Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2016520	10/11/2018
Name of Provider or Supplier	**Street Address, City, State**	
Bio-Labs Usa, Inc	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
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 Laboratory Director (LD), the laboratory failed to maintain the Attestation Statements (AS) signed by the analyst and the LD for tests performed with the American Proficiency Institute in the calendar years 2017 and 2018. The findings include: 1. The AS was not signed by the analyst and the LD for 3-2017 Syphillis event, 1 and 2 of 2018 Hematology/Coagulation events, 1-2018 Urine Drug testing event. 2. The LD confirmed on 10/11/18 at 10:20 am that AS were not signed by the analyst and the LD.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

	This STANDARD is not met as evidenced by: Based on lack of the Competency Assessment (CA) records and interview with the Laboratory Director (LD), the laboratory failed to perform a CA correctly on three of three testing personnel in 2017 and 2018. The finding includes: 1. The CA did not include how assessment was done and what records were reviewed. 2. The LD confirmed on 10/11/18 at 11:25 am that CA was not done correctly.
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 Laboratory Director (LD), the laboratory failed to evaluate coded results obtained for Hematology, Urinalysis and Urine Drug proficiency testing events performed with the American Proficiency Institute. The findings include: 1. The laboratory did not evaluate 'Not Graded' grade achived for event 1-2018 Blood Cell Identification sample # BCI-01. 2. The Laboratory did not evaluate 'Not Graded' grade for event 1-2018 Urobilinogen sample # UA-02. 3. The laboartory did not evaluate 'Not Graded' performance for event 1-2018 UDS Opiates (qual) sample # UDS-02. 4. The LD confirmed on 10/11/18 at 11:00 am that the laboratory failed to evaluate coded 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 Laboratory Director (LD), the laboratory failed to follow the procedure for reviewing results with flags obtained on the Coulter LH 750 analyzer used for Hematology testing in August 2018. The findings include: 1. The PM stated to rerun specimens flagged for Hemoglobin (HgB) and Hematocrit (Hct) failure and scan a slide. 2. A review of 4 patient results with HgB/Hct failure revealed samples were not repeated and a slide was not scanned but the results were reported. 3. The LD confirmed on 10 /11/18 at 11:50 am that the PM was not followed. b. Based on surveyor review of the PM and interview with the LD, the laboratory failed to establish a written procedure for all Hematology tests performed in the laboratory from 12/5/16 to the date of the survey. The finding includes: 1. The laboratory did not have a procedure for Cold Agglutinins. 2. The LD confirmed on 10/11/18 at 2:10 pm that the above procedure was not established.
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 Urine Toxicology 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 open and new expiration dates on Liquichek Urine Toxicology Control Lot # 72560 vial. 3) The TP #1 listed on CMS form 209 confirmed on 10/11/18 at 11:00 am the laboratory failed to put open and new expiration dates on the control material.
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 Laboratory Director (LD), the laboratory failed to verify that assayed QC material was within the acceptable range before it was put into use for analytes ran on the Coulter LH 750 analyzer in the calendar year 2018. The findings include: 1. Coulter 5C control lot # 879100 and 868000 expired on 2/17/18 and 2/19/18 respectively but the new control lot was verified on 2/20/18. 2. Coulter 5C control lot # 318608, 428602 and 538602 expired on 6/29/18 and 6/30/18 but the new control lot was verified on 7/5 /18. 3. Approximately 10 - 15 patients were run during each of the above time periods. 4. The LD confirmed on 10/11/18 at 11:30 am that the laboratory did not verify QC material before use.
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 surveyor review of the Test Report (TR) and interview with the Testing Personnel (TP), the laboratory failed to have all the required information on the TR from 12/05/16 to the date of survey. The finding includes: 1. "Urine Microscopy & Culture/Sensitiv" was listed as test performed on the TR but no Culture and sensitivity was performed. 2. The TP #1 listed on CMS form 209 confirmed on 10/11/18 at 1:10 pm that the TR was incorrect.
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: a) Based on surveyor review of the Final Report (FR) and interview with the Laboratiry Director (LD), the laboratory failed to ensure that the Reference Range (RR) was indicated on the FR for positive Rapid Plasma Reagin (RPR) test result from 12/6/16 to the date of survey. The LD confirmed on 10/11/18 at 1:55 pm that the RR was not on the FR for positive RPR test result. 20464 b) Based on surveyor review of the Final Report and interview with the Testing Personnel (TP), the laboratory failed to identify the source of the Reference Intervals (RI) used for Glucose and Total Bilirubin tests from 12/05/17 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 Glucose was 74-106 mg/dL but the manufacturer RI was 70-105 mg/dL. 3. The RI on the FR for Total Bilirubin was 0.2-1.2 mg/dL but the manufacturer RI was 0.3-1.0 mg/dL . 4. The TP #1 listed on CMS form 209 confirmed on 10/11/18 at 1:30 pm that the source of the RI was
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 Laboratory Director (LD), the laboratory failed to correct problems in the postanalytic system from 12/5/16 to the date of the survey. The findings include: 1. The laboratory reported a comment "Result was rechecked for prewarm" which was not accurate for test reported. 2. The FR reported CBC with Automated Differential but a Manual Differential was performed. 3. The LD confirmed on 10/11/18 at 1:40 pm that laboratory failed to correct problems on the FR.