

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0100927	(X3) Date Survey Completed 08/15/2019
Name of Provider or Supplier Danbury Medical Group Llc	Street Address, City, State 100 Reserve Rd, Ste 4a, Danbury, 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 (PT) desk review of the Danbury Medical Group 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 successfully perform in two consecutive testing events in the specialty of chemistry for the regulated analyte sodium (Na). Findings include: 1. Record review of the Center for Medicare & Medicaid Services (CMS) CASPER 0155D Report on 8/12/19 revealed the laboratory failed to obtain a score of at least 80% leading to unsatisfactory scores</p>

for two consecutive PT events for analyte # 0475 'Na' as follows: Year/Event # Score
2019 Event 1 60% 2019 Event 2 60% 2. Record review of the American Association
of Bioanalysts (AAB) PT results on 8/15/19 confirmed the above unsatisfactory
scores. Refer to citation: D2096.

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 Proficiency Testing (PT) record review the laboratory failed to achieve successful performance for the same analyte in two consecutive PT events in the specialty of chemistry. Findings include: 1. Record review of the Center for Medicare & Medicaid Services (CMS) CASPER 0155D Report on 8/12/19 revealed the laboratory failed to obtain a score of at least 80% leading to unsatisfactory scores for two consecutive PT events for analyte # 0475 sodium (Na) as follows: Year/Event # PT Score 2019 Event 1 60% 2019 Event 2 60% 2. 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% leading to unsatisfactory scores in two consecutive PT events as evidenced below. Year/Event # PT score 2019 - Event - 1 60% 2019 - Event - 2 60% 3. The above findings were confirmed by the laboratory manager in an electronic communication dated 8/13/19. 4. This is the first unsuccessful performance for the regulated analyte Na. 5. The laboratory performs 4,139 Na tests annually.