

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D1092530	(X3) Date Survey Completed 10/24/2019
Name of Provider or Supplier Clinical Molecular Profiling Core	Street Address, City, State 37 Convent Drive Room 6138/6144, Bethesda, MD	
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
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director (LD) and Testing person (TP), the laboratory failed to calibrate the Rees continuous temperature monitoring system. The findings include: 1. There were no available records for the calibration of the Rees continuous temperature monitoring system. 2. Calibration materials for temperature monitoring are available in the form of certified National Institute for Standards and Technology (NIST) thermometers. 3. During the exit interview on October 24, 2019 at approximately 12:15pm, The LD and TP confirmed that the laboratory had not calibrated the temperature monitoring system.</p>
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b),</p>

which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b) (1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on record review of the Rees Scientific temperature reading graph, and interview with the laboratory director (LD) and testing person (TP), the laboratory failed to document corrective actions for the out-of-range room temperatures for the month of June 2019. The findings include: 1. Laboratory records showed temperatures above the acceptable range of 18.0- 25.0 degrees on the Rees Scientific Input Room Temp chart for the month of June 2019 on 3 out of 30 days. 2. During an interview on October 24, 2019 at 11:59am, CMS surveyor asked "Would you be able to provide the documentation of corrective action for the out of range temperature". TP stated " We don't have one" 3. During the exit interview on the October 24, 2019 at approximately 12:15 pm. The LD and TP confirmed the lack of corrective action documentation of the temperature range

D6123

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on record review of the Rees Scientific temperature reading graph and interview conducted with the laboratory director (LD) and testing person (TP), the laboratory technical supervisor failed to ensure preventative maintenance records were reviewed and signed monthly for both the refrigerator temperature chart and room temperature tracking chart for the month June 2019. The findings include: 1. The Rees Scientific temperature reading graph showed an absence of signature from the laboratory technical supervisor on the Rees Scientific temperature reading graph. 2. During an interview on October 24, 2019 at 11:55am, CMS surveyor asked "which staff member verifies the temperature charts." TP stated the lab personnel for another laboratory under a different CLIA number that shares the fridge verifies and initial the chart. 3. During the exit interview on October 24, 2019 at approximately 12:15 pm, the LD confirmed the technical supervisor failed to review and verify the laboratory preventative maintenance documents.