

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D0966441	(X3) Date Survey Completed 01/29/2020
Name of Provider or Supplier Acp - Arthritis Associates	Street Address, City, State 2102 N Country Club, Ste 3, Tucson, AZ	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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 review of competency evaluation policies and forms and interview with facility personnel, the laboratory failed to follow established written policies to assess competency of laboratory personnel. Findings include: 1. The laboratory performs patient testing under the sub-specialty of Routine Chemistry, with an approximate annual test volume of 80. 2. The Laboratory Personnel Report, Form CMS-209 submitted for review during the survey conducted on 01/29/20 indicated that the laboratory had two testing personnel (TP). 3. The laboratory's established policy titled, "Competency Evaluation for Personnel Performing Clinical Testing" indicates for any newly hired personnel that competency evaluations will occur at six months, twelve months and annually thereafter. 4. No documentation of an annual competency evaluation was presented for review for 2018 and 2019 for two out of two testing personnel. 5. The facility personnel confirmed that the laboratory did not have documentation of a competency evaluation for 2018 and 2019 for the two testing personnel referenced above.</p>
D5391	<p>PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242.</p>

This STANDARD is not met as evidenced by:
Based on lack of Quality Assessment (QA) documentation and interview with the facility personnel, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the preanalytic systems. Findings include: 1. No written QA policies and procedures specific to the preanalytic systems were presented for review during the survey. 2. The facility personnel confirmed that the laboratory could not produce evidence of established preanalytic QA policies at the time of the survey.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
Based on lack of Quality Assessment (QA) documentation and interview with the facility personnel, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems. Findings include: 1. No written QA policies and procedures specific to the postanalytic system were presented for review during the survey. 2. The facility personnel confirmed that the laboratory could not produce evidence of an established postanalytic QA policy at the time of the survey.