

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0407998	(X3) Date Survey Completed 09/13/2024
Name of Provider or Supplier Creekside Medical Clinic	Street Address, City, State 2822 Jackson Blvd Suite 101, Rapid City, SD	
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
D0000	A recertification survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 9/13/24. Creekside Medical Clinic laboratory was found not in compliance with the following requirements: D6051, D6052, and D6053.
D6051	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the technical supervisor failed to assess staff competency through the testing of blind samples or external proficiency testing (PT) samples on the Frened chemistry analyzer for one of two testing personnel (LPN A) in 2023 and through the date of the survey. Assessment of blind testing of specimens and /or external proficiency testing samples helps ensure competency of staff to accurately report patient test specimens. Findings include: 1. Review on 9/13/24 of the laboratory's Laboratory Personnel Report (CLIA) (Clinical Laboratory Improvement Amendment) (Centers for Medicare and Medicaid Services form 209) revealed LPN A was listed as laboratory testing personnel. Review on 9/13/24 at 1:20 p.m. of the laboratory staff's competency assessment records revealed: *Licensed Practical Nurse (LPN) A's 2024 annual competency evaluation had been completed on 4/8/24. *In the area of "Assessment of test performance through testing previously analyzed specimens, internal blind testing sample or external proficiency testing Samples" had been documented as "No". *A request had been made for any other documentation of testing of blind testing samples. No additional documentation had been provided for review by the end of the survey. Interview on 9/13/24 at 1:20 p.m. with testing personnel B revealed, she confirmed: *She had completed LPN A's 2024 annual competency assessment. *LPN A had been trained to perform patient testing on the</p>

Frend analyzer. *Prostate specific antigen, total 25-hydroxy Vitamin D, and thyroid stimulating hormone levels had been processed on the Frend analyzer. *LPN A had been "back-up" testing personnel and only performed patient testing on the Frend analyzer on rare occasions. *LPN A had not participated in PT testing for any of the analytes reported from the Frend chemistry analyzer in in 2023 through the date of the survey. *LPN A had not run any other blind testing specimens for any of the analytes reported from the Frend analyzer in in 2023 and through the date of the survey. *She agreed it was important to assess staff competency to perform testing correctly, especially when the individual performed testing so infrequently.

D6052

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(vi)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.

This STANDARD is not met as evidenced by:
Based on record review and interview, the technical consultant failed to ensure annual staff competency assessments included assessment of problem solving skills for one of one laboratory staff (LPN A) in 2023and through the date of the survey. Assessment of problem solving skills helps ensure staff are able to recognize and correct issues with laboratory testing, before patent test results are reported. Findings include: 1.Review on 9/13/24 of the laboratory's Laboratory Personnel Report (CLIA) (Clinical Laboratory Improvement Amendment) (Centers for Medicare and Medicaid Services form 209) revealed LPN A was listed as laboratory testing personnel. Review on 9/13/24 at 1:20 p.m. of the laboratory staff's competency assessment records revealed: *Licensed Practical Nurse (LPN) A's 2024 annual competency evaluation had been completed on 4/8/24. * In the area of "Assessment of problem solving skills" had been documented as "No". *A request had been made for any other documentation of problem solving skills. No additional documentation had been provided for review before the end of the survey. Interview on 9/13/24 at 1:20 p.m. with testing personnel B revealed, she confirmed: *She had completed LPN A's 2024 annual competency assessment. *She had not documented any problem solving skills as LPN A had been "back-up" testing personnel and only performed patient testing on the Frend analyzer on rare occasions. *She agreed it was important to assess competency to perform testing correctly, especially when the individual performed testing so infrequently.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on record review and interview, the technical consultant failed to ensure one of two laboratory personnel (testing personnel B) had received two competency assessments during their first year of patient testing for the test methods they had been performing under the laboratory's Clinical Laboratory Improvement Amendment certificate. Competency assessment helps to ensure staff are able to correctly process

and accurately report patient test specimens. Findings include: 1. Review on 9/13/24 at 1:20 p.m. of the laboratory's employee competency assessments for testing personnel B revealed: *She had started testing patient specimens in April 2023. *There had been documentation of an initial competency assessment performed in April 2023. *Her annual competency assessment had been completed by laboratory director C on 9/8/24. *A request had been made for any other competency assessment documentation performed since April 2023. No additional documentation had been available for review by the end of the survey. Interview on 9/13/24 at 3:45 p.m. with laboratory director C revealed: *He had completed testing personnel B's 2024 annual competency assessment on 9/8/24. *He confirmed a second competency assessment had not been completed within testing personnel B's first year of patient testing. *He stated, "I'll take the hit for that one."