Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2164327	01/04/2023
Name of Provider or Supplier	**Street Address, City, State**	
Ritu Bhambhani Llc (Dba Complete Pain Care)	5430 Campbell Blvd #112, White Marsh, 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
D3029	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(2) Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance. This STANDARD is not met as evidenced by: Based on review of documentation submitted from the initial survey completed on 02/16/2021, review of the standard operating procedure manual (SOPM), and interview and email communication with the technical supervisor (TS), the laboratory failed to retain a copy of the SOPM for toxicology testing using liquid chromatography tandem mass spectrometry (LC/MS/MS) for at least two years after discontinuation. Findings: 1. The laboratory employed all new permanent staff beginning 10/01/2021. During the onsite survey on 12/07/2022, the TS stated that the previous SOPM was not available to the new staff and, therefore, a new SOPM was drafted and approved by the laboratory director. 2. The surveyor had a copy of the testing SOP titled "Complete Pain Care Standard Operating Procedure: Quantitative Determination of Drugs and Metabolites in Urine via LCMS/MS" that was approved by the laboratory director on 05/25/2021. In an email response received on 12/28/2022, the TS confirmed that this original SOP was not available to the laboratory. 3. In the email response received on 12/28/2022, the TS also confirmed that the original SOP detailing the laboratory's previous quality assessment policies and procedures was not available to the laboratory.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) 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. This STANDARD is not met as evidenced by: Based on review of documentation submitted from the initial survey completed on 02/16/2021, review of laboratory records, and interview and email communication with the technical supervisor (TS), the laboratory failed to retain all records documenting analytic systems activities for at least two years for toxicology testing performed using liquid chromatography tandem mass spectrometry (LC/MS/MS). Findings: 1. The laboratory employed all new permanent staff beginning 10/01/2021. During the onsite survey on 12/07/2022, the TS stated that not all documentation of testing activities was available to the new staff. 2. On 12/26/2022 the current TS emailed documents that were located on the previous TS's laptop. 3. The email received on 12/26/2022 included a document titled "QC PREP 04172021" which showed that the quality control (QC) reagents were prepared on 04/17/2021 and also expired on 04/17/2021. A revised version of this document was received from the previous TS on 05/24/2021 as part of the follow up to the initial survey and showed that the expiration date had been updated to 04/17/2022. The current TS stated in an email received on 12/28/2022 that the updated version of "QC PREP 04172021" with the corrected expiration date was not available to the laboratory. 4. The email received on 12/26/2022 included documentation of laboratory director review of QC results from the LC/MS/MS screening and confirmation assays for 01/01/2021-02/02/2021 and 05/12/2021-08/10/2021. There was no documentation of QC results review for 02/03/2021-05/11/2021 and 08/10/2021-10/01/2021. 5. The surveyor had a copy of the worksheet labeled "Maintenance Log WHITE MARSH APRIL 2021" (Log) that was received via email from the previous TS on 05/20/2021. The Log recorded the daily temperatures; the LC/MS/MS maintenance; lot numbers and expiration dates for the mobile phases, needle wash, hydrolysis buffer, and hydrolysis enzyme; column guard changes; and corrective actions. The records ended on 05/20/2021. 6. The surveyor asked the TS in an email sent on 12/28/2022 for the most recent copy of the Log showing maintenance activities performed after 05/20/2021. The TS confirmed in the response email received on 12/28/2022 that the requested Log was not available to the laboratory.
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on review of documentation submitted from the initial survey completed on 02/16/2021 and interview and email communication with the technical supervisor (TS), the laboratory failed to retain the summary of the original validation results for toxicology testing performed using liquid chromatography tandem mass spectrometry (LC/MS/MS). Findings: 1. The laboratory employed all new permanent staff beginning 10/01/2021. During the onsite survey on 12/07/2022, the TS stated that though the original raw data from the validation of the LC/MS/MS toxicology testing was available, the summary of the results and assay approval was not available. 2. The surveyor had a copy of the "Analytical Method Validation Report" that was received via email from the previous TS on 12/21/2020 which stated "This validation study has

	been reviewed, and the performance of the method is considered acceptable for patient testing. 11.20.20." 3. The surveyor asked the TS in an email sent on 12/28 /2022 if the referenced validation summary was available to the laboratory. The TS confirmed in the response email received on 12/28/2022 that the referenced validation summary was not available to the laboratory.
