Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D2032647	03/23/2022
Name of Provider or Supplier	**Street Address, City, State**	
Md Spine Solutions, Llc Dba Md Labs	10715 Double R Blvd, Suite 102, Reno, NV	

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
D0000	This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on March 22-23, 2022. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of laboratory policy, "Proficiency Testing Policy,"review of laboratory records, review of the College of American Pathologists (CAP) proficiency testing (PT) evaluations and interview with the chemistry and microbiology supervisors, the laboratory failed to verify the accuracy of their results with no test scores due to educational challenges and no referee consensus. Findings include: 1. Laboratory policy, "Proficiency Testing Policy," states, "Educational challenges or ungraded challenges must be manually evaluated and graded by the laboratory." 2. Review of the laboratory's PT records revealed that there was no documentation of review for DAI-A 2021, Urine Drug Adulterant, with no test scores due to an educational challenge as noted on the CAP PT evaluation for that event. 3. Review of the laboratory's PT records revealed that there was no documentation of review for D2-C 2020, Urine Culture Antibiotic Susceptibility Testing, with no test scores due to a lack of referee consensus as noted on the CAP PT evaluation for that event. 4.

	Review of the laboratory's PT records revealed that there was no documentation of review for MVP-B 2020 and MVP-C 2020, Molecular Vaginal Panel, with no test scores due to an educational challenge as noted on the CAP PT evaluation for those events. 5. Review of the laboratory's PT records revealed that there was no documentation of review for IDPN-A 2020 and IDPN-B 2020, ID Pneumonia Panel, with no test scores due to an educational challenge as noted on the CAP PT evaluation for those events. 6. The chemistry and microbiology supervisors confirmed the findings during the on-site survey on 3/22/2022 at approximately 2:00 PM. The laboratory performs approximately 271,885 chemistry and 35,624 microbiology tests annually.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on review of laboratory test records and interview with the chemistry supervisor, the laboratory failed to verify the accuracy of the oral fluid and urine drugs not on the list of analytes tested with the proficiency testing programs enrolled by the laboratory, at least twice annually in 2021. Findings include: 1. Review of laboratory records for twice a year accuracy checks for oral fluid drugs revealed that samples were tested on 7/21/2021 and no other dates in 2021. 2. Review of laboratory records for twice a year accuracy checks for urine drugs revealed that the comparison testing with a reference laboratory was conducted on 6/15/2021 and no other dates in 2021. 3. The chemistry supervisor interviewed on 3/22/2022 at approximately 1:00 PM confirmed the findings. The laboratory performs approximately 271,885 chemistry tests annually.
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 review of laboratory procedures, review of quality control records, review of laboratory instrument maintenance records, review of laboratory temperature records, and interview with the chemistry and microbiology supervisors, the laboratory failed to meet the analytic systems requirements in CFR 493.1251 through 493.1283. The laboratory did not require the testing personnel to read and follow the director approved procedures (refer to D5401); the laboratory failed to define storage conditions for laboratory reagents and store them appropriately (refer to D5413); the laboratory failed to ensure expired standards were not used (refer to D5417); the laboratory failed to ensure that instrument maintenance and function checks were conducted according to manufacturer's requirements (refer to D5429); the laboratory

	failed to ensure that twice annual comparison of test results were conducted (refer to D5775); and the laboratory failed to ensure that corrective actions were taken and documented for refrigerator and freezer temperatures outside of the acceptable ranges. (refer to D5785).
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: Based on review of the laboratory procedure manual and interview with the chemistry and microbiology supervisors, the laboratory failed to ensure that the laboratory personnel read and followed the written procedures in the manual. Findings include: 1. Review of the laboratory procedure manual revealed that the laboratory did not have a system in place for the laboratory personnel to indicate that the procedures were read and followed. 2. The chemistry and microbiology supervisors confirmed the finding during the on-site survey on 3/23/2022 at approximately 9:30 AM. 3. Director approved laboratory procedure, "LCMS Calibration Curves," states, "7.1.9. Verify the accuracy of the concentration for each calibrator. The acceptable range is +/-30% from the target value. If a calibrator falls outside of this range it fails and must be removed from the calibration curve." "7.1.11. Note that at least 5 points must be present and included in the curve calculations for each analyte." There were no guidelines in the procedure to manually integrate the calibrator/standard peaks to adjust the calibration curve for acceptable quality control results or whether this practice was allowed. 4. In a follow up telephone interview with the chemistry supervisor on 3/31/2022 at approximately 3:15 PM, the supervisor stated that the certifying scientists confirmed that the calibrator/standard peaks were manually integrated to adjust the calibration curve so that quality control results were within the acceptable range and patient results were reported. The laboratory performs approximately 271,885 chemistry and 35,624 microbiology tests annually.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on observation, review of laboratory temperature logs, and interview with the chemistry supervisor, the laboratory failed to define criteria for the proper storage of laboratory reagents consistent with the manufacturer's instructions. Findings include: 1. Waters analytical standards and calibrators for various analytes were found stored

