

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D2017133	<b>(X3) Date Survey Completed</b>  03/13/2019
<b>Name of Provider or Supplier</b>  Valley Pain Clinic	<b>Street Address, City, State</b>  2208 Danville Rd St G, Decatur, AL	
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>D5407</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory policy and procedure manual, the Indiko Plus procedures and an interview with the current Testing Personnel (TP), the surveyor determined the laboratory failed to ensure the current Laboratory Director documented her review and approval (as indicated by her signature and date) of procedures in use, after assuming her responsibilities as the Laboratory Director in June 2018. The findings include: 1. An on-site review of a copy of the Form CMS-116 submitted to the CLIA State Agency revealed a change in Laboratory Director in June 2018. 2. A review of the laboratory policy and procedure manual revealed the signature of the previous Laboratory Director dated 3/16/2018; the Indiko Plus procedures were also signed by the previous Director on 2/23/2018. The new Testing Personnel had also signed and "approved" the procedures on 2/12/2019. However, there was no evidence the procedures had been reviewed and approved by the current Laboratory Director after she had assumed her responsibilities in June 2018 (nine months previous to the date of this survey on 3/13/2019). 3. During a review of the manuals on 3/13/2019 at approximately 11:00 AM, the current Testing Personnel stated she had contacted the previous testing personnel, who had recently retired. The previous testing personnel stated he did not think the new Director had reviewed and approved the laboratory procedures because he had forgotten to bring her the manuals. Thus the above noted findings were confirmed. SURVEYOR ID#32558 Licensure and Certification Surveyor</p>