Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2164327	02/16/2021
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
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 the validation summary, review of the procedure and interview with the testing person (TP) and technical supervisor (TS), the laboratory failed to establish written policies and procedures for specimen storage and preservation for testing on the liquid chromatography with tandem mass spectrometry (LC/MS/MS) instrument. Findings: 1. The "Stability Study" section on page 4 of the laboratory's "Analytical Method Validation Report (November 2019) LC/MS/MS Pain Panel" states that specimens are stable when stored for 5 days, but doesn't specify under what conditions the specimens were stored at. 2. The "Testing Information" chart listed on page 7 of the laboratory's confirmatory testing procedure stated that specimens are stable less than 5 days at ambient temperature, at least 14 days at refrigerated temperatures (2 to 8C), and greater than 14 days at frozen temperatures (-20 to -5C). The laboratory's stability studies did not establish a specimen's stability beyond 5 days and the procedure does not include a reference to another study that established specimen stability. 3. The "Acceptance Criteria" section on page 33 of the laboratory's confirmatory testing procedure states that specimens should be rejected if "collected more than 30 days prior and / or not refrigerated." This statement conflicts with the previous statement that specimens are stable less than 5 days at ambient temperature. 4. During the survey on 02/16/2021 at 10:00 AM, the TP stated that the laboratory stores each specimen in the refrigerator for 6 weeks in case they receive a request to

	re-test a specimen. The laboratory's confirmatory testing procedure does not include instructions for the length of storage time and temperature once the specimens are tested. 5. During the survey on 02/16/2021 at 10:03 AM, the TS confirmed that specimens should be stored frozen for up to 6 weeks after specimen receipt and that the laboratory only performed stability studies showing that specimens were stable up to 5 days.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on review of the procedure and interview with the technical supervisor (TS), the laboratory failed to include detailed instructions on how to report results from the liquid chromatography with tandem mass spectrometry (LC/MS/MS) instrument when interference is present. Findings: 1. In the "Assay Interferences and Limitations" section on page 34 of the laboratory's confirmatory testing procedure it states that if "analyte interference is not resolved by re-extraction and/or Ion Ratio still fails - the sample should be reported as Negative or When prescription history match with findings, report as present unable to quantitate due to interference." 2. During the survey on 02/16/2021 at 1:00 PM, the TS stated that the result would not be reported as negative and confirmed that the written procedure should be updated.
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 review of the "Calibrators and QC [quality control] Reagent Prep Log" worksheet and interview with the testing person, the laboratory did not ensure that the standards were not used past the expiration dates recorded. Findings: 1. The

	laboratory validated the liquid chromatography with tandem mass spectrometry (LC /MS/MS) analyzer in October 2020 and have been testing 6-10 days per month. 2. The "Calibrators and QC Reagent Prep Log" worksheet has three columns with the following labels- "d-Internal Std Mix", "STOCK Standard Mix" and "Intermediate Std Mix." Under each column the testing person is required to document the "Date" and "Exp [expiration]" of each preparation. 3. The only documentation under the "d-Internal Std Mix" columns for "Date" and "Exp" were "26-Oct-20" and "26-Dec-20", respectively. The records did not show that a new solution of "d-Internal Std Mix" had been prepared since 26-Dec-20. 4. The first row under the column labeled "STOCK Standard Mix" for "Date" and "Exp" were blank and the second row listed the "Date" and "Exp" as "21-Jan-20" and "21-Jun-20", respectively. The records did not show the "Date" and "Exp" of the "STOCK Standard Mix" solution used in the lab after 21-Jun-20. 5. The documentation under "Intermediate Std Mix" for "Date" and "Exp" were "26-Oct-20" and "26-Dec-20", "2-1-21" and "4-1-21", and "25-Jan-21" and "25-Mar-21." The records did not show the "Date" and "Exp" of the "Intermediate Std Mix" solution used between 26-Dec-20 and 25-Jan-21. 6. During the exit interview on 02/16 /2021 at 1:30 PM, the TS confirmed that the worksheet did not have all the required documentation to show that reagents were not used past the expiration dates recorded.
D5467	CONTROL PROCEDURES CFR(s): 493.1256(d)(9)(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-- When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview with the technical supervisor (TS), the laboratory did not provide documentation showing that the calibration materials used to calibrate the system and quality control (QC) materials were prepared from different lot numbers. Findings: 1. According to the TS, the calibration and QC materials being used in the laboratory were prepared from the same lot numbers of Cerilliant standards. They do not have a second set of Cerilliant standards for the preparation of the two separate components. 2. During the exit interview on 02/16 /2021 at 1:30 PM, the TS confirmed that the calibration materials used to calibrate the system and QC materials were not prepared from different lot numbers.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by:

