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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>24D0403629 | <b>(X3) Date Survey Completed</b><br><br>07/18/2018 |
| <b>Name of Provider or Supplier</b><br><br>Community Memorial Hospital   | <b>Street Address, City, State</b><br><br>512 Skyline Blvd, Cloquet, 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>  |
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| <b>D5775</b>              | <p>COMPARISON OF TEST RESULTS<br/>CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by:<br/>. Based on observation, document review and interview with laboratory personnel, the laboratory failed to establish a system to evaluate and define the relationship between test results obtained from different analyzers or methodologies at least twice annually. Findings are as follows: 1. The laboratory performed Chemistry (Toxicology) and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 07/18/18 at 8:05 a.m. 2. The following items were observed and available for use during the tour of the laboratory. -Two MEDTOXScan Drugs of Abuse Test System toxicology analyzers -Sysmex XT-4000i hematology analyzer with automated differentials -Stain set up for manual differentials 3. The GS indicated the laboratory used the following test system for Chemistry and Hematology back up testing. -epoc Blood Analysis System 4. The laboratory's procedure manuals did not include a system to define and evaluate the relationship between test results obtained from different test methodologies or analyzers at least twice annually. Documentation of such an evaluation was not found during review of laboratory records. 5. In an interview on 07/18/18 at 5:00 p.m., the GS confirmed the laboratory did not have a system in place to evaluate the relationship between test results obtained from different analyzers or methodologies.</p> |
| <b>D6120</b>              | <p>TECHNICAL SUPERVISOR RESPONSIBILITIES<br/>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 document review and interview with laboratory personnel, the technical supervisor failed to ensure testing personnel (TP) received competency assessments for all test procedures performed in 2016 and 2017. 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 07/18/18 at 8:05 a. m. 2. Competency assessment documents for 9 of 9 TP in 2016 and 10 of 10 TP in 2017 did not include a complete evaluation of the following items. Analyzers - bioMerieux Vidas -MEDTOXScan -Biosite Triage Microscopic Examinations - Potassium Hydroxide -Vaginal wet preparations -Manual Differentials Kit tests - Amnisure Rupture of Fetal Membranes -OSOM hCG serum pregnancy test 3. The laboratory was unable to provide the missing competency documents upon request. 4. In an interview on 07/18/18 at 10:30 a.m., the GS confirmed a complete evaluation of the above items was not included in the 2016 and 2017 competency assessments.