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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>24D0951390             | <b>(X3) Date Survey Completed</b><br><br>08/21/2023 |
| <b>Name of Provider or Supplier</b><br><br>Minnesota Oncology - Burnsville   | <b>Street Address, City, State</b><br><br>675 Nicollet Blvd, Suite 100, Burnsville, 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>D5421</b>              | <p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br/>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:<br/>                     . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to complete a reportable range verification for one of one non-waived test systems implemented by the laboratory in 2022. Findings are as follows:<br/>                     1. The laboratory performed Chemistry testing as confirmed by Technical Supervisor 3 (TS3) during a tour of the laboratory at 10:10 a.m. on 08/21/23. 2. An Abbott i-STAT analyzer was observed as present and available for use during the tour of the laboratory. Testing using the CHEM8+ panel cartridge on this analyzer was implemented in July 2022 as indicated by Technical Supervisor 1 and confirmed in laboratory records. 3. Reportable range verification documentation for CHEM8+ testing on the i-STAT was not found during review of the laboratory's New Instrument Validation Studies for the i-STAT located in the 2023 QC Logs: i-STAT and Coagulation manual. The laboratory was unable to provide CHEM8+ reportable range verification records upon request. 4. The New Instrument Validation for the I-STAT &amp; Hema Jr. Signature + and Signature Elite procedure did not include instruction to perform reportable range verification. 5. In an interview at 12:50 p.m. on 008/21/23, TS1 confirmed the above finding. .</p> |