

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0947926	(X3) Date Survey Completed 01/30/2019
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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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: . Based on review of API (American Proficiency Institute) proficiency testing (PT) documentation for 2017 and 2018 and staff interview, the laboratory failed to provide the required attestation signatures for PT performed in the specialty of hematology. Findings: 1. API attestation statements for the second and third events 2017 and the first, second and third events 2018 were reviewed. The form for the second event 2017 was signed only by testing person 1 (CMS fom 209) and the remaining forms unsigned by the laboratory director or the person performing the test. 2. In an interview at the site on 01-30-2019, testing person 1 stated that hematology testing had been suspended in October 2017, and that PT was performed for the third event 2017 and the first event 2018 in anticipation of resuming patient testing. .</p>
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-</p>

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.

This CONDITION is not met as evidenced by:

. Based on review of API PT testing documentation for 2017 and 2018, confirmed by staff interview, the laboratory failed to participate successfully in proficiency testing in the specialty of hematology. Findings: 1. API PT testing documentation for 2017 and 2018 showed the following unacceptable scores: 2017 3rd event Platelet Count (x10⁹) Sample Reported Expected Grade HEM-14 206 94-159 Unacceptable HEM-15 108 53-89 Unacceptable 2018 1st event Platelet Count (x10⁹) Sample Reported Expected Grade HEM-01 161 50-85 Unacceptable HEM-02 328 167-280 Unacceptable HEM-04 991 257-429 Unacceptable HEM-05 848 89-150 Unacceptable 2. Scores below 60% for two consecutive testing events in the same analyte resulted in a score of "unsuccessful" for Platelet Count. 3. API scores for the second and third events 2018 in the specialty of hematology were all marked "Failure to Participate" resulting in overall scores of "unsuccessful" for all analytes. 4. In an interview at the site on 01-30-2019, testing person 1 stated that hematology testing had been suspended in October 2017 and PT performed through the first event of 2018, when the decision was made to discontinue the specialty. .

D2123

HEMATOLOGY

CFR(s): 493.851(c)

Failure to participate in a testing event is unsatisfactory performance and results in a 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 review of API PT documentation for 2018 and staff interview, the laboratory failed to notify the proficiency testing program of the suspension of patient testing and the associated circumstances involved in the failure to perform PT in the specialty of hematology. Refer to D2016.