

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0400666	(X3) Date Survey Completed 08/03/2022
Name of Provider or Supplier Centracare - Monticello Hospital	Street Address, City, State 1013 Hart Blvd, Monticello, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Laboratory Director (LD) failed to attest to the integration of proficiency testing samples into the routine patient workload on three of six occasions reviewed from 2022. 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 8:15 a.m. on 08/03/22. 2. The laboratory performed proficiency testing (PT) using the American Proficiency Institute (API) PT provider. 3. The LD's signature was required on the attestation statements for all PT events as indicated in the Proficiency Testing Process procedure found in the electronic procedures General Folder. 4. The Laboratory Director failed to sign the attestation statement for three of six API PT events reviewed in the January 2022 through June 2022 timeframe. See below. Event Specialty missing attestation 2022-1 Microbiology 2022-1 Chemistry (miscellaneous) 2022-1 Immunohematology 5. In an interview at 11:30 a.m. on 08/03/22, the GS confirmed the above finding. .</p>
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>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.</p>

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 from a regulated Specialty when the PT program did not evaluate or score the results in one of six events reviewed from 2022. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:15 a.m. on 08/03/22. 2. The laboratory performed PT using the American Proficiency Institute (API) PT provider. 3. Evaluation of non-graded PT results was required as indicated in the Proficiency Testing Process procedure found in the electronic procedures General Folder. 4. The following PT results from the 2022 Microbiology first event were not graded by API: CSF Culture MIC/Zone Diameter Value Sample SF-01 for 9 antibiotics API instructed to See Data Summary Gram Stain Sample GS-05 API instructed to See Data Summary Urine Culture MIC/Zone Diameter Value Sample UR-06 for 12 antibiotics API instructed to See Data Summary 5. The API Data Summary for the 2022 Microbiology first event was not present in laboratory records. An evaluation of the non-graded results was not found in laboratory records. 6. The laboratory was unable to provide an evaluation of the non-graded results upon request. 7. In an interview at 11:30 a.m. on 08/03/22, the GS confirmed the above finding. .

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 observation, document review, and interview with laboratory personnel, the Technical Consultant failed to ensure comprehensive initial training for four of four new testing personnel was performed and documented in 2022. 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 8:15 a.m. on 08/03/22. 2. The following non-waived analyzers, systems, and test kits were present and available for use during the tour: Biomerieux BacT/Alert microbial detection system Radiometer ABL 80 - blood gas analyzer Abbott Architect - chemistry analyzer Abbott i-STAT analyzer (back-up) Biomerieux Vidas - chemistry analyzer MedTox Diagnostics MedToxScan - chemistry analyzer Hologic TliQ - chemistry analyzer Werfen ACL TOP - coagulation analyzer Sysmex XT-4000i - hematology analyzer Sysmex XP-300 hematology analyzer (back-up) Polymedco Sedimat 13 hematology analyzer Bio-Rad gel cards, IH incubator, IH centrifuge - immunohematology system Serum hCG, Amnisure ROM test kits Microscopes - manual differential, body fluid count, urine sediment, vaginal wet preparation, KOH preparation, gram stain 3. Competency assessment of new testing personnel was required before testing specimens independently as established in the Laboratory Competency Assessment procedure found in the electronic procedures General Folder. 4. Four new testing personnel (TP) were hired in 2022 in the following timeframes as indicated by the GS at 12:20 p.m. on 08/03/22: TP5 - March 2022 TP6 - May 2022 TP7 - April 2022 TP8 - May 2022 5. Initial training documents for the new TP were not found in laboratory records as

indicated below. TP5 - TliQ, i-STAT, MedToxScan, Vidas, Architect TP6 - None found TP7 - None found TP8 - Serum hCG, Amnisure, TliQ, body fluid count, vaginal wet preparation, gram stain, BacT/Alert, ABL 80, i-STAT, Architect, Vidas Incomplete initial training documents were found in laboratory records as indicated below. TP5 - Immunohematology TP8 - Manual differential, immunohematology 7. The laboratory was unable to provide the missing training records upon request. 8. In an interview at 12:45 p.m. on 08/03/22, the GS confirmed the above finding. .

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 observation, document review, and interview with laboratory personnel, the Technical Consultant failed to assess competency at least semi-annually during the first year of patient specimen testing for one of one 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 8:15 a.m. on 08/03/22. 2. The following non-waived analyzers, test systems, and test kits were present and available for use during the tour: Biomerieux BacT/Alert microbial detection system Radiometer ABL 80 - blood gas analyzer Abbott Architect - chemistry analyzer Abbott i-STAT analyzer (back-up) Biomerieux Vidas - chemistry analyzer MedTox Diagnostics MedToxScan - chemistry analyzer Hologic TliQ - chemistry analyzer Werfen ACL TOP - coagulation analyzer Sysmex XT-4000i - hematology analyzer Sysmex XP-300 hematology analyzer (back-up) Polymedco Sedimat 13 hematology analyzer Bio-Rad gel cards, IH incubator, IH centrifuge - immunohematology system Serum hCG, Amnisure ROM test kits Microscopes - manual differential, body fluid count, urine sediment, vaginal wet preparation, KOH preparation, gram stain 3. Competency assessment of new testing personnel was required six months post-hire as established in the Laboratory Competency Assessment procedure found in the electronic procedures General Folder. 4. Initial training was performed and documented for Testing Personnel 4 (TP4) in October and November 2021 as indicated in personnel records. 5. Semi-annual competency assessment documents for TP4 were not found during review of laboratory records. 6. The laboratory was unable to provide the missing documents upon request. 7. In an interview at 12:45 p.m. on 08 /03/22, the GS confirmed the above finding. .