

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2116298	(X3) Date Survey Completed 04/11/2019
Name of Provider or Supplier Etowah Pain Associates	Street Address, City, State 3015 Steele Station Road, Rainbow City, AL	
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
D5407	<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 manuals and an interview with the current Laboratory Director, 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 April 2018. The findings include: 1. A review of the Form CMS-116 submitted to the CLIA State Agency on 4/4/2018 revealed a change in Laboratory Director request; an update in the records was made on 4/10/2018. 2. An on-site review of the laboratory policy and procedure manual revealed the signature of the previous Laboratory Director dated March 2017 (reviewed during the previous survey). However, there was no evidence the procedures had been reviewed and approved by the current Laboratory Director after she had assumed her responsibilities in April 2018 (one year previous to the date of this survey on 4/11/2019). 3. During an interview and review of the manuals on 4/11/2019 at 11:05 AM, the current Laboratory Director (LD) stated she had actually become the LD in March 2018; the LD stated she had reviewed the procedures in use by the Testing Personnel, but had not actually signed and dated her approval. Thus the above noted findings were confirmed. SURVEYOR ID#32558 Licensure and Certification Surveyor</p>
D6103	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must ensure that policies and procedures are established for</p>

monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on a review of the annual competency evaluations for the Testing Personnel, and interviews with the Testing Personnel and the Laboratory Director, the Laboratory Director failed to implement policies, procedures and checklists to assess and ensure the annual competency of the Testing Personnel in the performance of high-complexity Toxicology testing on the Diatron Pictus 400 analyzer. This affected one of one testing personnel. The findings include: 1. A review of the annual competency evaluations for the one Testing Personnel (dated 4/26/2018 and 2/27/2019) revealed a very general assessment (including "Emergencies, General Laboratory Safety, Chemical Safety, Biological Safety and Radiation Safety"). 2. During an interview on 4/11/2019 at 10:20 AM, the surveyor asked the Testing Personnel if anyone had evaluated her preanalytical, analytical, and postanalytical competency in the performance of the Urine Drug Screen testing on the Diatron Pictus 400 analyzer. The Testing Personnel reviewed the evaluations, and stated the form on file was used annually by the technician who had trained her on the Pictus 400, however there was no documentation of the Testing Personnel's competency in the actual test performance. 3. As the interview continued at approximately 10:25 AM, the surveyor then asked the Laboratory Director (also the Technical Supervisor) if she had assessed the Testing Personnel's competency in the performance of the Urine Drug Screen testing on the Diatron Pictus 400 analyzer. The Director stated she had reviewed operations and procedures in the laboratory with the testing personnel, however she had not documented an assessment of competency in 2018 or 2019. Thus the above noted findings were confirmed. [NOTE: The surveyor provided the CMS pamphlet "What Do I Need to Do to Assess Personnel Competency?" which provided details on CLIA requirements for competency.] SURVEYOR ID#32558 Licensure and Certification Surveyor