Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0685222	09/04/2020
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
D2089	ROUTINE CHEMISTRY CFR(s): 493.841(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) from the American Association of Bioanalyst (AAB) the laboratory had unsatisfactory performance in Routine Chemistry. Findings include: 1. 3rd event of 2019 revealed 0% for the following analytes. pH, PCO2, and PO2. 2. No documentation of corrective action taken for the failed proficiency testing. 3. The Director/Chief Nursing Officer and the laboratory staff concurred with these findings on 09/04/2020 at 16:00 PM. Onsite Investigation
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

	This CONDITION is not met as evidenced by: Based on review of the laboratory's procedure manuals and discussion with the staff the new laboratory director did not sign and date the procedure manuals used in the laboratory. Findings include: 1. Review of all procedures manuals revealed that the new laboratory director hired in March 2020 did not sign the following procedure manuals. a. Serology Procedure Manuals. b. Triage Meter Procedure Manuals. c. Urinalysis Procedure Manuals. d. Hematology Procedures Manuals. e. Dimension EXL Chemistry Procedure Manuals. f. I Stat Chemistry and Blood Gas Procedure Manuals. g. Individualized Quality Control Plan (IQCP) Procedure Manuals. 2. This deficiency was cited in the last survey conducted on 02/19/2019. This is a repeat deficiency. 3. The Director/Chief Nursing Officer and the laboratory staff concurred with these findings on 09/04/2020 at 16:00 PM.
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 new laboratory director did not sign and date the procedure manuals used in the laboratory. Findings include: 1. Review of all procedures manuals revealed that the new laboratory director hired in March 2020 did not sign the following procedure manuals. a. Serology Procedure Manuals. b. Triage Meter Procedure Manuals. c. Urinalysis Procedure Manuals. d. Hematology Procedures Manuals. e. Dimension EXL Chemistry Procedure Manuals. f. I Stat Chemistry and Blood Gas Procedure Manuals. g. Individualized Quality Control Plan (IQCP) Procedure Manuals. 2. This deficiency was cited in the last survey conducted on 02/19/2019. This is a repeat deficiency. 3. The Director/Chief Nursing Officer and the laboratory staff concurred with these findings on 09/04/2020 at 16:00 PM.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of quality control records for the ABL 80 Flex Co-Ox Radiometer, the laboratory's point of care respiratory department failed to perform external quality controls every 8 hours which includes low and high values each day of patient testing. Findings include: 1. The quality control records revealed the laboratory's point of care respiratory department was not performing external quality controls as specified by the manufacturer's manual which states " two levels every shift 1, 2, and 3 or every 8

	hours". 2. The last quality control was perform 5 months ago but no proof of documentation as conveyed by the respiratory manager. 2. The respiratory manager concurred with these finding on 09/04/2020 at 13:00 PM.
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, Personnel records, Competency records, and Quality Control records, the Laboratory Director (LD) did not fulfill her responsibilities to provide overall management and direction of the laboratory. Refer to D6079, D6091, D6092, D6102, D6103 and D6106.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of personnel records and discussion with the staff the laboratory failed to provide copies of diplomas or transcript of records for the testing personnel. Findings include: 1. 9 out of 16 testing personnel do not have copies of their diplomas or transcript of records at the time of survey. 2. 14 out of 16 testing personnel do not have documentation of their initial training, 6 months, and or annual competency evaluations at the time of survey. 3. 4 out of 4 testing personnel in the Laboratory's point of care respiratory department do not have copies of their diplomas or transcript of records at the time of survey. 4. 4 out of 4 testing personnel in the Laboratory's point of care respiratory department performing blood gasses do not have documentation of their initial training, 6 months, and annual competency evaluations at the time of survey. 3. The Director/Chief Nursing Officer, the Respiratory Manager and the laboratory staff concurred with these findings 09/04/2020 at 16:00 PM.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

