

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  38D0621772	<b>(X3) Date Survey Completed</b>  03/10/2020
<b>Name of Provider or Supplier</b>  Davies Medical Clinic-Oregon Medical Group	<b>Street Address, City, State</b>  345 N Grant Street, Canby, OR	
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><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 upon review of available written laboratory procedures and interview with the Laboratory Director (LD) , the laboratory failed to establish and follow written procedures for the assessment of employees performing PPMP and waived laboratory procedures. Findings include: 1. During an interview with the LD on 3/10/2020 at approximately 1030, the LD confirmed there were no written records of PPMP testing personnel (TP) competency for the past two (2) years. 2. No written evidence of bi-annual verification for personnel performing potassium hydroxide (KOH) wet mounts or isotonic saline wet mounts could be produced during the survey on 3/10/2020.</p>
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based upon review of available written laboratory procedures and interview with the Laboratory Director (LD) , the laboratory failed to establish and follow written procedures for the assessment of employees performing PPMP and waived laboratory</p>

	<p>procedures. Findings include: 1. No written evidence of bi-annual verification for personnel performing potassium hydroxide (KOH) wet mounts or isotonic saline wet mounts could be produced during the survey on 3/10/2020.</p>
<p><b>D5401</b></p>	<p><b>PROCEDURE MANUAL</b> 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: Based upon review of the laboratory records provided and interview with Testing Personnel (TP) during survey, the Laboratory Director (LD) failed to ensure that an approved procedure manual is available to all TP. Findings include: 1. There was no written and LD approved procedure manual for PPMP testing during survey 3/10 /2020. 2. The LD confirmed during interview 3/10/2020 at approximately 1045 that there was no written and approved procedure manual available for TP review or use.</p>
<p><b>D5403</b></p>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of a procedure manual and confirmation thereof during an interview with the Laboratory Director on 3/10/2020, please see Dtag 5401.</p>
<p><b>D5407</b></p>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p>

This STANDARD is not met as evidenced by:  
Based on the lack of a procedure manual and confirmation thereof during an interview with the Laboratory Director on 3/10/2020, please see Dtag 5401.