	in refrigerator #1 with an acceptable range of 0 to 8 degrees Celsius (C). The box containing the Waters standards and calibrators indicated the acceptable storage temperatures as 4 plus or minus 2 degrees C which is narrower than the established acceptable range. 2. Review of the laboratory temperature logs for the year 2020 revealed that the acceptable temperature ranges for refrigerator #1 and #2 as 0 to 8 degrees C and refrigerator #3 as 2 to 8 degrees C. 3. Review of the laboratory temperature logs for the year 2021 revealed that two different acceptable ranges were noted on the log sheets used. On the form with 31 days, the allowable temperature range for all the refrigerators is noted as 2 to 8 degrees C. On the form with 30 days, the allowable temperature range for refrigerator #1 and #2 is noted as 0 to 8 degrees C and refrigerator #3 as 2 to 8 degrees C. The chemistry supervisor was unable to explain the different temperature requirements for refrigerators #1, #2, and #3. 4. A box containing various calibrators for analytes with storage requirements for freezer temperatures were found in refrigerator #1. 5. An open bottle of sodium hydroxide and laboratory reagents indicating storage at ambient temperatures were found in refrigerator #1. 6. There were no temperature records for the incubators and heating blocks between March 2020 and January 2022. 7. The chemistry supervisor confirmed the findings during the on-site survey on 3/23/22 at approximately 11:30 AM. The laboratory performs approximately 271,885 chemistry tests annually.
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 observation and interview with the microbiology supervisor, the laboratory continued using the MacFarland turbidity standards which expired on 10/02/2021 for the daily calibration of the nephlometer on the Phoenix automated microbiology system. Findings include: 1. During the tour of the microbiology laboratory, a loading tray containing MacFarland turbidity standards which expired on 10/02/2021 was observed. Another set of unexpired MacFarland standards were found on top of the instrumentation. 2. The microbiology supervisor confirmed the finding on 3/22/2022 at approximately 9:30 AM. The laboratory performs approximately 35,624 microbiology tests annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) 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. This STANDARD is not met as evidenced by: Based on review of the Preventative Maintenance Log for five LC/MS instrumentation and interview with the chemistry supervisor, the laboratory failed to perform routine maintenance on its LC/MS instrumentation as required by the manufacturer. Findings include: 1. Review of the Preventative Maintenance Log for QCA 357 for 12/2020 revealed daily maintenance not completed on 12/14/2020 and

