

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2117056	(X3) Date Survey Completed 10/26/2018
Name of Provider or Supplier Jim Pang, Md, Pllc	Street Address, City, State 65 Germantown Court Ste 402, Cordova, TN	
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
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records and interview with the laboratory director and testing personnel number one, the laboratory failed to retain all PT records for at least two years in 2017 and 2018. The findings include: 1) Review of the available PT records for 2017 and 2018 revealed the following: for 2017 event one-no corrective action documentation located; for 2017 event two-no instrument printouts, no attestation records, no submitting records, no results records; for 2018 event one-no instrument printouts, no attestation records 2) Interview on October 26, 2018 at 11:30 a.m. with the laboratory director and testing personnel number one confirmed that the laboratory failed to retain all PT records for 2017 and 2018.</p>
D5205	<p>COMPLAINT INVESTIGATIONS CFR(s): 493.1233</p> <p>The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and quality assessment plan and interview with the laboratory director, the laboratory failed to have a system in place to conduct investigations of complaints, in 2017 and 2018. The findings include: 1) Review of the laboratory procedure manual and quality assessment plan revealed no procedure for complaint investigation was included. 2) Interview on October 29, 2018</p>

at 10:30 a.m. with the laboratory director confirmed the laboratory did not have a system in place to document and investigation complaints in the laboratory.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES

CFR(s): 493.1235

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.

This STANDARD is not met as evidenced by:

Based on review of the laboratory procedure manual, the quality assessment plan, no available personnel records and interview with the laboratory director and testing personnel number one, the laboratory failed to establish and follow written policies to assess testing personnel competency, initially, six months during the first years, then yearly, in 2017 and 2018. The findings include: 1) Review of the laboratory procedure manual, the quality assessment plan and no available personnel records revealed the laboratory did not have a written policy, plan, and/or checklist to follow for testing personnel competency, for initial training, six month and yearly. 2) Interview on October 26, 2018 at 12:15 p.m. with the laboratory director and testing personnel number one confirmed the laboratory failed to have a plan to follow for testing personnel initial, six month and yearly competencies. Testing personnel number one did not have a six month competency in 2017 and yearly competency in 2018.