

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0626322	(X3) Date Survey Completed 07/02/2018
Name of Provider or Supplier Legacy Medical Group	Street Address, City, State 335 Fairview St, Silverton, OR	
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
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based upon review of Provider records involving Microscopy and interview with staff, the Laboratory Director (LD) failed to fulfill his responsibilities. Findings include: 1. See Dtag 6004 and Dtag 6007</p>
D6004	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapporitions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of employee training records and discussion with staff, the Laboratory Director (LD) failed to fulfill the responsibilities of the LD and the Technical Consultant (TC). Findings include: 1. Policy written after the previous</p>

survey, citing what actions would be enforced regarding Provider Performed Microscopy (PPM) was not followed for biannual verification. (see Dtag 5217 and Dtag 6029 on previous survey). 2. Five (5) out of five (5) providers performing PPM have no documentation of biannual verification since the last survey in September of 2016.

D6007

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(1)

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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:

Based upon review of Laboratory Policy and review of personnel records, the Laboratory Director failed to ensure providers were competent to perform microscopic examinations of bodily fluids. Finding include: 1. Policy written after the previous survey, citing what actions would be enforced regarding Provider Performed Microscopy (PPM) was not followed for bi-annual verification. (see Dtag 5217 and Dtag 6029 on previous survey). 2. Five (5) out of five (5) providers performing PPM have no documentation of biannual verification since the last survey in September of 2016. 3. The form created to document Provider Education after the previous survey in September 2016 is not being used to document required bi-annual verification.