	12/29/2020 and weekly maintenance not completed for weeks one and five. The log for 12/2021 revealed daily maintenance not completed on 12/4-5, 11-12, 15, 18/19, 24-25/2021 and weekly maintenance not completed for weeks one and two. Daily Check Cal 1 was not completed on 28 out of 30 days and daily QA check was not completed on 23 out of 30 days in 12/2021. 2. Review of the Preventative Maintenance Log for QCA 827 for 8/2020 revealed weekly maintenance not completed for week one. The log for 12/2021 revealed daily maintenance not completed on 12/4-5, 11-12, 18/19, 23-26/2021 and weekly maintenance not completed for weeks one and two. Daily Check Cal 1 and daily QA check were not completed on 26 out of 30 days in 12/2021. 3. Review of the Preventative Maintenance Log for QCA 924 for 10/2020 revealed daily maintenance not completed on 10/12, 19, 22-23/2020 and weekly maintenance not completed for week three. The log for 12/2021 revealed daily maintenance not completed on 12/4-5, 11-12, 18/19, 24-25, 29/2021 and weekly maintenance not completed for week one. Daily Check Cal 1 was not completed on 23 out of 30 days and daily QA check was not completed on 22 out of 30 days in 12/2021. 4. Review of the Preventative Maintenance Log for QCA 1693 for 3/2020 revealed weekly maintenance not completed for week four. The log for 12/2021 revealed daily maintenance not completed on 12/4-5, 11-12, 15, 18-19, 24-26, 29/2021 and weekly maintenance not completed for weeks one and two. Daily Check Cal 1 was not completed on 27 out of 30 days and daily QA check was not completed on 20 out of 30 days in 12/2021. 5. Review of the Preventative Maintenance Log for QCA 1886 for 8/2021 revealed daily maintenance not completed for 8/13/21 and 8/27/2021 and weekly maintenance not completed for week one. Daily Check Cal 1 was not completed on 22 out of 22 days and daily QA check was not completed on 15 out of 22 days in 8/2021. The log for 12/2021 revealed daily maintenance not completed on 12/4-5, 11-12, 15, 18-19, 24-26/2021 and weekly maintenance not completed for weeks one and two. Daily Check Cal 1 was not completed on 28 out of 30 days and daily QA check was not completed on 23 out of 30 days in 12/2021. The laboratory performs approximately 271,885 chemistry tests annually.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (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. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the chemistry supervisor, the laboratory failed to perform the twice a year comparison of test results generated from the seven LC/MS instruments for drug analysis. Findings include: 1. Review of the laboratory's instrumentation comparison records revealed that the comparison testing of the six Xevo and one Acquity was conducted in December 2021. No other documentation of comparison testing were found for 2021. 2. The chemistry supervisor interviewed during the on-site survey on 3/22/2022 at approximately 2:00 PM confirmed the finding. The laboratory performs approximately 271,885 chemistry tests annually.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)

	(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of laboratory temperature logs and interview with the chemistry supervisor, no corrective actions were taken and documented for temperatures outside of the acceptable range. Findings include: 1. Review of refrigerator temperature records for January through March 2020 revealed 10 out of 64 records were below the acceptable range of 0 to 8 degrees C for refrigerator #2 and no corrective actions were taken and documented. 2. Review of freezer temperature records for freezers # 3 and #4 for January through March 2020 revealed 64 out of 64 records were above the acceptable range of -10 to -30 degrees C and no corrective actions were taken and documented. 3. The chemistry supervisor confirmed the findings during the on-site survey on 3/23/2022 at approximately 11:30 AM. The laboratory performs approximately 271,885 chemistry tests annually.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on review of laboratory quality control records and interview with the chemistry supervisor, the laboratory failed to issue corrected reports for reprocessed mitragynine test results from July through November 2021. Findings include: 1. During the on-site survey on 3/22/2022, review of the Levy-Jennings graph of QC records for mitragynine and interview with the supervisors, laboratory director and laboratory owner at approximately 2:00 PM , issues with mitragynine testing were revealed. Additional documents were requested and reviewed. 2. In a follow up telephone interview with the chemistry supervisor on 3/31/2022 at approximately 3:15 PM, the supervisor stated that the certifying scientists confirmed that the calibrator /standard peaks were manually integrated to adjust the calibration curve so that quality control results were within the acceptable range and patient results were reported. The supervisor indicated that investigations and studies were conducted in December 2021 for mitragynine and data from previously tested samples were reprocessed using the revised calibration curves and new targets were established for the LOW and HIGH QC, 10 and 100 ng/mL, respectively . The supervisor stated that from July to November 2021, approximately 5400 urine samples were processed for mitragynine of which 110 samples were reported as positive. 25 of the positive results should have been reported as negative and 40 reports showed greater than 30% discrepancy in the quantitative results. The supervisor indicated that corrected patient reports have not been issued for the reprocessed test results. The laboratory performs approximately 271,885 chemistry tests annually.

