| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 27D2288859 | 04/09/2026 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Indigenuity Clinical Lab, Llc | 502 N 30th, Billings, MT | |

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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| **D0000** | The Montana CLIA Program conducted an announced CLIA recertification survey on April 9, 2026. The laboratory was found out of compliance with the following conditions: 493.1213 Condition: Toxicology. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director. |
| **D5022** | TOXICOLOGY<br>CFR(s): 493.1213<br><br>If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.<br><br>This CONDITION is not met as evidenced by:<br>Based on record review, procedures, and an interview with testing personnel (TP2), the laboratory failed to ensure the requirements for the specialty of Toxicology. Findings: 1. The laboratory failed to perform twice-annual verifications of their confirmatory drug analysis with quantitation. (Refer to D5217) 2. The laboratory did not follow its procedures to verify new lots of control materials for acceptability prior to patient testing on the Agilent 1290 Infinity II LC/MS toxicology analyzer. (Refer to D5401) 3. The laboratory failed to define and perform a function check protocol to verify the accuracy of the centrifuge, microscope, and eight pipettes used in patient testing. (Refer to D5435) 4. The laboratory failed to perform two calibration verifications every six months for 52 analytes tested on the Agilent 1290 Infinity II LC /MS toxicology analyzer. (Refer to D5439) 5. The laboratory failed to run quality control (QC) materials each day of patient testing on the Agilent 1290 Infinity II LC /MS toxicology analyzer for 24 of 47 days of patient testing. (Refer to D5447) 6. The laboratory failed to have the Agilent 1290 Infinity II LC/MS test records for batch preparation and master mix preparation. (Refer to D5789) 7. The laboratory failed to |

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| | include, in their patient results reports for the high-risk panel, the test report date, the units of measurement for quantitative positive results, and the established cutoff value. (Refer to D5805) |
| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of proficiency testing (PT) records from the College of American Pathologists (CAP), patient results report and interview with testing personnel (TP2), the laboratory failed to perform two of two twice annual accuracy verification or proficiency testing for the specialty of toxicology (quantitative) for 52 of 52 analytes performed on the Agilent 1290 Infinity II LC/MS toxicology analyzer for the year 2025. Findings: 1. A review of patient result reports (order dates 07/10/2025, 09/16 /2025, and 10/20/2025) showed quantitative results being reported for positive drug findings. The laboratory failed to perform the required twice annual accuracy verification for confirmatory drug testing with quantitation. 2. A review of the 2025 CAP proficiency testing records showed the enrolled Urine Toxicology program did not include confirmatory drug analysis with quantitation and lacked documentation for the 2025 Urine Toxicology PT events UT-A, UT-B, and the 2025 Ethanol Biomarkers event ETB-A. 3. The laboratory did not have records of twice annual accuracy verification studies performed on the Agilent 1290 Infinity II LC/MS toxicology analyzer, which reported quantitative results for 52 analytes: 4-Anilino-N-Phenethylpiperidine (4-ANPP), 6-acetylmorphine, 7-aminoclonazepam, alpha-hydroxyalprazolam, alprazolam, amphetamine, benzoylecgonine, buprenorphine, bupropion, clonazepam, codeine, desmethyltranadol, diazepam, dihydrocodeine, 2-Ethylidene-1,5-Dimethyl-3,3-Diphenylpyrrolidine (EDDP), fentanyl, fluoxetine, gabapentin, hydrocodone, hydromorphone, hydroxybupropion, ketamine, lorazepam, 3,4-Methylenedioxymethamphetamine (MDMA), methadone, methamphetamine, methylphenidate, mitragynine, morphine, naloxone, naltrexone, norbuprenorphine, nordiazepam, norfentanyl, norhydrocodone, norketamine, noroxycodone, noroxymorphone, oxazepam, oxycodone, oxymorphone, Phencyclidine (PCP), phentermine, pregabalin, ritalinic acid, sertraline, temazepam, 11-Nor-9-Carboxy-9-Tetrahydrocannabinol (THC COOH), tramadol, xylazine, ethyl glucuronide (EtG), and ethyl sulfate (EtS). 4. An interview with TP2 on April 9, 2026, at 9:00 AM confirmed the laboratory did not perform twice annual verifications of their confirmatory drug analysis with quantitation for 52 analytes in 2025. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and an interview with testing personnel (TP2), the laboratory |

