

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D1104050	(X3) Date Survey Completed 01/30/2020
Name of Provider or Supplier Accupath Diagnostic Laboratories Inc	Street Address, City, State 1737 Tennessee Avenue, Suite B, Cincinnati, OH	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: ITEM 1: Based on document review and interviews with the Quality Manager (QM) and General Supervisor (GS), the laboratory failed to follow the procedure manual for training and competency assessments. This deficient practice had the potential to affect all patients tested under the subspecialty of general immunology from March 2019 to January 2020. Findings include: 1. Review of the laboratory's policy titled "Training and Competency Assessment Policy", approved by the Laboratory Director on 07/25/2018 found the following statement: "A. Training 1. An employee who is new to a job function must receive training on all tasks performed, as well as applicable instruments/methods, before being allowed to test independently. This includes employees new to the laboratory, employees who have transferred or have been promoted to different job duties." 2. Review of initial competency assessment documents for the GS revealed competency for the Sysmex hematology instrument was signed off on 03/27/2019, flow bone marrow was signed off on 03/21/2019 and flow instrument room was signed off on 03/25/2019 by personnel not list on the form CMS 209. 3. An interview with the QM and the GS on 01/30/2020 at 10:50 AM confirmed the initial competency assessments (in line 2 above) occurred at a different location. ITEM 2: Based on document review and interviews with the Quality Manager (QM) and General Supervisor (GS), the laboratory failed to follow the procedure manual for training and competency assessments. This deficient practice had the potential to affect all patients tested under the subspecialty of general immunology from March 2019 to January 2020. Findings include: 1. Review of the</p>

laboratory policy titled "Training and Competency Assessment Policy", approved by the Laboratory Director 07/25/2018 found the following statement: "C. Competency Assessment Schedule Competency is assessed at the following times o After training /re-training o Semi-annually during the first year. o Annually after the first year o After an extended absence from assigned job duties." 2. Review of the 2019 annual "Technical Competency Evaluation Form" for Testing Personnel #1 (TP#1) revealed a 2019 assessment date of 01/29/2020. 3. An interview with the QM and the GS on 01/30/2020 at 10:50 AM confirmed the 2019 annual competency assessment for TP#1 did not occur annually after the first year. ITEM 3: Based on document review and interviews with the Quality Manager (QM) and General Supervisor (GS), the laboratory failed to follow the procedure manual for training and competency assessments. This deficient practice had the potential to affect all patients tested under the subspecialty of general immunology from March 2019 to January 2020. Findings include: 1. Review of the laboratory policy titled "Training and Competency Assessment Policy", approved by the Laboratory Director 07/25/2018 found three out of eight elements listed as direct observations. 2. Review of the 2019 six month "Technical Competency Evaluation Form for BM/PB Sample Processing" for the GS revealed three direct observation elements. 3. Further review of the 2019 six month "Technical Competency Evaluation Form for BM/PB Sample Processing" for the GS revealed all seven elements initialed as completed by a designee not listed on the form CMS 209. 3. An interview with the QM and the GS on 01/30/2020 at 10:50 AM confirmed the six-month technical competency for the GS was not completed with the designee on site to observe and sign off. The designee via a phone interview on 01/30/2020 at 10:52 AM also confirmed they had initialed and signed off on the form from a different location and was not present during the assessment.