D6076	LABORATORY DIRECTOR CFR(s): 493.1441 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. This CONDITION is not met as evidenced by: Based on review of laboratory procedures and interview with laboratory supervisors, the laboratory director failed to provide overall management and direction in accordance with CFR 493.1445 of this subpart. The laboratory director failed to ensure that corrective action for proficiency testing was implemented as documented in the laboratory's Report of Corrective Action Form (refer to D6092); failed to ensure quality control programs are established and maintained (refer to D6093);and failed to ensure that the quality assessment programs identified failures in quality as they occur (refer to D6094).
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the laboratory's Report of Corrective Action (RCA) Drugs of Abuse in Blood, Serum, or Urine for the proficiency testing program enrolled with the Pennsylvania Department of Health, review of the laboratory's procedure, "Daily QC Program," and interview with the chemistry supervisor, the laboratory failed to implement the corrective action documented on the RCA form on 5/03/2021 for the unacceptable result for ethylglucoronide. Findings include: 1. The corrective action on the RCA form completed on 5/03/2021 for the unacceptable result for ethyglucoronide stated, "To prevent similar problems in the future, all levels of QC must meet acceptance criteria for EtG." 2. Review of the laboratory's procedure, "Daily QC Program," updated on 6/04/2021, did not show that the procedure had been revised to clearly state that all three levels of quality control performed for ethylglucoronide must be acceptable before patient test results are reported. 3. The chemistry supervisor confirmed the finding on 3/22/2022 at approximately 3:00 PM, after consulting with testing personnel #1 on CMS Form 209, that patient results are reported when two out of three levels of quality control are acceptable for ethylglucoronide. The laboratory performs approximately 271,885 chemistry tests annually.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by:

Based on review of laboratory procedures, quality control (QC) records, and interview with the chemistry and microbiology supervisors, the laboratory director and the laboratory owner, the laboratory director failed to ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings include: 1. During the on-site survey on 3/22/2022, review of the Levy-Jennings graph of QC records for mitragynine and interview with the supervisors, laboratory director and laboratory owner at approximately 2:00 PM , issues with mitragynine testing were revealed. Additional documents were requested and reviewed. 2. Director approved laboratory procedure, "Daily QC Program," states, "2.1 Both LOW and HIGH quality controls are to be run daily before specimen analysis. Results must fall within +/- 30% (or otherwise noted %) of target concentration to be acceptable." "7.3 The acceptable ranges for these drugs (mitragynine) are 14-26 ng/mL and 140-260 ng/mL for QCL and QCH, respectively." "7.4 In the event an analyte falls out of the target QC range (+/-30% of the target value) on any given day, corrective action must be taken." 3. Director approved laboratory procedure, "LCMS Calibration Curves," states, "7.1.9. Verify the accuracy of the concentration for each calibrator. The acceptable range is +/-30% from the target value. If a calibrator falls outside of this range it fails and must be removed from the calibration curve." "7.1.11. Note that at least 5 points must be present and included in the curve calculations for each analyte." There were no guidelines in the procedure to manually integrate the calibrator/standard peaks to adjust the calibration curve for acceptable quality control results or whether this practice was allowed. 4. Review of the mitragynine standard/calibrator chromatograms for XV2 from 10_01_21_53D_Cal Curve_MG_Run1.qld last altered on 10/04/2021 11:15 revealed that the peaks Cal 3, Cal 4, Cal 5, Cal 6, and Cal 7 had been manually integrated and no documentation was provided for the corrections made. 5. Review of the % deviation table for the mitragynine standard/calibrator of 10_01_21_53D_Cal Curve_MG_Run1.qld last altered on 10/04/2021 11:15 revealed that the 5.0 ng/mL standard had a 63.4% and the 10.0 ng/mL standard had a -34.0% deviation which is greater than the acceptable +/- 30% target value deviation. There was no documentation whether the two points were excluded from the calibration curve following the LCMS Calibration Curve procedure. 6. Review of the % deviation table of the 400 mitragynine internal standard of 10_01_21_53D_Cal Curve_MG_Run1.qld last altered on 10/04/2021 11:15 revealed one of eight % deviation greater than +/-30% deviation at 40.8%. 7. Review of the LOW and HIGH quality control results from the 10_01_21_XV2_MG_Run 1_B1.qld last altered on 10 /04/2021 at 15:58 revealed the results to be acceptable. Review of the % deviation table of the 400 mitragynine internal standard from the 10_01_21_XV2_MG_Run 1_B1.qld last altered on 10/04/2021 at 15:58 revealed four of five % deviation greater than +/- 30% (44.7%, 86.6%, 53.1% and 47.8%) with no corrective actions documented. QC results were acceptable but four out of five internal standards failed with the adjusted calibration curve. 8. In a follow up telephone interview with the chemistry supervisor on 3/31/2022 at approximately 3:15 PM, the supervisor stated that the certifying scientists confirmed that the calibrator/standard peaks were manually integrated to adjust the calibration curve so that quality control results were within the acceptable range and patient results were reported. The supervisor indicated that investigations and studies were conducted in December 2021 for mitragynine and data from previously tested samples were reprocessed using the revised calibration curves and new targets were established for the LOW and HIGH QC, 10 and 100 ng /mL, respectively . The supervisor stated that from July to November 2021, approximately 5400 urine samples were processed for mitragynine of which 110 samples were reported as positive. 25 of the positive results should have been reported as negative and 40 reports showed greater than 30% discrepancy in the quantitative