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| | did not follow its procedures to verify new lots of control materials for acceptability prior to patient testing on the Agilent LC MS toxicology analyzer during 2025. Findings: 1. A review of the "Agilent Main Panel LC MS/MS Procedure" revealed staff failed to follow its procedure as stated: "Lot-to-Lot testing is performed to ensure the new lot of QC and Calibrators are acceptable to use before putting into production." 2. No verification studies of new lots of QC material or calibrators tested on the Agilent LC MS toxicology analyzer were available for review. 3. An interview with TP2 on April 9, 2026, at 2:40 PM confirmed the lot to lot testing data for new QC material and calibrators used on the Agilent LC MS toxicology analyzer during 2025 could not be found. |
| **D5435** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(b)(2)<br><br>(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, record review and an interview with testing personnel (TP2), the laboratory failed to define and perform a function check protocol to verify the accuracy of one of one centrifuge, one of one microscope, and eight of eight pipettes used in patient testing from January 1, 2025, to December 31, 2025. Findings: 1. Observed in the laboratory on April 9, 2026, at 10:45 AM, was one Eppendorf 5430 centrifuge, one Nikon Eclipse E200 microscope, and eight pipettes (Eppendorf Basic Research Plus 10-100 L, 20-200 L, 100-1000 L; Eppendorf Repeater M4 1 L-10 mL; and MICROMAN E M10E 1-10 L, 10-100 L, 50-250 L, and 100-1000 L). None of the equipment displayed Biomedical stickers indicating completion of a function check for 2025, and no documentation of 2025 function checks was available. 2. A review of laboratory procedures showed the laboratory had not defined the function checks for each piece of equipment used in patient testing. 3. A review of the Test Volume Report revealed one manual blood smear review using the microscope and 2,938 toxicology tests that used the centrifuge and pipettes as part of the testing process from January 1, 2025, to December 31, 2025. 4. An interview with TP2 on April 9, 2026, at 10:00 AM confirmed the function check protocol had not been defined or performed to verify the accuracy of the centrifuge, microscope, and eight pipettes used in patient testing from January 1, 2025, to December 31, 2025. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>(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 |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with testing personnel (TP2), the laboratory failed to perform two of two calibration verifications every six months for 52 of 52 analytes tested on the Agilent 1290 Infinity II LC/MS toxicology analyzer for the year 2025. Findings: 1. A review of 2025 calibration records for the Agilent 1290 Infinity II LC/MS toxicology analyzer for the following analytes: 4-Anilino-N-Phenethylpiperidine (4-ANPP), 6-acetylmorphine, 7-aminoclonazepam, alpha-hydroxyalprazolam, alprazolam, amphetamine, benzoylecgonine, buprenorphine, bupropion, clonazepam, codeine, desmethyltranadol, diazepam, dihydrocodeine, 2-Ethylidene-1,5-Dimethyl-3,3-Diphenylpyrrolidine (EDDP), fentanyl, fluoxetine, gabapentin, hydrocodone, hydromorphone, hydroxybupropion, ketamine, lorazepam, 3,4-Methylenedioxymethamphetamine (MDMA), methadone, methamphetamine, methylphenidate, mitragynine, morphine, naloxone, naltrexone, norbuprenorphine, nordiazepam, norfentanyl, norhydrocodone, norketamine, noroxycodone, noroxymorphone, oxazepam, oxycodone, oxymorphone, Phencyclidine (PCP), phentermine, pregabalin, ritalinic acid, sertraline, temazepam, 11-Nor-9-Carboxy-9-Tetrahydrocannabinol (THC COOH), tramadol, xylazine, ethyl glucuronide (EtG), and ethyl sulfate (EtS), revealed no documentation of a calibration verification, including at least a minimum, midpoint, and maximum value, had been performed every six months for each analyte in 2025. 2. An interview with TP2 on April 9, 2026, at 11:20 AM confirmed the laboratory failed to perform calibration verification every six months for 52 analytes tested on the Agilent 1290 Infinity II LC/MS toxicology analyzer during 2025. |
| **D5447** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(i)(g)<br><br>(d)(3)(i) Each quantitative procedure, include two control materials of different concentrations;<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with testing personnel (TP2), the laboratory failed to run quality control (QC) materials each day of patient testing on the Agilent 1290 Infinity II LC/MS toxicology analyzer for 24 of 47 days of patient testing from July 22, 2025, to December 22, 2025. Findings: 1. A review of the "Agilent Main Panel LC-MS/MS Procedure" revealed the laboratory failed to run quality control as stated, "Every batch of samples will contain at least one calibration curve, at least six total quality control injections and one enzyme control, two blanks, and at least one double blank." 2. A review of the Agilent LC MS quality control records from July 22, 2025, to December 22, 2025, for the Agilent 1290 Infinity II LC/MS analyzer revealed the laboratory lacked one calibration curve, two sets of high, medium, and low QC, one enzyme control, two blanks, and one double blank for the following days |

