

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0098252	(X3) Date Survey Completed 08/19/2019
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
D0000	A proficiency testing desk review of the Brett J. Gerstenhaber, MD, Laboratory was conducted pursuant to 42CFR Part 493 of the Clinical Laboratory Improvement Amendments (CLIA) of 1988.
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on proficiency testing (PT) record review, the laboratory failed to obtain a score of 80% in two out of three consecutive testing events in the specialty of chemistry for the regulated analyte PO2 blood gas (0325) leading to an unsuccessful PT performance. Refer to tag D2096.</p>

D2096

ROUTINE CHEMISTRY

CFR(s): 493.841(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on record review and staff interview the laboratory failed to achieve successful performance score for the same analyte in two out of three consecutive testing Proficiency Testing (PT) events in the specialty of Chemistry. Findings include: 1. Record review of the American Association of Bioanalysts (AAB) PT results on 8/12 /19 revealed the laboratory failed to obtain a score of at least 80% for the regulated analyte PO2 blood gas leading to unsatisfactory performance in 2 out of 3 PT events as evidenced below. Year/Event # PT score 2018 - Event -3 60% 2019 - Event -2 0% 2. Telephone interview with the laboratory director (LD) on 8/15/19 at 2:15 PM confirmed the laboratory did not obtain a score of at least 80% in 2 out of 3 PT events for the regulated analyte PO2 blood gas. LD further stated PT samples were not tested during the 2019 event 2 because the testing personnel was on vacation. 3. The laboratory performs 50 blood gas tests annually.