

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  42D2053504	<b>(X3) Date Survey Completed</b>  03/29/2018
<b>Name of Provider or Supplier</b>  Carolina Pain Physicians	<b>Street Address, City, State</b>  9404 Highway 78, Ladson, SC	
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: During an onsite initial survey on 3/29/2018, procedure manual review, testing personnel record review, and testing personnel interview, the laboratory failed to follow written policies and procedures to assess the competency of one of one testing personnel for 2017. Findings include: 1. The laboratory's procedure manual stated that all testing personnel performing urine drug screen testing on the Indiko Plus analyzer will have an initial assessment performed when hired, a competency assessment at six months, and annual competency assessment evaluations thereafter. 2. Review of testing personnel's file revealed that the last competency assessment was performed on 1/6/2016. 3. During the exit interview at 12:15 pm, testing personnel confirmed that an annual competency assessment had not been performed in 2017.</p>
<b>D5407</b>	<p><b>PROCEDURE MANUAL</b> 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: During an onsite initial survey on 3/29/2018, based on procedure manual review and testing personnel interview, the laboratory failed to ensure that the procedure manual was approved, signed, and dated by the current laboratory director. Findings include:</p>

	<p>1. The signature of the current laboratory director on file was not present on any of the laboratory procedures reviewed. 2. Testing personnel confirmed during the exit interview at 12:15 pm that the current laboratory director had not signed &amp; dated the procedure manual.</p>
<p><b>D6106</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p> <p>This STANDARD is not met as evidenced by:  During an onsite initial survey on 3/29/2018, based on procedure manual review and testing personnel interview, the laboratory director failed to ensure that an approved procedure manual was available to testing personnel (see D5407).</p>
<p><b>D6120</b></p>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b>  CFR(s): 493.1451(b)(7)(8)</p> <p>(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by:  During an onsite initial survey on 3/29/2018, based on procedure manual review, testing personnel record review, and testing personnel interview, the laboratory director/technical supervisor failed to ensure that competency assessments were performed annually as required (see D5209).</p>