

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0405983	(X3) Date Survey Completed 09/27/2018
Name of Provider or Supplier Centracare Melrose	Street Address, City, State 525 Main St W, Melrose, MN	
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
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to ensure microscopic examination proficiency testing was performed consistent with the number of times the laboratory routinely tested patient samples. Findings are as follows: 1. The laboratory performed Microbiology, Chemistry, and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 09/27/18 at 8:10 a.m. 2. The laboratory performed proficiency testing (PT) using the American Proficiency Institute (API) proficiency testing provider. 3. Microscopic examination PT for Blood Cell Identification, Urine Sediment, Fern Test, Sperm presence/absence, Vaginal Wet Preparation and Vaginal Wet Preparation (KOH) from the API 2017 and 2018 events were completed by multiple testing personnel as indicated on Competency Assessment forms. See below where x indicates the testing personnel completed the microscopic examination PT for that event. Event Testing Personnel 1 2 3 4 5 6 2017-1 x x x x x 2017-2 x x x 2017-3 x x x x x 2018-1 x x x x x x 2018-2 x x x x x x 4. In an interview on 09/27/18 at 10:45 a.m., the GS confirmed the PT had been performed by multiple testing personnel prior to the submission date deadline and patient specimens would not routinely be handled in this manner.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p>

This STANDARD is not met as evidenced by:
 . Based on document review and interview with laboratory personnel, the laboratory failed to evaluate unacceptable proficiency testing (PT) results. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 09/27/18 at 8:10 a.m. 2. The laboratory performed PT using the American Proficiency Institute (API) PT provider. 3. The laboratory received unacceptable PT results from API in Hematology as listed below. Event Sample Test Lab API result 2018-1 PNT-03 Mono* 1.8 0.0-1.5 2018-2 PNT-06 Mono 5.8 0.0-5.5 4. An evaluation of the unacceptable PT results was not found during review of laboratory records. The laboratory was unable to provide evaluations upon request. 5. In an interview on 09/27/18 at 11:30 a.m., the GS confirmed a documented evaluation of the unacceptable results was not performed. * Note Mono - Monocytes

D5213

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
 CFR(s): 493.1236(b)(1)

The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:
 . Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of non-graded proficiency testing (PT) results. Findings are as follows: 1. The laboratory performed Microbiology and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 09/27/18 at 8:10 a.m. 2. The laboratory performed PT using the American Proficiency Institute (API) PT provider. 3. The laboratory received non-graded results from API due to no consensus in Microbiology and Hematology for the events and tests listed below. The Data Summaries from API with the expected results for these tests were not included in the laboratory's records. Event Sample ID Test 2017-2 UA-03 Urobilinogen 2017-2 UR-06 Susceptibility 2018-1 BCI-01 Blood Cell Identification 2018-2 BCI-10 Blood Cell Identification 2018-2 UR-06 Susceptibility 4. An evaluation of the non-graded PT results was not found during review of laboratory records. The laboratory was unable to provide evaluations upon request. 5. In an interview on 09/27/18 at 11:30 a.m., the GS confirmed an evaluation of the non-graded PT results was not performed.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
 CFR(s): 493.1236(c)(1)

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.

This STANDARD is not met as evidenced by:
 . Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of a non-regulated analyte at least twice annually. Findings are as follows: 1. The laboratory performed Tick Identification testing as confirmed by the General Supervisor during a tour of the laboratory on 09/27/18 at 8:10 a.m. 2. Twice annual verification of accuracy documents for Tick Identification

were not found during review of laboratory proficiency testing records from 2017 through date of survey, 09/27/18. The laboratory was unable to provide verification of accuracy documents upon request. 3. In an interview on 09/27/18 at 12:50 p.m., the GS confirmed the accuracy of Tick Identification testing had not been verified in 2017 or 2018.

D5431

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(2)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the laboratory failed to ensure functions checks for a Chemistry analyzer were performed and documented as required. Findings are as follows: 1. The laboratory performed Chemistry as confirmed by the General Supervisor (GS) during a tour of the laboratory on 09/27/18 at 8:10 a.m. 2. An i-STAT system was observed as present and available for use during the tour. 3. Twice annual verification of the i-STAT thermal probe was required as indicated in the manufacturer's operator's manual provided by the laboratory. 4. The thermal probe check was performed and documented on one occasion, on 05/21/18, in the January 2017 to September 2018 time frame as indicated in laboratory records. Documentation of other maintenance activities performed on 01/13/17, 05/24/17, and 11/23/17 were found but the thermal probe check was not included. 5. In an interview on 09/27/18 at 3:30 p.m., the GS confirmed the above finding. In emails received on 10/04/18 and 10/05/18, the GS indicated the thermal probe checks had been performed but were not documented.

D6045

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(7)

(b) The technical consultant is responsible for-- (b)(7) 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;

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the technical consultant failed to ensure all Microbiology training for new testing personnel was documented. Findings are as follows: 1. The laboratory performed Trichomonas, Gardnerella vaginalis and yeast testing using the BD Affirm Microbial Identification system under the specialty of Microbiology as confirmed by the General Supervisor (GS) during a tour of the laboratory on 09/27/18 at 8:10 a.m. 2. BD Affirm Microbial Identification system training and initial competency documents for 1 of 1 new testing personnel were not found during review of the laboratory's records. The laboratory was unable to provide the documents upon request. 3. In an interview on 09/27/18 at 9:00 a.m, the GS confirmed BD Affirm Microbial Identification system training was not documented for the new testing personnel.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(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 document review and interview with laboratory personnel, the technical consultant (TC) failed to evaluate testing personnel for competency in all moderately complex test procedures performed by the laboratory in 2017. Findings are as follows:

1. The laboratory performed Trichomonas, Gardnerella vaginalis and yeast testing using the BD Affirm Microbial Identification system under the specialty of Microbiology as confirmed by the General Supervisor (GS) during a tour of the laboratory on 09/27/18 at 8:10 a.m.
2. Review of personnel records indicated 5 of 5 testing personnel were not evaluated for competency on the BD Affirm Microbial Identification system in 2017. The laboratory was unable to provide the missing competency assessment documents upon request.
3. In an interview on 09/27/18 at 9:25 a.m., the GS confirmed the above findings.