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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>14D2109810             | <b>(X3) Date Survey Completed</b><br>01/09/2018 |
| <b>Name of Provider or Supplier</b><br>North Naperville Immediate Care   | <b>Street Address, City, State</b><br>1804 N. Naper Blvd Suite 111, Naperville, IL |   |
| 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><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b><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 review of laboratory records and interviews with laboratory personnel; the laboratory failed to demonstrate it can obtain performance specifications established by the manufacturer for troponin I testing on I-Stat analyzer. Findings Include: 1. During tour of the laboratory facility on 01-09-2018, with TC#1 at 11:35 am, TC#1 confirmed the facility began testing for troponin I on the I-Stat analyzer, serial number 382618, on 03-01-2017. 2. Review of verification of performance documentation provided by TC#1 for troponin I testing on the I-Stat analyzer failed to document the accuracy and precision of troponin I testing prior to use for patient testing. 3. On survey date 01-09-2018, at 1:35 pm, the above findings were confirmed by TC#1 and TC#2.</p> |
| <b>D5447</b>              | <p><b>CONTROL PROCEDURES</b><br/>CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--<br/>At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different</p>   |

concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interviews with laboratory personnel; the laboratory failed to ensure two levels of quality control (QC) materials were ran each day of testing before reporting patient test results for troponin I on the I-Stat analyzer. Findings include: 1. Interview with TC#1 at 11:35 am, on 01-09-2018, confirmed quality controls for troponin I testing on the I-Stat analyzer are performed with each lot/shipment and every 30 days. 2. Interview with TC#2 at 12:25 pm on 01-09-2018 confirmed no Individual Quality Control Plan was in place for troponin I testing on the I-Stat analyzer. 3. Review of patient testing performed on the I-Stat analyzer found that two levels of control materials were not documented each day of testing for troponin I for 3 of 4 dates reviewed when patient test results were reported. Patient Identification Test Date QC Ran Date T1 12-21-2017 12-08-2017 T3 05-01-2017 04-07-2017 T4 12-29-2017 12-08-2017 4. On survey date 01-09-2018, at 1:35 pm, TC#1 and TC#2 confirmed that two levels of quality control material were not performed each day of patient testing for troponin I on the I-Stat analyzer.