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of documentation submitted from the initial survey completed on 02 /16/2021, review of the quality assessment (QA) records, and interview and email communication with the technical supervisor (TS), the laboratory failed to retain QA records for at least two years. Findings: 1. The laboratory employed all new permanent staff beginning 10/01/2021. During the onsite survey on 12/07/2022, the TS stated that previous QA documentation was not available in the laboratory. 2. The surveyor had a copy of the "Quality Assurance Report" (QA report) dated 03/05/2021 that was received via email on 03/24/2021 as part of the plan of correction for the initial survey. 3. The surveyor asked the TS in an email sent on 12/28/2022 if the referenced QA report was available to the laboratory. The TS confirmed in the response email received on 12/28/2022 that the referenced QA report was not available to the laboratory.
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 review of personnel records and email communication with the technical supervisor (TS), the laboratory failed to ensure that an assessment of competency of the TS was performed and documented. Findings: 1. The laboratory employed all new permanent staff beginning 10/01/2021. 2. The original procedure for performing laboratory staff competency was not available for review (cross-refer to D3029). 3. There were no records for the assessment of the previous TS's competency for fulfilling the duties of the TS. 4. In an email received on 12/28/2022, the current TS confirmed that an assessment of the previous TS's competency for fulfilling the duties of the TS was not available.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions

	for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of documentation submitted from the initial survey completed on 02 /16/2021, review of patient testing records, and interview with the technical supervisor (TS), the laboratory failed to ensure that specimens beyond the laboratory's acceptable stability criteria were rejected for testing for toxicology analytes using liquid chromatography tandem mass spectrometry (LC/MS/MS). Findings: 1. The SOP titled "Complete Pain Care Standard Operating Procedure: Quantitative Determination of Drugs and Metabolites in Urine via LCMS/MS" that was approved by the laboratory director on 05/25/2021 and received as part of the follow up to the initial survey completed on 02/16/2021 stated that urine specimens received for toxicology testing were stable for 14 days when refrigerated. 2. During the survey on 12/07/2022, the TS stated that urine specimens received for toxicology testing were shipped and stored at refrigerated temperatures and confirmed that urine specimen stability was 14 days when refrigerated. 3. Review of patient testing records showed that 57 patient samples were collected between 08/24/2021-08/27/2021 and tested on 09/12/2021, longer than 14 days after collection. 4. During the survey on 12/07/2022 at 2:00 PM, the TS confirmed that patient specimens that were refrigerated longer than 14 days after collection were tested and reported.
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 record review and interview with the technical supervisor (TS), the laboratory failed to ensure that reagents were stored according to manufacturer's instructions for toxicology testing performed using liquid chromatography tandem mass spectrometry (LC/MS/MS). Findings: 1. The laboratory used toxicology reference standards from Cerilliant to prepare LC/MS/MS assay calibrators and quality control reagents. 2. Cerilliant certificates of analysis stated to store reference standards at -25 C to -10 C. 3. Temperature records for the freezer were missing from 05/20/2021-10/08/2021 (refer to D3031 numbers 5-6). 4. Temperature logs were reviewed from 10/2021-11/2022 for a total of 14 months. 5. Beginning on 10/08/2021 the temperature charts listed the acceptable freezer temperature as less than or equal to -15 C. 6. Temperature logs showed that daily freezer temperatures were out of Cerilliant's acceptable range for the reference standard storage and out of the laboratory's defined acceptable range for one or more days in 14 of 14 months reviewed. 7. There was no documentation of corrective actions taken when the freezer temperatures were out of acceptable range. 8. During the survey on 12/07/2022 at 2:

	00 PM, the TS confirmed that no corrective actions were performed when the laboratory's freezer temperature was out of acceptable range for reference standard storage.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the quality control (QC) records and the list of the validated screening analytes, the laboratory failed to ensure that analytes tested for toxicology screening using liquid chromatography tandem mass spectrometry (LC/MS/MS) had performance characteristics established and verified. Findings: 1. Records for the screening assay QC results from 01/06/2021-02/02/2021 and 05/12/2021-08/10/2021 were reviewed. 2. A list of analytes that were originally validated and tested using the LC/MS/MS screening assay was received via email on 01/04/2023. 3. The QC results from 01/06/2021-02/02/2021 included the analyte MDMA (methylenedioxymethamphetamine) which was not included on the list of validated screening analytes. 4. The QC results from 05/12/2021-08/10/2021 included the analytes hydrocodone and cocaine which were not included on the list of validated screening analytes.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, review of the validation summary from the initial survey completed on 02/16/2021, and interview with the technical supervisor (TS), the laboratory failed to ensure that QC was performed for all reportable analytes for toxicology confirmation testing using liquid chromatography tandem mass spectrometry (LC/MS/MS). Findings: 1. The laboratory employed all new permanent staff beginning 10/01/2021. During the onsite survey on 12/07/2022, the TS stated that not all QC documentation was available to the new staff (cross-refer to D3031 number 4). 2. On 12/26/2022, the current TS emailed documents that were located on the previous TS's laptop including laboratory director review of QC results

