

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2148459	(X3) Date Survey Completed 09/29/2020
Name of Provider or Supplier Chi St Vincent Oncology	Street Address, City, State 500 S University, Suite 815, Little Rock, AR	
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 2020 CMS Casper Reports 155D, 153D and the American Proficiency Institute (API) proficiency testing results, it was determined the laboratory failed to participation in proficiency testing for the specialty of Hematology and each Hematology analyte. Survey Finding follow: Failure to participate in proficiency testing for the specialty of Hematology in two of two proficiency testing events results in a unsuccessful performance for each testing event as cited at D 2123.</p>
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 the 2020 CMS Casper Reports 155D, 153D and the American Proficiency testing results, it was determined the laboratory failed to participate in the first and second proficiency testing events of 2020, resulting in a score of 0% for the specialty of Hematology and each Hematology analyte. Survey Findings Follow: A. The laboratory received a of 0% for the speciality of Hematology in the first and second proficiency testing event of 2020. B. The laboratory received a score of 0% for the test of White Blood Cell Differential, Red Blood Cell Count, Hemoglobin, Hematocrit, Platelets and White Blood Cell Count in the first and the second proficiency testing event of 2020.

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 a review of the 2020 proficiency testing results, it was determined the Laboratory Director failed to ensure that corrective action was followed when proficiency testing results were unacceptable, and failed to provide overall management and direction as cited at: D 6019- Laboratory Director failed to ensure that corrective action was followed when proficiency testing results were unacceptable.

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 2020 CMS Casper Reports 155D, 153D and American

Proficiency Institute proficiency testing results, it was determined the Laboratory Director failed to ensure that corrective action is followed when proficiency testing results are unacceptable as cited at D 2123.