| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 21D2289614 | 09/25/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Privium Consultants | 7801 Old Branch Avenue #202, Clinton, MD | |

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 |
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| **D3011** | FACILITIES<br>CFR(s): 493.1101(d)<br><br>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.<br><br>This STANDARD is not met as evidenced by:<br>Based on procedure manual and record review and interview with the office manager (OM), the laboratory failed to ensure that the laboratory's eyewash station was maintained in order to ensure protection from physical, chemical, and biochemical hazards, and biohazardous materials. Findings: 1. The procedure, "Eyewash Inspection" states, "Eyewash bottle will be inspected monthly to ensure seal has not been broken and the eyewash bottle is not expired." 2. A review of "Eyewash Inspection Logs" from September 2023 through June 2024 showed that eyewash bottle checks were not performed four out of ten months. 3. During an interview on 09/25/2024 at 3:45 PM, the OM confirmed that monthly eyewash bottle checks were not performed. |
| **D3031** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(3)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on laboratory record review and interview with the office manager (OM), the laboratory failed to retain all analytic systems records for at least 2 years. Findings: 1. |

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| | "Laboratory Temperatures & Humidity Logs" were reviewed from September 2023 through June 2024. The log includes space to document room and refrigerator temperatures, humidity, and the "Reaction Temp" and "Wash Temp" of the chemistry analyzer. 2. Temperature log record review showed that the "Laboratory Temperatures & Humidity Log" for April 2024 was missing. 3. During an interview on 09/25/2024 at 3:45 PM, the OM confirmed that the laboratory did not maintain all analytic systems records for at least 2 years. |
| **D5315** | SPECIMEN SUBMISSION, HANDLING, AND REFERRAL<br>CFR(s): 493.1242(c)<br><br>The laboratory must refer a specimen for testing only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with the office manager (OM), the laboratory failed to maintain a copy of the Clinical Laboratory Improvement Amendments (CLIA) license for each reference laboratory used in order to vet the laboratory's certification in CLIA. Findings: 1. The laboratory performs qualitative toxicology screening on urine specimens. During an interview on 09/25/2024 at 10:00 AM, the OM stated that the laboratory sends out specimens which require confirmatory testing to two outside laboratories. 2. Record review showed that the laboratory did not have a copy of the CLIA license for either of the two referral laboratories, showing that the laboratories were CLIA-certified or met equivalent requirements as determined by the Centers for Medicare and Medicaid Services. This was confirmed by the OM during an interview at 3:45 PM. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>I. Based on procedure manual review and interview with the office manager (OM), the laboratory failed to ensure that all of the procedures in the written procedure manual were complete and included all of the information required. Findings: 1. Procedure manual review showed that three of the procedures were incomplete. The procedure, "Fire and Electrical Precautions" included a page which stated, "This page is intentionally blank. Insert emergency exit floor plan" but did not include the emergency exit floor plan; 2. The procedure, "Contingency Plan" included a page which stated, "This page is intentionally blank to insert a copy of the specimen storage /handling requirements for the Reference Lab" but did not include the specimen storage/handling requirements; and 3. The procedure, "Reference Laboratory" included a page which stated, "This page is intentionally blank to insert a copy of the CLIA certificate for the Reference Lab" but did not include a copy of the CLIA licenses for the laboratory's two reference laboratories. Cross-refer to D5315. 4. During an interview on 09/25/2024 at 3:45 PM, the OM confirmed that the laboratory's written procedure manual was not complete. II. Based on procedure |

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| | manual review and interview with the office manager (OM), the laboratory failed to follow procedures for saving data from the Laboratory Information System (LIS) to an external data storage device. Findings: 1. The procedure, "LIS Back Up Protocol" states that "All the data in the laboratory information system will be saved to an external data storage device on a weekly basis." 2. During an interview on 09/25/2024 at 4:15 PM, the OM stated that the laboratory was not backing up the data from the LIS onto an external storage device, to ensure that patient information was maintained. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (14) Description of the course of action to take if a test system becomes inoperable.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review, the validation study for toxicology screening of patient samples failed to include a written procedure that identified the source of the samples used for validating the accuracy and precision of the testing. Findings: 1. Record review showed that the laboratory did not have a written procedure for the accuracy and repeatability studies that identified the source of the reagent or samples tested to perform the studies. 2. During interview on 9/25/2024 at 11:00 am with the office manager, it was confirmed that there were no additional validation records available for review. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. |

