Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0685222	02/19/2019
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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manuals and discussion with the staff the laboratory director did not sign and date the procedure manuals used in the laboratory. Findings include: 1. The surveyor reviewed all of the laboratory's procedure manuals and noticed that the new laboratory director did not sign and date any of the procedure manuals. 3. The laboratory did change to the new laboratory director effective 09/21/2017. 2. The laboratory manager concurred with these findings on 02/19/2019 at 17:00
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected

	by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of calibration records and discussion with staff the laboratory failed to perform calibration verification every six months for the D-dimer and Brain natriuretic peptide (BNP) test analytes using the Biosite Triage Meter. Findings include: 1. The surveyor requested and the laboratory failed to provide documentations of calibration verifications for BNP and D-dimer test analytes for the year 2017 and 2018. 2. The last documented calibration verifications of the BNP and D-dimer were 10/01/2016. 3. The laboratory manager concurred with these findings on 02/19/2019 at 17:00.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) 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. This STANDARD is not met as evidenced by: Based on review of quality control procedures and quality control logs for serum Human Chronic Gonadotropin (HCG) test system and discussions with the laboratory staff the laboratory was not performing 2 levels of external controls (positive and negative) each day of patient testing. Findings include: 1. The surveyor reviewed the quality control logs for the Fisher Sure View HCG combo kits which can be used for both urine and serum. 2. The laboratory occasionally performed serum HCG but did not perform a positive and a negative control each time a serum specimen was used. 3. The surveyor requested but the laboratory failed to provide a written Individualized Quality Control Plan (IQCP) for the serum HCG test system. The laboratory follows the manufacturer's package insert (PI) in performing external quality control which was per new lot number and shipment of the test kits. 4. The laboratory manager concurred with these findings on 02/19/2019 at 17:00
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's policy and procedures, testing personnel (TP)

	qualification and competency records, and quality control and calibration records the Laboratory Director (LD) did not fulfill her responsibilities to provide overall management and direction of the laboratory. Refer to D6102, D5407, D5439 and D6102.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of personnel records and discussions with the staff the laboratory failed to provide the necessary documentation of education of the testing personnel . Findings include: 1. The surveyor requested and the laboratory failed to provide the diplomas or transcript of records of 2 out of 4 new testing personnel (TP) that were hired on 03/2018 and 10/2018 at the time of survey. 2. The laboratory manager concurred with these findings on 02/19/2019 at 17:00