	from the LC/MS/MS confirmation assays for 01/06/2021-02/02/2021. 3. Records for the preparation of the QC reagents used for patient testing from 01/06/2021-02/02 /2021 were missing. 4. The surveyor had a list of analytes from the validation summary that was received via email from the previous TS on 12/21/2020 as part of the initial survey. 5. When compared to the analytes listed in the validation summary and the QC preparation records from 04/17/2021, the QC results review from 01/06 /2021-02/02/2021 was missing 19 analytes: 1) buproprion, 2) cyclobenzaprine, 3) desmethylvenlafaxine, 4) dextromethorphan, 5) dextrorphan, 6) dihydrocodeine, 7) doxepin, 8) fluoxetine, 9) ketamine, 10) MDA (methylenedioxyamphetamine), 11) MDEA (N-methyl diethanolamine), 12) naltrexone, 13) N-desmethyl-tapentadol, 14) norcodeine, 15) normeperidine, 16) O-desmethyltramadol, 17) sertraline, 18) trazadone, and 19) venlafaxine. 6. In an email received on 12/28/2022, the current TS could not confirm if results for the 19 analytes with missing QC records were being reported for patient specimens during 01/06/2021-02/02/2021.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, review of the list of originally validated screening analytes, and email communication with the technical supervisor (TS), the laboratory failed to ensure that QC was performed for all reportable analytes for toxicology screening testing using liquid chromatography tandem mass spectrometry (LC/MS/MS). Findings: 1. The laboratory employed all new permanent staff beginning 10/01/2021. During the onsite survey on 12/07/2022, the TS stated that not all QC documentation was available to the new staff (refer to D3031 number 4). 2. On 12/26/2022, the current TS emailed documents that were located on the previous TS's laptop including laboratory director review of QC results from the LC /MS/MS screening assays for 01/01/2021-01/31/2021 and 05/12/2021-08/10/2021. 3. A list of analytes that were originally validated and tested using the LC/MS/MS screening assay was received via email on 01/04/2023. 4. When compared to the list of validated analytes, the screening QC results review from 01/01/2021-01/31/2021 was missing five analytes: 1) alprazolam, 2) codeine, 3) fentanyl, 4) secobarbital, and 5) THC-COOH (carboxy-tetrahydrocannabinol). 5. When compared to the list of validated analytes, the screening QC results review from 05/12/2021-08/10/2021 was missing benzoylecgonine. 6. In an email received on 12/28/2022, the current TS could not confirm if results for the analytes with missing QC records were being reported for patient specimens between 01/01/2021-01/31/2021 and 05/12/2021-08/10/2021.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must

	be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of quality control (QC) reports and interview and email communication with the technical supervisor (TS), the laboratory failed to ensure that corrective actions were taken and documented when QC results failed to meet the laboratory's criteria for acceptability. Findings: 1. The laboratory employed all new permanent staff beginning 10/01/2021. During the onsite survey on 12/07/2022, the TS stated that not all QC documentation was available to the new staff (refer to D3031 number 4). 2. On 12/26/2022, the current TS emailed documents that were located on the previous TS's laptop including laboratory director review of QC results from the LC/MS/MS screening and confirmation assays for 05/12/2021-08/10/2021. 3. Review of the screening assay QC results showed that the analyte barbiturates was out of acceptable range on July 8, 19, and 23 in 2021. 4. Review of the confirmation assay QC results showed that the following analytes were out of acceptable range in 2021: a. Clonazepam on May 26, July 8, and August 8 b. Ketamine on July 19 c. Butalbital on May 24; June 10, 14, 23, and 28; and July 5, 8, 12, 14, 19, 24, 27 and 30 d. Phenobarbital on June 10, 14, 23, 28; July 8, 12, 14, 19, 27, and 30; and August 8 e. Secobarbital on June 10 and 23 and July 14, 19, 24, 27, and 30 5. There was no documentation of corrective actions that were taken and whether patient results were reported. 6. In an email received on 12/28/2022, the TS could not confirm if corrective actions were documented for failed QC as the previous testing person reviewed the QC data remotely and recorded all QC notes and corrective actions in a personal notebook instead of the QC software application that was shared with all laboratory members and the TS did not currently have access to the notebook.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the technical supervisor (TS), the laboratory director (LD) failed to document the review of the PT results evaluation forms to ensure that any problems requiring corrective action were identified in a timely manner. Findings: 1. The laboratory was enrolled with College of American Pathologists (CAP) in the Urine Toxicology (UT) PT program which included three annual testing events (A, B, and C). 2. Results evaluation forms were reviewed for four PT events from 2021-2022. 3. The laboratory was missing the results evaluation form for the 2021 UT-A event. 4. The evaluation forms for the 2021 UT-B and UT-C events were missing the LD's signature and date of review. 5. The evaluation form from the 2022 UT-A event was signed as reviewed by the LD but not dated. 6. During the survey on 12/07/2022 at 2:00 PM, the TS confirmed that documentation of the LD's review of PT results evaluations were either missing or incomplete in four PT events.
