

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2057982	(X3) Date Survey Completed 07/06/2023
Name of Provider or Supplier Isaac Spine Joint & Pain Institute	Street Address, City, State 3320 Perimeter Hill Dr, Nashville, TN	
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
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records and staff interview, the laboratory failed to evaluate non-graded PT scores for drug monitoring in pain management (DMPM) and ethanol biomarkers (ETB) in 2022 (9 of 55 PT results) and 2023 (3 of 27 PT results). The findings include: 1. Review of the laboratory PT records revealed the following: a) 2022 DMPM-A: -DMPM-01 Morphine result ungraded. -DMPM-02 Noroxycodone result ungraded. b) 2022 DMPM-B: -DMPM-05 Buprenorphine result ungraded. -DMPM-05 Gabapentin result ungraded. -DMPM-07 Methamphetamine result ungraded. -DMPM-08 Clinical Study result ungraded. c) 2022 ETB-A: -ETB-01 Ethyl gluc. qual CONF result ungraded. -ETB-01 Ethyl gluc. quant CONF result ungraded. -ETB-01 Ethyl sulfate result ungraded. d) 2023 DMPM-A: -DMPM-03 Hydrocodone result ungraded. -DMPM-03 Norbuprenorphine result ungraded. e) 2023 ETB-A: -ETB-03 Ethyl gluc. qual CONF result ungraded. None of the 12 ungraded results reviewed had been evaluated by the laboratory to determine the accuracy of the results. 2. Interview with the general supervisor on 7/6/2023 at 1:00 p.m. confirmed the laboratory failed to evaluate non-graded PT scores for accuracy for drug monitoring in pain management and ethanol biomarkers analytes in 2022 and 2023 (12 of 82 PT results reviewed).</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an</p>

ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedure manual and interview with the General Supervisor, the laboratory failed to establish written procedures for Quality Assessment at the time of survey (7/6/2023). The findings include: 1. A review of the laboratory's procedure manual revealed no written policies to monitor, assess and correct problems identified in the laboratory. 2. Interview on 7/6/2023 at 1:00 p.m. with the laboratory's General Supervisor confirmed there was no written Quality Assessment Policy for the laboratory at the time of survey.