

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0098252	(X3) Date Survey Completed 06/03/2019
Name of Provider or Supplier Brett J Gerstenhaber Md, Llc	Street Address, City, State 2080 Whitney Ave, Suite 210, Hamden, CT	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have a policy in place to assess the competency of all laboratory personnel. Findings include: 1. Review of the laboratory's policies and procedure manual on 6/3/19 revealed the following: a. The laboratory did not have a policy in place to assess the competency of the clinical consultant (CC) and technical consultant (TC). b. Competency documentation for the above laboratory personnel was not available for 2017 and 2018. 2. Staff interview with the TC on 6/3/19 at 11:15 AM confirmed the laboratory did not have a policy in place to assess the competency of the above laboratory personnel and they were not assessed in 2017 and 2018. 3. The laboratory performs 50 pH, PCO2 and PO2 tests annually.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish a policy</p>

for documenting daily quality control (QC) for blood gas testing in the specialty of chemistry. Findings include: 1. Record review of the laboratory's QC /maintenance logs on 6/3/19 revealed the OPTI Check control is run prior to patient testing and documented on the maintenance log. 2. Record review of the laboratory's patient test logs on 6/3/19 revealed patient samples tested for pH, PO2 and PCO2 are recorded in a log book with their name, date test was performed and results. 3. Record review comparison of the above logs on 6/3/19 revealed the following Opti Check control was not always documented in the maintenance log for the days patient samples were tested. Specifically for 2/5, 2/16, 2/20, 3/19 in 2018 and 1/28, 2/19 in 2019. 4. Record review of the laboratory's procedures on 6/3/19 revealed the laboratory failed to provide evidence or documentation of a policy for documenting the Opti check QC. 5. Staff interview with TP on 6/3/19 at 11:00 AM confirmed the above findings.

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory failed to document all quality control (QC) procedures performed or have a procedure in place to monitor QC shifts and trends in the subspecialty of routine chemistry. Findings include: 1. Record review on 6/3/19 of the laboratory's QC records revealed: a) The laboratory does not monitor QC results over time to monitor shifts and trends. b) The laboratory does not document corrective action when the QC is out of range. 2. Staff interview with testing personnel (TP) on 6/3/19 at 10:00 AM confirmed the laboratory does not have a mechanism in place to monitor QC shifts and trends and does not document corrective action when the QC is out of range. TP stated he/she does not know how to monitor QC for shifts or trends. 3. The laboratory performs 50 blood gas pH, PCO2, and PO2 tests annually.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on record review and staff interview the laboratory failed to indicate their name and address on their electronic outpatient final test reports in the specialty of chemistry. Findings include: 1. Record review of 3 of 3 electronic patient final reports on 6/3/19 revealed the reports did not indicate the laboratory's name and address of the laboratory performing the pH, CO₂ and O₂ tests for 1/28, 2/19 and 3/22 in 2019. 2. Staff interview with the laboratory director 6/3/19 at 12:30 PM confirmed the outpatient final reports failed to indicate where the laboratory tests were performed. 3. The laboratory performs 50 pH, CO₂ and O₂ tests annually.