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 documentation submitted from the initial survey completed on 02/16/2021, review of quality control (QC) records, and interview and email communication with the technical supervisor (TS), the laboratory director (LD) failed to ensure that the QC program was maintained to identify failures in quality as they occur. Findings: 1. The testing procedure titled "Complete Pain Care Standard Operating Procedure: Quantitative Determination of Drugs and Metabolites in Urine via LCMS/MS," approved by the laboratory director on 05/25/2021, and received as part of the initial survey, stated that "the QC samples are analyzed using the instrument software MultiQuant ...This file is reviewed on a monthly basis by the lab director or technical supervisor." 2. There was no documentation of QC results review for 02/03/2021-05/11/2021 and 08/10/2021-10/01/2021 (cross-refer to D3031 number 4 for findings). 3. Records for QC review of the confirmation and screening assays from 05/12/2021-08/10/2021 were signed as reviewed by the LD but not dated to ensure corrective actions could be implemented in a timely manner. 4. Available records showed that the laboratory was not performing QC results review on a monthly basis from 02/2021-10/2021 as stated in the testing procedure. 5. The confirmation assay QC results for 01/06/2021-02/02/2021 were signed as reviewed by the LD on 02/02/2021 and were missing 19 analytes (cross-refer to D5447 for findings). 6. The screening assay QC results for 01/01/2021-01/31/2021 and 05/12/2021-08/10/2021 were signed as reviewed by the LD, included analytes that were not listed as validated, and were missing analytes that were validated as part of the test menu (cross-refer to D5423 and D5449 for findings). 7. The screening and confirmation QC results for 05/12/2021-08/10/2021 showed no documentation of corrective actions taken for analytes that failed to meet the laboratory's acceptance criteria (cross-refer to D5783 for findings).
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 documentation submitted from the initial survey completed on 02/16/2021 and email communication with the technical supervisor (TS), the laboratory director (LD) failed to ensure that the quality assessment (QA) program was maintained to identify failures in quality as they occur. Findings: 1. The document titled "Personnel Requirements" that was received via email on 05/20/2021 as part of the initial survey stated that the TS was responsible for "Assuring QC [quality control] and QA programs are conducted in timely manner by reviewing QC/QA parameters via email/Zoom/ or in person on a biweekly basis." 2. The laboratory employed all new permanent staff beginning 10/01/2021. 3. There was no documentation from 02/02/2021-10/01/2021 of TS review of QC/QA parameters on a biweekly basis. 4. The

	surveyor had a copy of the "Quality Assurance Report" (QA report) dated 03/05/2021 that was received via email on 03/24/2021 as part of the plan of correction for the initial survey. The QA report was not available to the current staff (cross-refer to D3039 for findings). 5. The QA report stated "This QA is the first in this laboratory. The standard will be assessed twice w/in this calendar year." No other QA reports were available for 2021. 6. In an email received on 12/28/2022, the current TS confirmed that there was no documentation of biweekly or monthly QC review from the previous TS and that any QA reports completed prior to 10/01/2021 were not available to the laboratory.
D6118	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(5) The technical supervisor is responsible for resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and interview and email communication with the technical supervisor (TS), the TS failed to ensure that corrective actions were taken when QC results failed to meet the laboratory's acceptable performance criteria. Cross-refer to tag D5783 for findings.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for 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; (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. This STANDARD is not met as evidenced by: Based on review of documentation submitted from the initial survey completed on 02/16/2021, review of personnel records, and email communication with the technical supervisor (TS), the TS failed to ensure that all testing personnel (TP) were evaluated for competency and that all training and competency records were maintained in the laboratory. Findings: 1. The laboratory employed all new permanent staff beginning 10/01/2021. 2. The training and competency records for two of the three TP reviewed during the initial survey were not maintained in the laboratory. 3. In August and September of 2021 four TP, including the previous TS, were temporarily performing patient testing. 4. Training and competency records for performing patient testing using the laboratory's testing panel, equipment, procedures, and reporting requirements were missing for three of the four temporary TP, including the previous TS. 5. In an email received on 12/28/2022, the current TS confirmed that training and competency records were not available for all previous TP.