	results. The supervisor indicated that corrected patient reports have not been issued for the reprocessed test results. The laboratory performs approximately 271,885 chemistry tests annually.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the Quality Assessment Monthly Review Forms, review of the laboratory procedures, review of the temperature logs, review of the LC/MS maintenance forms, review of the laboratory proficiency testing evaluations, review of the laboratory procedure, "Proficiency Testing Policy," review of the laboratory's QC records, and interview with the chemistry and microbiology supervisors, the laboratory director failed to ensure that the QA programs were maintained to assure the quality of laboratory services and to identify failures in quality as they occur. Findings include: 1. Laboratory procedure, "Quality Assurance (QA) Program," states,"Participation in proficiency testing surveys (CAP, RTI, PGx surveys), with passing score (>80%) several times per year and/or split-lab data comparison for any analytes/tests not included in PT surveys twice per calendar year." The laboratory director failed to ensure that the twice per calendar year split-lab data comparison for analytes/tests not include in PT surveys was performed in 2021. Refer to D5217. 2. Laboratory procedure, "Quality Assurance (QA) Program," states, "Quality assessment monthly review form, checked and signed during the monthly visits from the lab director, indicating all staff competencies, preventative maintenance, QC logs, proficiency testing surveys/records were reviewed and up-to-date." The Quality Assessment Monthly Review Forms from May through December 2019 were signed by the laboratory director on 2/06/2020. January through February 2020 forms were signed on 11/18/2021. The completed forms from 2019 and 2020 were not reviewed in a timely manner. There were no forms completed since February 2020. 3. Laboratory procedure, "Proficiency Testing Policy," states, "Educational challenges or ungraded challenges must be manually evaluated and graded by the laboratory." The laboratory director failed to ensure that ungraded PT results were evaluated by the laboratory in 2020 and 2021. Refer to D5215. 4. Review of the temperature logs for 2020 to present revealed out-of-range temperature records, These out-of-range temperatures were not identified and no corrective actions were documented. Refer to D5785. 5. Review of the maintenance forms for 2020 to present revealed daily and weekly routine maintenance were not performed as required by the manufacturer. Refer to D5429. 6. Review of the director approved procedure, "LCMS Calibration Curves," and QC records for mitragynine revealed that the laboratory director failed to ensure that the procedure provided guidelines when calibrator/standard peaks are manually integrated to adjust the calibration curves for acceptable QC results. Refer to D5401. 7. Review of the QC records for mitragynine from October to November 2021 revealed that the calibrator/standard peaks were manually integrated to adjust the calibration curves for acceptable QC results and no documentation was provided for the corrections made. Refer to D6093. The chemistry and microbiology supervisors confirmed the findings on 3/23/2022 at approximately 2:00 PM.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES

	CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory personnel records and interview with the microbiology supervisor, the technical supervisor failed to ensure that testing personnel are evaluated at least semiannually during the first year the individual tests patient specimens. Findings include: 1. Review of laboratory personnel records revealed that one of seven testing personnel in microbiology did not have semiannual evaluations during the first year the individual tests patient specimens in 2021. 2. The microbiology supervisor interviewed during the on-site survey on 3/22/2022 at approximately 11:00 AM confirmed the finding. The laboratory performs approximately 35,624 microbiology tests annually.