

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  38D0716183	<b>(X3) Date Survey Completed</b>  07/25/2023
<b>Name of Provider or Supplier</b>  St Charles Prineville Laboratory	<b>Street Address, City, State</b>  384 Se Combs Flat Road, Prineville, OR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D6032</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(14)</p> <p>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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and 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 results reporting, and whether consultant or director review is required prior to reporting patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedures and personnel records, the Laboratory Director (LD) failed to ensure a written document designating what each person listed as testing personnel (TP), technical supervisor (TS), technical consultant (TC) or general supervisor (GS) on the CMS 209 form is allowed to perform, train other TP to perform, assess competency in each specialty and report final results. Finding include: 1. During review of the CMS 209 forms submitted to me during survey July 25, 2023 (5 pages) and review of the competency assessments for all TP, no designation of duties by the LD could be produced. 2. The TS and the LD confirmed that no current written document designating who could perform what test(s) and to what degree during interview on July 25, 2023 at approximately 1:30 pm.</p>
<b>D6103</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must ensure that policies and procedures are established for</p>

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 testing personnel (TP) competency records and interview with the Technical Supervisor (TS) and Laboratory Director (LD) during survey July 25, 2023, the LD failed to ensure all TP in the Clinical Laboratory, in the Nursing Department, and in the Radiology Department had competency assessments twice a year in the first year and at least annually after the first year of employment for the testing they were performing on patient specimens. Findings include: 1. During review of TP competency records (TP # 1 - 8) in the Clinical Laboratory, composed of Medical Laboratory Technicians (MLT's) and Medical Laboratory Scientists (MLS's), it was revealed that six (6) out of eight (8) TP had no competency assessments for any testing platform or analyte they routinely perform patient testing on for the year 2022. 2. During review of TP competency records in the Clinical Laboratory (TP #1 - 6) composed of Medical Laboratory Technicians (MLT's) and Medical Laboratory Scientists (MLS's), it was revealed that five (5) out of six (6) TP had no competency assessments for any testing platform or analyte they routinely perform patient testing on for the year 2023 to date. 3. During review of the nursing personnel competency records who routinely use and report patient results using the moderately complex iSTAT instrument by Abbott Laboratories, it was revealed that seven (7) out of eight (8) Registered Nurses (RN's) had no competency assessments for tests they routinely perform in 2022 or 2023 to date. 4. During review of the Radiology personnel who perform Creatinine testing for suspect stroke patients using the moderately complex iStat instrument by Abbott Laboratories, it was revealed that five (5) out of five (5) Radiology TP had no competency assessments for 2022 or 2023 to date. 5. Interview with the TS, TP#5 and LD conducted at approximately 1400 during survey on 07/25 /2023 confirmed that there were no competency assessments conducted in the year 2022 and 2023 to date for any of the above TP. 6. The laboratory reports performing 536,215 tests on human bodily fluid specimens in the year 2022 and 351,750 tests on human bodily fluid specimens in the year 2023 to date.