| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 35D0409114 | 07/10/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| West River Health Services New England Clinic | 820 2nd Ave W, New England, ND | |

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 |
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| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review, staff interview, and policy review, the laboratory failed to twice annually verify the accuracy of 2 of 2 non-regulated analytes (wet preparation and urine microscopic examination) in 2022. The laboratory performed approximately seven wet preparations and 90 urine microscopic examination patient tests in 2022. Findings include: 1. Reviewed at 12:15 p.m. on 07/10/23, the laboratory's test menu listed wet preparations and urine microscopic examinations available for patient testing. 2. Reviewed at 12:20 p.m. on 07/10/23, the 2022 proficiency testing records indicated the laboratory did not participate in proficiency testing for wet preparations and urine microscopic examinations. 3. Reviewed at 12:30 p.m. on 07/10/23, the 2022 verification records failed to include evidence of a second accuracy verification in 2022 for wet preparations and urine microscopic examinations. 4. Upon request, the laboratory failed to provide evidence of a second accuracy verification in 2022 for wet preparations and urine microscopic examinations. 5. During interview at 1:05 p.m. on 07/10/23, the laboratory director (#1) confirmed the laboratory performed patient testing for wet preparations and urine microscopic examinations in 2022 and did not verify the accuracy of these tests a second time in 2022. 6. Review of the following policies/procedures occurred on 7/10/23: - "Wet Mount," dated 01/01/97, stated, ". . . Quality Control for outlying clinics: Quality Control . . . will be checked at least twice a year by reviewing and identifying photos from proficiency surveys with known results. The Laboratory Technical consultant will provide the survey photos and evaluate for correct identification. . . ." - "Urine Microscopic Examination Procedure," dated 02/08/93, stated, ". . . Quality Control . . . will be checked at least twice a year by reviewing and identifying photos from proficiency surveys with known results. |

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| | The Laboratory Technical consultant will provide the survey photos and evaluate for correct identification. . . ." |