzer. 2. The LC confirmed on 1/17/25 at 11:40 am that the laboratory failed to have a procedure to verify new lots of controls before they were put in use.

D5805

TEST REPORT
CFR(s): 493.1291(c)

(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 Urinalysis Microscopic Test Reports (UMTR), and interview with the Laboratory Consultant (LC), the laboratory failed to ensure patient test results were reported accurately for Urinalysis tests performed from 12/20/24 to 1/15/25. The finding includes: 1. A review of Patient Test Reports (PTR) revealed three out of three patient reports results reported inaccurately for Urinalysis Microscopic tests. The results from the UMTR were as follows: a) Sample number 241220005 had an White Blood Cell (WBC) out of range but was reported as normal on the UMTR. b) Sample number 2412190013 had Squamous Epithelial cells out of range but was reported as normal on the UMTR. c) Sample number 241220005 had WBC out of range but was reported as normal on the UMTR. 2. The LC confirmed on 1/15/25 at 1:10 pm, Urine microscopic results out of range were not reported accurately. B) Based on surveyor review of PTR and interview with the LC, the laboratory failed to ensure PTR had accurate information from 12/20/24 to 1/15/25. The finding includes: 1. Review of PTR revealed six out of six PTR had the statement " Tests performed at: Accu Reference Medical Lab, 1901 E. Linden Ave. Suite 4, Linden, NJ 070361195." 2. The LC stated "all tests were not performed at Accu Reference Laboratory and it was a known issue that is being resolved. " 3. The LC confirmed on 1/15/25 at 1:20 pm, PTR did not have accurate information.

D5807

TEST REPORT
CFR(s): 493.1291(d)

(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), Procedure Manual (PM), and interview with the Laboratory Consultant (LC), the laboratory failed to ensure that the Reference Interval (RI) was accurate for Creatinine run on the Cobas AU480 analyzer from May 2022 to 1/15/25. The finding includes; 1. The PM stated that RI's for Creatine was 0.7-1.30 mg/dL 2. The RI on the FR for Creatine was .60-1.20 mg/dL 3. The LC confirmed on 1/15/25 at 11:30 am that the laboratory failed to ensure the RI was accurate.

D6086

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(3)(ii)

(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

This STANDARD is not met as evidenced by:

A) Based on surveyor review of the Performance Specification (PS) records and interview with the Laboratory Consultant (LC), the Laboratory Director (LD) failed to ensure that PS procedures performed for Toxicology testing performed on the Beckman Coulter AU480 and Medtox Scan analyzers were adequate from May 2021 to 1/15/25. The findings include: 1. There was no documented evidence that accuracy, precision, linearity and patient range studies were performed on the MedtoxScan analyzer for toxicology testing. 2. There was no raw data for PS performed for toxicology testing on the Beckman Coulter AU480. 3. The LC confirmed on 1/15/25 at 11:15 am, the PS records were not adequate. 48354 B) Based on surveyor review of the Performance Specification (PS) records and interview with the Laboratory Consultant (LC), the Laboratory Director (LD) failed to ensure that PS procedures performed for Hematology testing performed on the Beckman Coulter DxH 560 analyzer were adequate from 2/16/22 to 1/15/25 . The findings include: 1. There were no procedures for the verification of the Beckman Coulter DxH 560 analyzer. 2. The reference ranges were not verified for the Beckman Coulter DxH 560 analyzer before being used for patient testing. 3. The LD did not sign or approve the PS for the Beckman Coulter DxH 560 analyzer before being used for patient testing. 4. The LC confirmed on 1/15/25 at 12:30 pm, the PS records were not adequate.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(12)

(e)(12) 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 surveyor review of Testing Personnel (TP) records and interview the Laboratory Consultant (LC), the Laboratory Director (LD) failed to ensure that TP had the required training and competency assessments from 2/16/22 to 1/15/25 . The findings include: 1. There were no training records or competency assessments available for review for TP #1 as listed on the CMS 209 form. 2. The LC confirmed on 1/15/25 at 11:45 am, the LD failed to ensure training records or competency assessments for TP were available for review.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(13)

(e)(13) 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 Competency Assessment (CA) records, Procedure Manual (PM) and interview with the Laboratory Consultant (LC) the Laboratory Director (LD) failed to have established written procedures for assessing the competency of TP from 2/16/22 to 1/15/25. The finding includes: 1. There were no written procedures or polices for how to assess the competency of new employees and the annual competency of TP. 2. The LC confirmed on 1/15/25 at 1:30 pm the LD failed to establish written policies and procedures for CA.