

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  38D0932318	<b>(X3) Date Survey Completed</b>  11/02/2020
<b>Name of Provider or Supplier</b>  Legacy Medical Group	<b>Street Address, City, State</b>  861 W Main St, Molalla, 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>D5449</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of Quality Control (QC) records and discussion with staff during survey 11/02/2020, the laboratory failed to follow manufacturer's instruction for performing QC on urine dipsticks. Findings include: 1. Upon request for QC records for urinalysis during survey 11/02/2020, none could be produced. 2. During interview with staff at approximately 1200, staff confirmed that the laboratory does not perform QC on the urine dipsticks.</p>
<b>D5807</b>	<p><b>TEST REPORT</b> CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: Based on review of patient reports with Hematology and Urinalysis results on them and discussion with the Office Manager, the laboratory failed to ensure appropriate units of measure for normal ranges and patient results were included on the report. Findings include: 1. There were no units of measure on the patient report for any</p>

analyte in Hematology. 2. There were no units of measure on the patient report for any analyte in Urinalysis. 3. The Office Manager confirmed that they do not include units of measure for either of these specialties on patient reports during interview 11/02/2020 at approximately 1:00 pm.