

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  13D1105419	<b>(X3) Date Survey Completed</b>  03/12/2020
<b>Name of Provider or Supplier</b>  Southern Idaho Pain Institute Pc	<b>Street Address, City, State</b>  120 Rose St N, Twin Falls, ID	
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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and testing person interview the laboratory failed to document annual competency assessments for the testing person, the general supervisor, and the technical supervisor for 2018 and 2019. Findings: 1. A review of available records revealed no documentation for 2018 and 2019 of competency evaluations for the testing person, general supervisor, and technical supervisor. 2. An interview with the testing person on 03/12/2020 at 9:10 AM confirmed the above findings.</p>
<b>D5413</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review, procedure review, and interview of the testing person the</p>

laboratory failed to document the temperature of the incubator. Findings: 1. A review of available temperature charts did not reveal any documentation of the incubator temperature. 2. A review of the LCMS Standard Operating Procedure, V1.1 3/5/2018, page 14 revealed the following statement, "Incubate plate for 120 minutes at 55 degrees Celsius". 3. An interview of the testing person on 03/12/2020 at 10:45 AM confirmed that the laboratory was not documenting the temperature of the incubator.

**D5435**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:  
Based on observations of available thermometers, record review, and interview of the testing person the laboratory failed to perform calibration checks on all thermometers in use at the time of the survey. Findings: 1. Observation of 4 of 4 digital thermometers on 03/12/2020 at 10:10 AM revealed documentation on the back of the thermometers that stated recalibration was due on November 6, 2019. 2. A review of available records revealed no documentation of periodic calibration checks of the 4 observed digital thermometers or the one glass thermometer used in the incubator. 3. An interview of the testing person on 03/12/2020 at 10:15 AM confirmed the above findings.

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:  
Based on a review of test reports and interview of the testing person the laboratory failed to include the correct address of the location where the tests were performed. Findings: 1. A review of test reports revealed that the address of the location where the tests were performed was not on the report. 2. An interview of the testing person on 03/12/2020 at 9:35 AM confirmed the above finding.