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| | This STANDARD is not met as evidenced by:<br>Based on temperature log record review and interview with the office manager (OM), the laboratory failed to monitor and document laboratory room temperature and room humidity to ensure proper reagent storage and reliable test system operation. Findings: 1. "Laboratory Temperatures & Humidity Logs" were reviewed from September 2023 through June 2024. The log includes space to document room and refrigerator temperatures, humidity, and the "Reaction Temp" and "Wash Temp" of the chemistry analyzer. 2. Temperature log review showed that room temperature was not documented for five out of ten months. The log for April, 2024 was not present at the time of the survey. 3. During an interview on 09/25/2024 at 3:45 PM, the OM confirmed that the room temperature was not documented daily to ensure proper reagent storage and reliable test system operation. |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of "Reagent - Calibrator" inventory logs and interview with the office manager (OM), the laboratory failed to ensure that chemistry quality control and calibration materials were not used after they had exceeded their expiration date. Findings: 1. The laboratory began testing in October 2023. Record review showed that there was one page of the "Reagent - Calibrator" inventory log available at the time of the survey. A review of this log showed that the laboratory began documenting receipt of reagents on 08/20/2024 when the newly hired testing person identified the need to document reagent receipt, lot numbers, and expiration dates. 2. "Reagent - Calibrator" inventory log review from 08/20/2024 to 09/23/2024 showed that the laboratory received the "Multi Drug Calibrator Level 2" (lot number E53695, expiration date 05 /30/2025) and the "Buprenorphine Urine Calibrator" (lot number E53168, expiration date 04/30/2025) on 08/20/2024; the "Negative 10-1 Calibrator Blank" (lot number E53468, expiration date 01/31/2026) on 09/05/2024; and the "Acetyl Morphine Urine Calibrator" (lot number E53983, expiration date 07/31/2025), the "Benzodiazepines Urine HEIA" (lot number EK24050, expiration date 02/28/2026), and the "Tramadol Urine HEIA" (lot number EK23542, expiration date 09/30/2025) on 09/23/2024. 3. During an interview on 09/25/2024 at 3:00 PM, the OM stated that there were no other reagent logs available, and confirmed that prior to 08/20/2024 the laboratory was not using the reagent log that was part of the written procedure to ensure that reagents were not used when they had exceeded their expiration date. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review, the laboratory did not identify the testing person on |

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| | preventive maintenance records for the ImmTox analyzer. Findings: 1. The laboratory began urine toxicology testing in October 2023. The testing person did not initial the daily ImmTox startup maintenance record for 8 of 12 days during the month of November 2023. |
| **D5781** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(1)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on temperature log record review and interview with the office manager (OM), the laboratory failed to document corrective action when laboratory humidity and refrigerator and instrument temperatures were out of range. Findings: 1. "Laboratory Temperatures & Humidity Logs" were reviewed from September 2023 through June 2024. The log includes space to document room and refrigerator temperatures, humidity, and the "Reaction Temp" and "Wash Temp" of the chemistry analyzer. 2. Temperature log record review showed that on 09/20/2023, under "Comments /Corrective Actions" was written, "9/20 old refrigerator was malfunctioned." There was no corrective action documented. 3. The laboratory room humidity was out of range in October 2023 for four out of eight days recorded with no corrective action documented. 4. On 11/14/2023, the "ImmTox Reaction Temp" was documented as "32.19" C. The acceptable range was "36.0 - 38.0 C." There was no corrective action documented. 5. A review of the separate "Corrective Action Log" showed that the lab was not documenting temperature and humidity readings that failed to meet the laboratory's criteria for acceptability and corrective actions taken for all of 2023. 6. During an interview on 09/25/2024 at 3:45 PM, the OM confirmed that the laboratory failed to document corrective actions when laboratory temperatures and humidity were out of the laboratory's acceptable range. |
| **D5787** | TEST RECORDS<br>CFR(s): 493.1283(a)<br><br>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview, the laboratory failed to implement policies to ensure that test records were complete. Findings: 1. During an interview on 9/25/24 at |

