

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D0405629	<b>(X3) Date Survey Completed</b>  08/19/2022
<b>Name of Provider or Supplier</b>  Centracare - Redwood	<b>Street Address, City, State</b>  101 Caring Way, Redwood Falls, MN	
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>D5421</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by:                      . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to complete a performance verification (PV) for one non-waived test implemented by the laboratory in 2021. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:10 a.m. on 08/19/22. 2. A MedTox Diagnostics MedToxScan Profile-V device was observed as present and available for use during the tour of the laboratory. Urine Drug Screens (UDS) were performed on this analyzer. 3. PV documentation for UDS on the MedToxScan Profile-V device was not found during review of laboratory records. The laboratory was unable to provide a PV upon request. 4. A PV procedure was not found during review of laboratory procedure manuals. 5. The GS stated the device was put into use in March 2021 and indicated a total of 953 UDS tests were performed on the MedToxScan Profile-V device from implementation to date of survey, 08/19/22. See below Year Number of tests 2021 650 2022 303 6. In an interview at 11:40 a.m. on 08/19/22, the GS confirmed the above finding. .</p>
<b>D6120</b>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> CFR(s): 493.1451(b)(7)(8)</p>

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the Technical Supervisor failed to ensure comprehensive initial training for four of five new testing personnel was performed and documented in 2021. Findings are as follows: 1. The laboratory performed Microbiology, Immunology, Chemistry, and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:10 a.m. on 08/19/22. 2. The following tests were performed by the laboratory as indicated by the GS during the tour: Gram stain (GS) KOH microscopic examination (KOH) Vaginal wet preparation examination (VWP) Amnisure ROM (ROM) MedToxScan Profile-V urine drug screen (UDS) Manual differential (Diff) Manual cell count (CC) 3. Competency evaluation of all personnel was required as established in the Job Competence Verification procedure found in the Laboratory Policy Manual. 4. Initial training documentation was not found during review of personnel records for the following testing personnel (TP): TP3, TP4, TP5, TP7. See below Test TP missing training records GS TP4, TP7 KOH TP3, TP4, TP5, TP7 VWP TP3, TP4, TP5, TP7 ROM TP4UDS TP7Diff TP3, TP4, TP5CC TP3, TP4, TP5 5. The laboratory was unable to provide the missing training records upon request. 6. In an interview at 11:30 am., the GS confirmed the above finding. .

**D6127**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(9)

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

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the Technical Supervisor failed to complete comprehensive competency assessments at least semi-annually during the first year of patient specimen testing for four of five testing personnel hired in 2021. Findings are as follows: 1. The laboratory performed Microbiology, Immunology, Chemistry, Hematology, and Immunohematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:10 a. m. on 08/19/22. 2. The following non-waived test systems, analyzers, devices and test kits were present and available for use during the tour: Siemens Dimension EXL 200 chemistry analyzer Siemens EPOC blood gas analyzer MedTox Profile-V urine drug screen analyzer Abbott Cell-Dyn Ruby hematology analyzer Beckman Coulter ACT 5diff hematology analyzer Sysmex CA-600 coagulation analyzer Quidel Triage Meter Pro chemistry analyzer Adeza T-Li System chemistry analyzer Gram stain microbiology test system Bio-Rad Immunohematology test system Microscopes for microscopic examinations Amnisure ROM test kit Serum hCG test kit 3. Competency evaluation of all personnel was required as established in the Job Competence Verification procedure found in the Laboratory Policy Manual. 4. Initial training was

performed and documented for the following Testing Personnel (TP) as indicated in personnel records: TP Initial training dates TP3 January-March 2021 TP4 April-September 2021 TP5 May-August 2021 TP6 March-May 2021 5. Semi-annual competency assessment documentation was not found in personnel records as listed below: TP3 - Direct Observation of test performance was not found in the semi-annual competency assessment TP4 - No semi-annual competency assessment documentation was found TP5 - Direct Observation of test performance was not found in the semi-annual competency assessment TP6 - No semi-annual competency assessment documentation was found 6. The laboratory was unable to provide the missing documents upon request. 7. In an interview at 11:35 a.m. on 08/19/22, the GS confirmed the above finding. .

**D6128**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:  
. Based on observation, document review, and interview with laboratory personnel, the Technical Supervisor failed to assess competency at least annually for three of three tenured Microbiology testing personnel in 2021. Findings are as follows: 1. 1. The laboratory performed Microbiology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:10 a.m. on 08/19/22. 2. KOH microscopic examination (KOH) and Vaginal wet preparation examination (VWP) was performed by the laboratory as indicated by the GS during the tour. An Olympus BX43 microscope was present and available for use during the tour. 3. Competency evaluation of all personnel was required as established in the Job Competence Verification procedure found in the Laboratory Policy Manual. 4. Annual competency assessment documentation for the above tests was not found during review of 2021 laboratory records for the following Testing Personnel (TP): GS, TP1, TP2. 5. The laboratory was unable to provide the missing records upon request. 6. In an interview at 11:35 am. on 08/19/22, the GS confirmed the above finding. .