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| | of patient testing: December 22, 17, 15, 11, 10, 3, and 1, 2025. November 20, 13, 6, and 3, 2025. October 30, 29, 28, and 8, 2025. August 25, 21, 19, 18, 11, 7, and 6, 2025. July 31 and 30, 2025 3. A review of the Test Volume Sheet revealed 2,938 toxicology patient tests resulted during the past 12 months. 4. An interview with TP2 on April 9, 2026, at 2:35 PM confirmed the lack of QC records for the Agilent 1290 Infinity II LC/MS analyzer for 24 of 47 days of patient testing from July 22, 2025, to December 22, 2025. |
| **D5775** | COMPARISON OF TEST RESULTS<br>CFR(s): 493.1281(a)(c)<br><br>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with testing personnel (TP2), the laboratory failed to perform and evaluate four of four comparison studies for 2025 between the two toxicology analyzers and between manual and automated differential blood count methods. Findings: 1. A record review revealed no twice annual comparison studies were performed in 2025 between the Agilent 1290 Infinity II LC/MS and ImmTox 270 toxicology analyzers for analytes: 6 acetylmorphine (6 AM Heroin metabolite), Amphetamine, Barbiturates, Benzodiazepines, Benzoylecgonine (Cocaine metabolite), Buprenorphine, Cannabinoids (THC), EDDP (Methadone metabolite), Fentanyl, Methamphetamine, Opiates, Oxycodone, Phencyclidine, and Tramadol. 2. A record review revealed no twice annual comparison studies were performed in 2025 between manual differential blood counts and automated differential blood counts performed on the Sysmex XN 430. 3. The laboratory's procedures lacked instructions to perform twice annual comparison studies and to provide written criteria for acceptable differences in test values for each instrument comparison. 4. A review of the Test Volume Sheet revealed the laboratory reported one manual blood smear and 84 Complete Blood Counts with automated differentials during the past 12 months. 5. An interview with TP2 on April 9, 2026, at 12:00 PM confirmed the laboratory failed to perform and evaluate any comparison studies for 2025 between the two toxicology analyzers and between manual and automated differential blood count methods. |
| **D5789** | TEST RECORDS<br>CFR(s): 493.1283(b)<br><br>(b) Records of patient testing including, if applicable, instrument printouts, must be retained.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with testing personnel (TP2), the laboratory failed to have two of two test records (batch preparation and master mix preparation) for the Agilent 1290 Infinity II LC/MS toxicology analyzer from August 15, 2024, to April 9, 2026. Findings: 1. A review of the "Agilent Main Panel LC-MS/MS Procedure" revealed the laboratory had failed to document their batch and master mix preparation process as follows: a. "Step #3 Analytical: Top Stock Solutions and Reagents Top Stock Solutions Note: ... The name of each top stock and associate prep |

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| | documents are listed below and their respective preparation sheet for each can be found in Appendix II." Auxiliary Solutions: Master Mix Preparation "Master Mix Prep Sheet_A_V3: The Master Mix is a mixture of the internal standard (IS) solution, enzyme, and buffer. The master mix should be used during main batch preparation using the Main Panel Batch Run Form. All samples, except the Double Blank, will receive the Master Mix." b. "Step #3 Analytical: Sample Preparation The Prep Note: before starting this section, obtain the appropriate version of the batch run form (BRF). This form can be found in Appendix II of this document. This document helps direct the analyst through the steps of batch preparation and must be filled in real-time, with the analyst's initials and dating each step as it is completed. The BRF must be filled out each time batch preparation occurs to keep track of timing, and lots used for auditing and quality control purposes." 2. No Agilent 1290 Infinity II LC/MS test records of the Batch Run Form and the Master Mix Preparation forms were available for review. 3. An interview with TP2 on April 9, 2026, at 2:15 PM confirmed the lack of test records for batch preparation and master mix preparation used to perform patient testing on the Agilent 1290 Infinity II LC/MS toxicology analyzer from August 15, 2024, to April 9, 2026. |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and an interview with testing personnel (TP2), the laboratory failed to include, in their patient results reports for the high-risk panel, the test report date and the units of measurement for quantitative positive results for five of five reports from June 11, 2024, to October 20, 2025. Findings: 1. A review of five high-risk panel reports labeled "Confirmatory Summary Results" (Order dates: 06/11/24, 10 /14/25, 10/20/25, 09/16/25, 07/10/25), failed to list the test report date and the units of measurement for quantitative positive results. 2. A review of the toxicology test volume sheet revealed 2,938 patient tests resulted in the year 2025. 3. An interview with TP2 on April 9, 2026, at 2:45 PM confirmed the patient results report for the high-risk panel did not include the test report date and the units of measurement for quantitative positive results from June 11, 2024, to October 20, 2025. |
| **D6076** | LABORATORY DIRECTOR<br>CFR(s): 493.1441<br><br>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.<br><br>This CONDITION is not met as evidenced by: |

