

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0627068	(X3) Date Survey Completed 10/09/2018
Name of Provider or Supplier Coquille Valley Hospital Laboratory	Street Address, City, State 940 East Fifth Street, Coquille, 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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Record review of the American Proficiency Institute (API) proficiency testing reveals that your laboratory has unsuccessful proficiency testing for Immunohematology. Refer to D2159, D2169, D2178, and D2187.</p>
D2159	<p>ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a</p>

	<p>score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Review of the American Proficiency Institute (API) proficiency testing (PT) shows failure to return proficiency testing results on time resulted in unsatisfactory performance. Findings include: 1. 2nd Event 2018 - ABO Group and D (Rho) typing - 0% 2. This finding was confirmed by Lab Tech per phone conversation on 10/09/2018 at 15:00 PM.</p>
D2169	<p>UNEXPECTED ANTIBODY DETECTION CFR(s): 493.861(c)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Review of the American Proficiency Institute (API) proficiency testing (PT) shows failure to return proficiency testing results on time resulted in unsatisfactory performance. Findings include: 1. 2nd Event 2018 - Unexpected Antibody Detection - 0% 2. This finding was confirmed by Lab Tech per phone conversation on 10/09/2018 at 15:00 PM.</p>
D2178	<p>COMPATIBILITY TESTING CFR(s): 493.863(c)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Review of the American Proficiency Institute (API) proficiency testing (PT) shows failure to return proficiency testing results on time resulted in unsatisfactory performance. Findings include: 1. 2nd Event 2018 - Compatibility Testing - 0% 2. This finding was confirmed by Lab Tech per phone conversation on 10/09/2018 at 15:00 PM.</p>
D2187	<p>ANTIBODY IDENTIFICATION CFR(s): 493.865(c)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Review of the American Proficiency Institute (API) proficiency testing (PT) shows failure to return proficiency testing results on time resulted in unsatisfactory</p>

performance. Findings include: 1. 2nd Event 2018 - Antibody Identification - 0% 2.
This finding was confirmed by Lab Tech per phone conversation on 10/09/2018 at 15:
00 PM.