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| | 12:30 pm, the testing person (TP) stated that each sample on the "Result Log" must include a "PID" number or a "SID" number for each test. The "PID" number is used to document the lot number of the quality control, standard or blank reagent tested and the "SID" number identifies the patient sample. On 10/25/2023, twelve of forty-one samples tested did not have A "PID" number or a "SID" number, and on 10/24/23 all 84 samples tested did not have a "PID" or "SID" number. Review of the 9/19/2023 "Result Log" showed that there were no "PID" or "SID" numbers for sample positions B1, S1, S5, S2, S4, S3, S8, S7, S6, S12, S11, S10, S9. 2. Review of the 10/25/2023 "Result Log" showed that twelve of forty-one tests performed did not have test results entered into the result column of the "Result Log". 3. Review of the 10/25/2023 "Result Log" showed that forty-one of forty-one tests performed did not have the Lot number and expiration date columns of the "Result Log" filled in. 4. Review of the 9 /19/2024 "Result Log" showed that the sample positions were identified both alpha numerically (e.g. B-1) as well as numerically (e.g. 1-20), and on 10/29/24 an email request was made to the laboratory to clarify the discrepancies described for this finding and findings #2 and #3 above, but the laboratory did not respond. |
| **D5801** | TEST REPORT<br>CFR(s): 493.1291(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of validation studies for the toxicology screen testing and interview with the office manager (OM) on 9/25/24 at 12:30 pm, the laboratory failed to document validation studies to initially check the accuracy and reliability of the laboratory information system (LIS) to transmit patient data to the electronic medical record (EMR). Findings: 1. The laboratory failed to have validation studies or procedures to show the accurate transmission of data across the LIS interface with the EMR upon install. 2. The OM confirmed during interview on 9/25/24 at 12:30 pm that the laboratory failed to have initial verification records showing that toxicology testing data was being transferred through the LIS/EMR interface in an accurate manner. |
| **D6021** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. |

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| | This STANDARD is not met as evidenced by:<br>Based on procedure manual and quality assurance (QA) record review and interview with the office manager (OM), the laboratory director (LD) failed to follow the established QA program to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings: 1. The procedure, "Quality Assurance Plan" includes 11 QA forms for documenting the QA reviews specified in the procedure: "Quality Assurance Time Table"; "Laboratory Compliance Audit"; "Laboratory Quality Assurance Form"; "Quality Assurance/Quality Control Monthly Review Documentation"; "Patient Test Management Monitor"; "Test Tracking Management Audit"; "Quality Assurance Monitor: Specimen Labeling and Requisition review"; "LIS Quality Assessment Review"; "LIS Quality Assurance Assessment"; "Safety"; and "Technical Task Quality Assurance Calendar". 2. During an interview on 09/25/2024 at 12:50 PM, the OM stated that there were no completed QA logs available for review. 3. A review of "ImmTox Maintenance Logs," "Eyewash Inspection Logs," "Corrective Action Logs," "Laboratory Temperature & Humidity Logs," and "Reagent - Calibrator" inventory logs from September 2023 through June 2024 showed that the LD failed to sign and date the bottom of the forms to indicate that they had reviewed the logs and were aware that the logs were incomplete (cross-refer to D3011, D5413, and D5417), missing (cross-refer to D3031), or that corrective actions had not been taken for temperature and humidity readings that failed to meet the laboratory's criteria for acceptability (cross-refer to D5781). 4. The procedure, "Quality Assurance Plan" "9. Communication and Staff meetings" states that "QA assessment, implementation of solutions and follow-up review will be communicated to staff via Lab Director. Staff meetings will be held on a regular basis and documented." QA record review showed that there was no documentation of staff meetings being held. 5. During an interview on 09/25/2024 at 3:45 PM, the OM confirmed that the LD failed to follow the laboratory's QA program. |
| **D6052** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)(vi)<br><br>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review, the technical consultant (TC) failed to ensure that the competency evaluation that was performed for testing person #2 was completed in a manner to ensure any additional training involving trouble shooting or problem solving could be identified and provided, if needed. Findings: 1. The TC had testing person #2 take two quizzes, one for ImmTox error codes and a second for trouble shooting and problem solving, even though the technical consultant checked the box that the employee was competent for both, the TC did not grade either quiz and left the place to record the grade blank. Since the quiz was not scored or marked for correctness of the answers provided by the testing person, it could not be determined if any responses may have been incorrect and required additional training. |