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| | Based on record review, procedures, and an interview with testing personnel (TP2), the laboratory director failed to provide overall management and direction in accordance with 493.1445. Findings: 1. The laboratory director failed to ensure the requirements for the specialty of Toxicology. (Refer to D5022) 2. The laboratory director failed to provide evidence of completing one of two onsite visits for the year 2025 (Refer to D6080) 3. The laboratory director failed to ensure the laboratory was enrolled in a hematology proficiency testing (PT) program from January 1, 2025, to May 16, 2025. (Refer to D6088) 4. The laboratory director (LD1) failed to maintain the quality control and quality assessment programs for toxicology from August 15, 2024, to April 9, 2026. (Refer to D6093) |
| **D6080** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(c)<br><br>(c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with testing personnel (TP2), the laboratory director failed to provide evidence of completing one of two onsite visits for the year 2025. Findings: 1. A review of the "Quality Assessment Plan" records revealed documentation with the laboratory director's wet signature dated August 7, 2025. No additional records were provided as evidence of a second onsite visit by the laboratory director for 2025. 2. An interview with TP2 on April 9, 2026, at 8:20 AM confirmed the laboratory director did not complete one of two onsite visits for the year 2025. |
| **D6088** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(4)<br><br>(e)(4) Ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed and that--<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with testing personnel (TP2), the laboratory director failed to ensure the laboratory was enrolled in a proficiency testing (PT) program from January 1, 2025, to May 16, 2025, for the specialty of hematology. Findings: 1. A review of hematology patient result reports revealed the laboratory reported 78 patient complete blood counts (CBC) with automated differential using the Sysmex XN-430 and reported one patient manual blood smear review from March 5, 2025, to August 26, 2025. 2. A review of 2025 records from the College of American Pathologists (CAP) revealed the laboratory lacked documentation of proficiency testing participation for Blood Cell Identification: Events BCP-A, BCP-B, and Hematology Automated Differential Survey: Events FH9-A, FH9-B. 3. A review of the "Quality Assessment Plan" signed by the laboratory director on August 7, 2025, confirmed PT was not ordered until May 16, 2025. 4. An interview with TP2 on April |

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| | 9, 2026, at 1:00 PM confirmed the laboratory director had not enrolled the laboratory in a PT program from January 1, 2025, to May 16, 2025, for the specialty of hematology. |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;<br><br>This STANDARD is not met as evidenced by:<br>Based on record review of toxicology and interview with testing personnel (TP2), the laboratory director (LD1) failed to maintain the quality control and quality assessment programs for toxicology from August 15, 2024, to April 9, 2026. Findings: 1. A review of Teams meeting notes dated August 25, 2025, with LD1 in attendance, revealed toxicology quality control was not monitored over time.The meeting notes stated, "Orchard (laboratory information system) does not offer Levey-Jennings Charts for toxicology." No documentation of a toxicology quality control monitoring was available for review. 2. A review of "Action Items" meeting notes dated October 8, 2025, revealed toxicology quality control records were not maintained. The notes stated, "LCMS QC documentation currently limited to Daily QC Log." (Refer to D5447) 3. During an interview on April 9, 2026, at 3:00 PM, TP2 confirmed LD1 did not maintain the toxicology quality control and quality assessment programs from August 15, 2024, to April 9, 2026. |
| **D6120** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(7)(8)<br><br>(b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of personnel records, the CMS-209 Laboratory Personnel Report, and an interview with testing personnel (TP2), technical supervisor (TS1) failed to perform one of two annual competency assessments documenting the six required procedures for testing personnel (TP1) for the year 2025. Findings: 1. A review of personnel records for TP1 listed on the CMS 209 form lacked documentation of a hematology competency assessment for the year 2025. 2. An interview with TP2 on April 9, 2026, at 8:30 AM confirmed the lack of a hematology competency assessment documenting the six required procedures for TP1 for the year 2025. |