

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0310064	(X3) Date Survey Completed 04/12/2018
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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
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: _____ Chemistry: The laboratory failed to maintain satisfactory participation in two out of three events for the Sodium Analyte, resulting in the first unsuccessful proficiency testing (PT) participation for Sodium (Refer to D2089 and D2097). _____</p>
D2089	<p>ROUTINE CHEMISTRY CFR(s): 493.841(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a</p>

score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:

_____ Based on a desk review of the 2017 CMS CASPER Report 0155D and the Laboratory's 2017 PT (Proficiency Testing) records, the laboratory failed to participate in event two for Chemistry resulting in a 0% score for the Sodium Analyte. The findings include: 1. Review of the CASPER Report 0155D revealed 0% score for event two of 2017 for Sodium. 2. Review of the Laboratory's 2017 event two PT report revealed "Failure to Participate" resulting in a score of 0% for Sodium. _____

D2097

ROUTINE CHEMISTRY
CFR(s): 493.841(g)

Failure to achieve an overall testing event score of satisfactory performance for 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 a desk review of the CMS 0155D report and the Laboratory's 2017 and 2018 PT program evaluations, the laboratory failed to maintain satisfactory performance for the Sodium Analyte, event two 2017 and event one 2018, resulting in the first unsuccessful participation for the Sodium Analyte. The findings include: 1. Review of the CMS 0155D report revealed the 2017 event two score as 0% for Sodium for "Failure to Participate" and the 2018 event one score as 60%. 2. Review of the laboratory's 2017 event two PT program evaluation report revealed "Failure to Participate", resulting in a score of 0%. 3. Review of the laboratory's 2018 event one PT program evaluation report revealed sample numbers CH-03 and CH04 with unacceptable grades for Sodium, resulting in a score of 60%. _____