	Based on review of the procedure manual and interview with the technical supervisor (TS), the laboratory director did not specify in writing, the responsibilities and duties of each person engaged in the performance of the preanalytic, analytic and post analytic phases of testing, that identifies which examination and procedure each individual is authorized to perform, and whether supervisory or director review is required prior to reporting patient test results. Findings: 1. The duties and responsibilities in the procedure manual reflected the requirement defined in the CLIA regulations. During the interview the TS described monthly reviews performed onsite and quality control review that was performed remotely through the Internet along with the laboratory director. 2. During the exit interview on 02/16/2021 at 1:30 PM, the TS confirmed that the laboratory's approved procedure manual did not specify in writing all the responsibilities of the TS that are performed onsite, remote reviews of the quality control and how to document the findings to share with the laboratory director.
D6123	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: I. Based on review of the daily temperature logs and interview with the technical supervisor (TS), the TS did not ensure that the testing personnel implemented corrective actions when the recorded humidity value was not within acceptable limits each day of testing. Findings: 1. The daily temperature logs for November 2020 through February 2021 were reviewed. The acceptable range listed on the worksheet for humidity was 35-85%. 2. During the month of November 2020 four of the four recorded values were less than 35%, December 2020 six of the seven recorded values were less than 35%, January 2021 seven of the ten recorded values were less than 35%, and February 2021 six of the six recorded values were less than 35%. 3. During the exit interview on 02/16/2021 at 1:30 PM, the TS confirmed that there was an error with the defined humidity range on the worksheet and no corrective actions had been taken. II. Based on review of the "Column & Guard Changes" and "Calibrators and QC [quality control] Reagent Prep Log" worksheets and interview with the testing person, the TS did not ensure that all the required information was recorded. Findings: 1. The laboratory validated the liquid chromatography with tandem mass spectrometry (LC/MS/MS) analyzer in October 2020. 2. The worksheet labeled "Column & Guard Changes" has two columns for recording the "Date in Service" and "Lot #" for the "New Column" and "New Column Guard." According to the testing person the "New Column" is to be changes monthly and the "New Column Guard" is to be changed weekly. 3. The column labeled "New Column" had the following "Date in Service" recorded- 10-Oct-2020, 2-Dec-2020, and 7-Dec-2020 along with the Lot #. The column tabled "New Column Guard" had no dates and Lot #'s recorded. 4. The "Calibrators and QC Reagent Prep Log" worksheet has three columns with the following labels- "d-Internal Std Mix", "STOCK Standard Mix" and "Intermediate Std Mix." Under each column the testing person is required to document the "Date" and "Exp [expiration]" of each preparation. 5. The records did not show that a new solution of "d-Internal Std Mix" had been prepared since 26-Dec-20. The records did not show the "Date" and "Exp" of the "STOCK Standard Mix" solution used in the lab after 21-Jun-20. The records did not show the "Date" and "Exp" of the "Intermediate

	Std Mix" solution used between 26-Dec-20 and 25-Jan-21. Cross refer to Tag D5417 for details. 6. During the exit interview on 02/16/2021 at 1:30 PM, the TS confirmed that the required "Date in Service" and "Lot #" were not being recorded by the testing person and that the worksheet did not have all the required documentation to show that reagents were not used past the expiration dates recorded.
D6178	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(4) Each individual performing high complexity testing must follow the laboratory's established policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance. This STANDARD is not met as evidenced by: The testing person did not implement corrective actions when the recorded humidity value was not within acceptable limits each day of testing. Cross refer to Tag D6123.