

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0685222	(X3) Date Survey Completed 10/16/2020
Name of Provider or Supplier Lower Umpqua Hospital District Laboratory	Street Address, City, State 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
D6107	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15)</p> <p>The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on the complainant's email statement, the blood bank record review and discussion with staff, the laboratory staff failed to follow the written delegation of duties specified by the laboratory director, signed and dated on June 29, 2020. Findings include: 1. The email sent by Complainant (previous laboratory manager) dated October 15, 2020, stated that a technologist started training a phlebotomist (A) on moderate and complex testing, including blood bank high complexity tests after the previous laboratory manager was placed on administrative leave August 28, 2020. . 2. A phone call Interview with Laboratory Director (LD) on October 16, 2020 at 9 am confirmed that she had not authorized the phlebotomist(A) to be trained in blood bank or work in blood bank. The LD carefully reviewed the blood bank log book for testing activity for the month of September 2020 and found evidence of training documentation, which she had totally missed in her first review of blood bank activities. 3. Evidence of the phlebotomist(A)'s initials were documented on 09/19 /2020 at 1415 with co-sign initials of the medical technologist on blood bank log sheet with a comment "training for MLT Program". 4. The medical technologist was assigned to perform blood bank tests as a high complexity testing personnel however,</p>

there were no responsibilities or duties specified in writing by current laboratory director for providing training to the phlebotomist(A) laboratory staff. 5. The complaint is substantiated.

D6174

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1495(a)

Each individual performs only those high complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.

This STANDARD is not met as evidenced by:

Based on an email from complainant, review of records and interview conducted on an unannounced onsite CLIA investigation, the laboratory staff failed to ensure only Laboratory Director approved individuals with the required degree of skill commensurate with required education training or experience and technical abilities may perform blood bank high complexity tests. findings include: 1. The email sent by Complainant (previous laboratory manager) dated October 15, 2020, stated that a technologist started training a phlebotomist (A) on moderate and complex testing, including blood bank high complexity tests after the previous laboratory manager was placed on administrative leave August 28, 2020. 2. Record review confirmed Blood Bank log sheet entry dated September 19, 2020 at 1415, has documentation of patient ID 0919:BB00001R , specimen ID YAKT 1972, with test results for a type and screen. The blood bank tests, ABO Grouping , Rh Typing and Antibody Detection, were performed and resulted with initials of blood bank technologists, cosigned by phlebotomist(A) on the additional comment documented as "Training for MLT program". 3. On an unannounced onsite CLIA investigation October 1, 2020, record review of the phlebotomist(A) testing personnel's academia, training and competency records and review of the written delegations of duties authorized and signed June 29, 2020 by the current laboratory director, revealed this individual did not qualify as high complexity testing personnel and was not authorized to be trained or to perform blood bank tests. 4. Also, on the unannounced onsite CLIA investigation October 1, 2020 phlebotomist(A) was interviewed at 10:30 am by the CLIA surveyor regarding her assigned laboratory duties. This individual stated that she was trained to perform moderate complexity test by another laboratory manager, but is now only performing waived tests and assigned to phlebotomy . When asked specifically if she worked in blood bank, or was trained in blood bank, phlebotomist(A) clearly stated she is not allowed in blood bank and denied performing blood bank tests. Interviewed concluded at 11:00 am. 5. The complaint is substantiated.