

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  36D2172414	<b>(X3) Date Survey Completed</b>  11/10/2021
<b>Name of Provider or Supplier</b>  Pain Evaluation And Management Center	<b>Street Address, City, State</b>  1550 Yankee Park Place, Dayton, OH	
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>D5781</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on record reviews and an interview with the General Supervisor (GS), the laboratory failed to document any corrective actions taken when the 4500 MS Q-Trap test procedures performed outside of established operating parameters. This deficient practice had the potential to affect 98 patients tested with the 4500 MS Q-Trap HPLC on 04/20/2021 and 73 patients tested with the 4500 MS Q-Trap HPLC on 06/08/2021. Findings Include: 1. Review of the laboratory's requested documents for a remote inspection sent via email 10/28/2021 at 3:44 PM found two Innovative Lab Services service requests. The service request dated 04/23/2021 for the 4500 MS Q-Trap HPLC contained the following statement: "Customer is experiencing retention time shift on the HPLC" The service request dated 06/15/2021 contained the following statement: "Replaced the purge valve on pump B, would not tighten" 2. Further review of the laboratory's requested documents for a remote inspection, received 10/28/2021 at 3:44 PM, did not find any instructions to document errors and incidents along with the actions taken to correct the problem(s) identified. 3. On 11/10/2021 at 11:30 AM during a phone interview the inspector requested documentation for the retention time shift and for the purge valve on pump B leak, and the actions taken for patient</p>

testing during that time. The GS confirmed there was no documentation for the retention time shift or for the purge valve issue, or the actions taken for patient testing during that time. MS: mass spectrometry HPLC: high-performance liquid chromatography