

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0370794	(X3) Date Survey Completed 03/28/2019
Name of Provider or Supplier Summit Women's Center	Street Address, City, State 15801 W McNichols Road, Detroit, MI	
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 procedure review, record review, and interview with the office manager, the laboratory failed to ensure written competency policies were established and implemented for seven (#1 - #7) of seven testing personnel (TP) performing moderately complex ABO Rh testing from April 2017 to April 2019. Findings include: 1. Procedure review revealed the laboratory competency policy did not contain one of the six minimum regulatory requirements: "Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples." 2. Record review revealed for seven of seven TP the competency assessments lacked documentation for the missing regulatory requirement from April 2017 to April 2019. 3. During the interview on March 28, 2019 at 9:17 AM, the office manager acknowledged the competency assessment did not contain all the minimum regulatory requirements.</p>
D6018	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to</p>

identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

. Based on record review and interview with the office manager, the laboratory director failed to ensure the final American Proficiency Institute (API) proficiency testing (PT) reports were reviewed by the appropriate TP for three (1st - 3rd events 2018) of six events reviewed. Findings include: 1. Record review of the final API reports revealed the appropriate TP did not review the 1st - 3rd events of 2018. 2. During the interview on March 28, 2019 at 11:10 AM, the office manager acknowledged the TP did not document review of the final PT reports. ***Repeat Deficiency from September 20, 2016 survey***