

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0213986	(X3) Date Survey Completed 01/16/2018
Name of Provider or Supplier Heart Center, The	Street Address, City, State 7610 Carroll Avenue Suite 300, Takoma Park, MD	
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: Based on review of the federal proficiency testing data report and correspondence received by the technical consultant via email on November 6, 2017, the laboratory failed to successfully participate in the American Proficiency Institute proficiency testing program for chemistry testing, in which the laboratory is certified under CLIA. (Refer to D2087) Findings: Repeat Deficiency</p>
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p>

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:

Based on review of the federal proficiency testing data report and correspondence received by the technical consultant via email on November 6, 2017, the laboratory failed to attain a score of 80% for the American Proficiency Institute proficiency testing program for routine chemistry testing Findings: 1. American Proficiency Institute proficiency testing program 2017 3rd event Chloride 0% 2. American Proficiency Institute proficiency testing program 2017 2nd event Chloride 60%

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of the federal proficiency testing data report and correspondence received by the technical consultant via email on November 6, 2017 the laboratory director failed to ensure that the laboratory successfully participated in the American Proficiency Institute proficiency testing program for chemistry testing, in which the laboratory is certified under CLIA. (Refer to D6019 and D2087) Findings: Repeat Deficiency The laboratory director has not fulfilled the duties of the director to ensure that the laboratory successfully participates in the American Proficiency Institute proficiency testing program for chemistry testing

D6019

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iv)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on review of the federal proficiency testing data report and correspondence received by the technical consultant via email on November 6, 2017, the laboratory director failed to ensure that an approved corrective action plan was followed when the laboratory failed to successfully attain a score of 80% in the American Proficiency Institute proficiency testing program for chemistry testing. Findings: Repeat Deficiency A. Cross-reference D2087. B. The laboratory director failed to ensure that a proficiency testing corrective plan was approved and followed to prevent failures when performing the American Proficiency Institute proficiency testing program for chemistry testing.