

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D1086652	<b>(X3) Date Survey Completed</b>  08/20/2024
<b>Name of Provider or Supplier</b>  Consultants In Pain Management	<b>Street Address, City, State</b>  2000 Stein Dr, Chattanooga, TN	
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>D5411</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, a review of instrument printouts and final patient test reports, a review of the manufacturer operator's manual, a lack of documentation, and staff interviews, the laboratory failed to follow the manufacturer's instructions for verifying one of five patient results containing complete blood cell (CBC) result flags. The findings include: 1. Observation of the laboratory on 08/20/2024 at 8:00 a.m. revealed a Horiba ABX Micros 60 (ID: 607CS96005) analyzer used for CBC patient testing. 2. A review of five patient test reports from the hematology analyzer on 08/20/2024 revealed the "G1G2" WBC flag present for patient 2408200010. 3. A review of the Horiba ABX Micros 60 hematology analyzer operator's manual section titled "8. Flags" under item "3- Morphology flags of a blood cell population" revealed the following: - "G1" is stated as an "excessive cell number in the 160-220 fL zone. Possible eosinophilia, myelocytes or polynucleated neutrophils." - "G2" is stated as an "excessive cell number in 220-250 fL zone. This flag follows abnormal granulocyte peak displacement. Possible granulocyte membrane anomalies, lyse flow problem, old blood or granulocyte cell size less than 250 fL." - All morphology flags are to be manually verified for the presence of pathological elements. 4. The laboratory did not have documentation verifying patient 2408200010's CBC results. 5. An interview with the general supervisor on 08/20/2024 at 1:00 p.m. confirmed that the laboratory did not have a system to identify and verify results that contained WBC result flags. Key: WBC= White Blood Cell count, fL= femtoliter</p>

**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 laboratory observation, manufacturer's instructions-for-use (IFU), records review, and staff interviews, the laboratory failed to define appropriate freezer temperature ranges, leading to the improper storage of calibration materials used in chemistry and endocrinology testing for one hundred and ninety days in 2023 and 2024. The findings include: 1. Observation of the laboratory on 08/20/24 at 8:45 a.m. revealed a Frigidaire freezer (SN: BA03206247) used to store the following: - Access hLH Calibrators (Lot: 439312) - Access 25(OH) Vitamin D Total Calibrators (Lot: 439572) - Access Prolactin Calibrators (Lot: 439313) - Access Folate Calibrators (Lot: 439365) - Access Free T4 Calibrators (Lot: 439424) 2. A review of the calibrator IFUs revealed the following storage temperature requirements: - Access hLH Calibrators: -15 to -30C - Access 25(OH) Vitamin D Total Calibrators: -15 to -30 C - Access Prolactin Calibrators: -20C or colder - Access Folate Calibrators: -20C or colder - Access Free T4 Calibrators: -20C or colder 3. A review of the laboratory's 2023 and 2024 "Freezer Temperature Records" revealed a defined temperature range of "0C to Colder". Staff documented temperatures warmer than -20C for 190 days and warmer than -15C for eight days. 4. An interview with the general supervisor on 08/20 /2024 at 1:00 p.m. confirmed that the laboratory did not define freezer temperature ranges consistent with the manufacturer's instructions, leading to the improper storage of calibration materials in 2023 and 2024. Key: C = degrees celcius

**D6128**

**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 annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on a review of the Centers for Medicare & Medicaid Services Laboratory Personnel Report (CLIA) (FORM CMS-209), the laboratory's competency assessment policy, testing personnel (TP) records, and staff interviews, the technical supervisor (TS) failed to evaluate the annual competency for one of three testing personnel in 2023 and 2024. The findings include: 1. A review of the FORM CMS-209 revealed three persons (TP-1, TP-2, and TP-3) who perform moderate and high complexity patient testing. The laboratory listed the Laboratory Director as the TS and TP-1 as the GS. 2. A review of the laboratory's competency assessment policy revealed the following statements: -"The technical supervisor is responsible for performing and

documenting competency assessments. The technical supervisor competency will be performed by the Laboratory Director. If the Lab Director serves as the Technical Supervisor, Technical Consultant and or the Clinical Consultant then the Laboratory Director will also perform and document the laboratory competencies. The technical supervisor may delegate in writing the performing and documenting of the competency to the General Supervisor." 3. A review of the laboratory's testing personnel records revealed that TP-2 signed TP-1's annual competencies on 07/25/2024 and 07/26/2023. 4. An interview with the general supervisor on 08/20/2024 at 1:00 p.m. confirmed that TP-2 is not designated as the laboratory's TS or GS and performed TP-1's 2023 and 2024 competency assessment.