A CLIA recertification survey conducted on January 7, 2019 found Red River Women's Clinic laboratory in compliance with all applicable parts of 42 CFR, Part 493, The Clinical Laboratory Improvement Amendments.
DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES
AND PLAN OF CORRECTION

(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:
35D0946316

(X2) MULTIPLE CONSTRUCTION
A. BUILDING 
B. WING 

(X3) DATE SURVEY COMPLETED
02/07/2017

NAME OF PROVIDER OR SUPPLIER
RED RIVER WOMEN'S CLINIC

STREET ADDRESS, CITY, STATE, ZIP CODE
512 1ST AVE N
FARGO, ND 58102

(X4) ID PREFIX TAG

SUMMARY STATEMENT OF DEFICIENCIES
(EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)

ID PREFIX TAG PROVIDER'S PLAN OF CORRECTION
(EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)

(X5) COMPLETION DATE

D 000 INITIAL COMMENTS

D 000

A CLIA recertification survey conducted on February 7, 2017 found Red River Women's Clinic laboratory in compliance with all applicable parts of 42 CFR, Part 493; The Clinical Laboratory Improvement Amendments.

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.
D 000 INITIAL COMMENTS

A CLIA recertification survey conducted on February 19, 2015 found Red River Women's Clinic laboratory in compliance with all applicable parts of 42 CFR, Part 493; The Clinical Laboratory Improvement Amendments.
## Statement of Deficiencies and Plan of Correction

### RED RIVER WOMEN'S CLINIC

<table>
<thead>
<tr>
<th>ID PREFIX TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
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<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
<th>COMPLETION DATE</th>
</tr>
</thead>
</table>
| D6054         | 493.1413(b)(9) TECHNICAL CONSULTANT RESPONSIBILITIES  
- The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.  
- This STANDARD is not met as evidenced by:  
  - Based on record review, policy review, and staff interview, the laboratory failed to ensure a technical consultant evaluated and documented annual competency evaluations in 2011-2012 for 3 of 5 testing personnel sampled (Testing Personnel #2, #3, and #4). Failure to evaluate testing personnel annually limits the laboratory's ability to ensure testing personnel perform patient testing accurately.  
  - Findings include:  
    1. Reviewed at approximately 3:55 p.m. on 04/01/13, the 2011-2013 patient testing logbook revealed the following testing personnel performed patient testing:  
       - Testing Personnel #2 in 2012  
       - Testing Personnel #3 in 2011-2012  
       - Testing Personnel #4 in 2011  
    2. Reviewed at approximately 4:20 p.m. on 04/01/13, the 2011-2012 testing personnel competency evaluations failed to include Testing Personnel #2, #3, and #4.  
    3. Reviewed at approximately 4:30 p.m. on 04/01/13, the policy "Lab Personnel," dated 06/04/07, stated, ". . . All personnel performing moderate complexity tests shall be evaluated semi-annually in the first year, then annually |
| D6054         | 1. The test processes found to be deficient will be corrected by annually evaluating all testing personnel, including personnel #2, #3 & #4 (physicians).  
2. Other test systems having the potential to be affected will be identified by including physicians as testing personnel in the future. Any new physicians will be deemed testing personnel & included in the annual competency evaluation.  
3. The measures to be put into place will be to include physicians as testing personnel when conducting the Quarterly Quality Assurance Review.  
4. No corrective actions need to be taken for patients.  
5. The deficiency will be corrected by May 7th, 2013. All testing personnel will have been present & evaluated by that date.  
6. The facility will monitor the effectiveness of its corrective action by including physicians in testing personnel. The Quarterly Quality Assurance Review will include physicians as testing personnel -- and the Quarterly Quality Assurance Review will be the tool used to ensure that the testing is done annually on ALL testing personnel. |

**LABORATORY DIRECTORS OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE**

*Signature*

**DATE**

*Date*

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Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting provided the institution demonstrates that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are based on data collected following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are due within 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction should be obtained within 14 days.
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<tr>
<td>D6054</td>
<td>Continued From page 1 thereafter . . . &quot; 4. During interview at approximately 4:40 p.m. on 04/01/13, Personnel #1 confirmed the laboratory did not perform annual competency evaluations of Testing Personnel #2, #3, and #4.</td>
<td>D6054 7. The Technical Consultant and Clinic Director will monitor the corrective action quarterly and yearly.</td>
</tr>
</tbody>
</table>
#### INITIAL COMMENTS

A CLIA recertification survey conducted on April 26, 2011 found Red River Women's Clinic laboratory in compliance with all applicable parts of 42 CFR, Part 493; The Clinical Laboratory Improvement Amendments.