Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0685222	02/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Lower Umpqua Hospital District Laboratory	600 Ranch Rd, Reedsport, 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	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: Proficiency Testing (PT) desk review of the American Association of Bioanalysts (AAB) proficiency testing (PT) shows the laboratory had unsuccessful participation for the 2nd and 3rd event of 2017 for Compatibility Testing in Immunohematology. Refer to D2173 and D2179.
D2173	COMPATIBILITY TESTING CFR(s): 493.863(a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory

	performance. This STANDARD is not met as evidenced by: PT desk review of the AAB PT reveals that the laboratory failed two consecutive testing events for compatibility testing for 2017. Findings include: 1. AAB PT 2nd event of 2017 Compatibility Testing - 80%. 2. AAB PT 3rd event of 2017 Compatibility Testing - 80%.
D2179	COMPATIBILITY TESTING CFR(s): 493.863(d) (1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: PT desk review of the AAB PT reveals that the laboratory failed two consecutive testing events for compatibility testing for 2017. Findings include: 1. AAB PT 2nd event of 2017 Compatibility Testing - 80%. 2. AAB PT 3rd event of 2017 Compatibility Testing - 80%.