	This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) from the American Association of Bioanalyst (AAB) the laboratory had unsatisfactory performance and missed proficiency testing for the year 2019. No documentation of corrective actions for the unsatisfactory performance and also with the missed proficiency testing. Findings include: 1. 1st Event of 2019 revealed PCO2 = 80 %. No corrective action for the missed proficiency testing. 2. 2nd Event of 2019 revealed pH and PCO2 = 80 %. No corrective action for the missed proficiency testing. 3. 3rd Event 2019 revealed Bacteriology = 80%. No corrective action for the missed proficiency testing. 3. 3rd event of 2019 revealed pH, PCO2 and PO2 = 0% . No documentation of corrective action taken for the failed proficiency testing.. 4. 3rd Event 2019 Compatibility Testing = 80%. No corrective action for missed proficiency testing. 5. The Director /Chief Nursing Officer and the laboratory staff concurred with these findings on 09/04 /2020 at 16:00 PM.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) from the American Association of Bioanalyst (AAB) the laboratory had unsatisfactory performance and missed proficiency testing for the year 2019. No documentation of corrective actions for the unsatisfactory performance and also with the missed proficiency testing. Findings include: 1. 1st Event of 2019 revealed PCO2 = 80 %. No corrective action for the missed proficiency testing. 2. 2nd Event of 2019 revealed pH and PCO2 = 80 %. No corrective action for the missed proficiency testing. 3. 3rd Event 2019 revealed Bacteriology = 80%. No corrective action for the missed proficiency testing. 3. 3rd event of 2019 revealed pH, PCO2 and PO2 = 0% . No documentation of corrective action taken for the failed proficiency testing.. 4. 3rd Event 2019 Compatibility Testing = 80%. No corrective action for missed proficiency testing. 4. The Director /Chief Nursing Officer and the laboratory staff concurred with these findings on 09/04 /2020 at 16:00 PM.
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. Review of personnel records the laboratory failed to provide

	copies of diplomas or transcript of records of 9 out of 16 new testing personnel (TP) that were hired after the last survey 02/19/2019. 2. Review of personnel records from the Laboratory's point of care respiratory department performing blood gasses revealed 4 out of 4 testing personnel using the ABL 80 Flex CO-Ox radiometer do not have the copies of their diplomas or transcript of records. 3. This deficient practice was cited during the last survey 02/09/2019. This is a repeat deficiency. 2. The Director/Chief Nursing Officer , Respiratory Manager, and the laboratory staff concurred with these findings on 09/04/2020 at 16:00 PM.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, competency and training records, the laboratory failed ensure that testing personnel were competent to perform testing in all specialties and sub specialties of the laboratory. Findings include. 1. There was no procedure for assessing competency for testing personnel. 2. 14 out of 16 testing personnel do not have documentation of their initial training, 6 months, and or annual competency evaluations at the time of survey. 3. 4 out of 4 testing personnel from the Laboratory's point of care respiratory department performing blood gasses do not have documentation of their initial training, 6 months, and annual competency evaluations at the time of survey. 2. The Director/Chief Nursing Officer, the Respiratory Manager, and the laboratory staff concurred with these findings on 09/04 /2020 at 16:00 PM.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manuals and discussion with the staff the new laboratory director did not sign and date the procedure manuals used in the laboratory. Findings include: 1. Review of all procedures manuals revealed that the new laboratory director hired in March 2020 did not sign the following procedure manuals. a. Serology Procedure Manuals. b. Triage Meter Procedure Manuals. c. Urinalysis Procedure Manuals. d. Hematology Procedures Manuals. e. Dimension EXL Chemistry Procedure Manuals. f. I Stat Chemistry and Blood Gas Procedure Manuals. g. Individualized Quality Control Plan (IQCP) Procedure Manuals. 2. The Director/Chief Nursing Officer and the laboratory staff concurred with these findings on 09/04/2020 at 16:00 PM.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES

	CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Base on review of training and competency records and discussion with the staff the Technical Supervisor (TS) failed to assess and document competency testing of the testing personnel. Findings include. 1. 14 out of 16 testing personnel do not have documentation of their initial training, 6 months, and or annual competency evaluations at the time of survey. 2. 4 out of 4 testing personnel from the Laboratory's point of care respiratory department performing blood gasses do not have documentation of their initial training, 6 months, and annual competency evaluations at the time of survey. 2. The Director/Chief Nursing Officer, the Respiratory Manager, and the laboratory staff concurred with these findings on 09/04/2020 at 16:00 PM.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of personnel records and discussion with the staff the laboratory failed to provide copies of diplomas or transcript of records for the testing personnel. Findings include: 1. 9 out of 16 testing personnel do not have copies of their diplomas or transcript of records at the time of survey. 2. 4 out of 4 testing personnel from the Laboratory's point of care respiratory department do not have copies of their diplomas or transcript of records at the time of survey. 3. The Director/Chief Nursing Officer, the Respiratory Manager and the laboratory staff concurred with these findings 09/04 /2020 at 16:00 PM.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)

	(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of personnel records and discussion with the staff the laboratory failed to provide copies of diplomas or transcript of records for the testing personnel. Findings include: 1. 9 out of 16 testing personnel do not have copies of their diplomas or transcript of records at the time of survey. 2. 4 out of 4 testing personnel from the Laboratory's point of care respiratory department do not have copies of their diplomas or transcript of records at the time of survey. 3. The Director/Chief Nursing Officer, the Respiratory Manager and the laboratory staff concurred with these findings 09/04 /2020 at 16:00 PM.