

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D2164327	<b>(X3) Date Survey Completed</b>  05/01/2024
<b>Name of Provider or Supplier</b>  Ritu Bhambhani Llc (Dbas Complete Pain Care)	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D6094</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the quality assessment (QA) plan, proficiency testing (PT) procedure and interview with the testing person (TP), the laboratory director (LD) failed to ensure that the established QA plan clearly defined which worksheets are uploaded into "Medialab" for review by the LD and the process for assessing the accuracy of non-regulated analytes which are not included in a formal PT program. Findings: 1. The "Purpose" section of the procedure labeled "QA 100.0 QA 100.0 Quality Assurance Plan MDCPC" states "Monitoring includes pre-analytic, analytic, and post-analytic testing phases. The plan describes a standardized quality control system that maximizes the quality of laboratory testing to produce accurate, reliable and timely results. This plan will enable personnel to establish written procedures to be followed as required by the Clinical Laboratory Improvement Amendments (CLIA)." The TP stated that all the QA records, e.g., maintenance records, PT records, Levy-Jennings graphs, temperature and humidity, pipette calibration, and other laboratory records are uploaded into "Medialab" on a monthly basis for the LD to review. The TP confirmed that the QA plan and other laboratory policies and procedures do not define which records are to be uploaded to LD for review. 2. The "Purpose" section of the procedure labeled "QA 102.0 QA 102.0 Proficiency Testing MDCPC" states "For those analytes (non-regulated analytes) which are not included in a formal proficiency testing program, the laboratory must provide a method to assess and verify the accuracy and reliability of their analytes." The TP explained that the staff at Catalyst Lab Solutions provides blind specimens to the lab three times a year. The specimen covers all the analytes tested at the lab. The specimens are</p>

evaluated and the results sent back to the lab. The PT procedure does not identify who provides the specimens; how often they are provided; and how to maintain the results.

3. During the exit interview on 05/01/2024 at 12:30 PM, the TP confirmed that the QA and PT plans did include the information listed above.