

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  36D0337191	<b>(X3) Date Survey Completed</b>  06/04/2019
<b>Name of Provider or Supplier</b>  University Suburban Health Ctr	<b>Street Address, City, State</b>  1611 S Green Road, Room 011, South Euclid, OH	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<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 record review, and an interview with the Laboratory Manager, the laboratory failed to establish a written policy and procedure to assess competency of the Technical Supervisor (TS), and the General Supervisor (GS) as specified in the personnel requirements in subpart M. All patients tested at this laboratory have the potential to be affected. Findings Include: 1. Review of the laboratory's CMS-209 Personnel Report form, approved and signed by the Laboratory Director on 6/4/19, found 1 person serving as both the TS and GS. 2. Review of the laboratory's 'Competency Assessment' policy and procedure failed to find a policy and procedure for assessing the competency of the TS and GS based on the regulatory responsibility of that role, at a frequency determined by the laboratory. 3. An interview with the Laboratory Director, on 6/4/19 at 10:39 am, confirmed that the lab failed to establish a policy and procedure for assessing the competency of the TS and GS based on the regulatory responsibility of those roles, at a frequency determined by the laboratory.</p>
<b>D5473</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p>

This STANDARD is not met as evidenced by:  
Based on record review and an interview with Testing Personnel #2, the laboratory failed to document manual differential stain quality control procedures for the intended stain reactivity to ensure predictable staining characteristics each day of use. All patients tested at this laboratory have the potential to be affected. Findings Include: 1. Review of the laboratory's 'Manual Differential' policy and procedure, on 6/4/19, failed to find instructions for documenting manual differential staining quality control each day of patient testing. [Note: the policy did contain a list of 'staining problems' indicating stain reactions, problems, and possible solutions; however, the policy failed to provide instructions on how to document Manual Differential stain quality control for each day of patient testing.] 2. Review of quality control documentation from 2018 and 2019 failed to find any manual differential stain quality control documentation. 3. An interview with Testing Personnel #2, on 6/4/19 a 1:10 pm, confirmed that although the lab looked for staining problems each day of patient testing, the lab failed to document manual differential stain quality control each day of patient testing.

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:  
Based on record review and an interview, the laboratory failed to indicate, on final test reports, a specimen source for each test. All patients tested at this laboratory have the potential to be affected. Findings Include: 1. Review of final test reports failed to find a specimen source listed for each test. 2. An interview with Laboratory Director, on 6/4/19 at 2:16 pm, confirmed that the specimen source was not included on the final test report for each test.