| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number**<br><br>34D0981573 | **(X3) Date Survey Completed**<br><br>12/18/2018 |
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| **Name of Provider or Supplier**<br><br>Novant Health Kernersville Family Medicine | **Street Address, City, State**<br><br>291 Broad Street, Kernersville, NC | |
| 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** |
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| **D5437** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(a)<br><br>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of manufacturer's instructions, review of the laboratory's policies and procedures, review of 2016, 2017, and 2018 Vitros 250 calibration records, and interview with TP (testing personnel) 12/18/18, the laboratory failed to perform and document calibration at least once every six months as required. The Vitros 250 Chemistry System Operator's Manual states on page 6-1 "6 Calibrating You must properly calibrate all tests performed by the analyzer using Vitros calibrators along with Vitros Slides. ... You should calibrate every six months ..." The laboratory's procedure manual states "... Frequency of Calibration ... Calibration or calibration verification must be performed at least once every 6-months. ..." Review of 2016, 2017, and 2018 Vitros 250 calibration records revealed the laboratory failed to perform and document calibration at least once every six months for the following analytes: 1. albumin - calibration performed 6/27/16, 2/3/17, 2/14/17, 6/14/17, 3/16/18; 2. alkaline phosphatase - calibration performed 12/29/16, 2/7/17, 6/27/17, 3/9/18; 3. BUN (blood urea nitrogen) - calibration performed 12/14/16, 1/27/17, 2/27/17, 6/28/17, 2/27/18; 4. total bilirubin - calibration performed 11/18/16, 2/14/17, 4/3/17, 8/4 |

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| | /17, 6/11/18; 5. total protein - calibration performed 12/29/16, 2/3/17, 5/12/17, 6/14 /17, 8/4/17, 5/18/18. During interview at approximately 3:15 p.m., TP #1 stated that Vitros 250 calibrations are performed when the slide lot number changes. She stated that they did not realize that some of the calibrations were performed at intervals that exceeded six months. |