

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1102926	(X3) Date Survey Completed 08/14/2019
Name of Provider or Supplier Varki Cancer Care Center Pa	Street Address, City, State 1321 Nw 14th St Ste 305, Miami, FL	
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 recertification survey, conducted on 8/14/2019 found that Varki Care Center PA clinical laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of CMS form 209, Laboratory Personnel Report; based on review of American Proficiency Institute (API) proficiency testing (PT) records and interview with Testing Personnel (TP) B; the laboratory failed to have all testing personnel (TP) rotate through the testing of PT for the hematology specialty for a period of 2 out of 2 years (2017 - 2018) reviewed. Findings include: Review of CMS form 209, signed and dated by the Laboratory Director (LD) on 8/13/2019 had 4 testing personnel listed (TPA, TP B, TP C and TP D). Review of API; PT records found that TP A did not perform PT during 2017 and that TP B did not perform PT during 2018. During an interview on 8/14/2019 at 11:30 AM, with TP; it was confirmed that TP B and TP A did not participate in PT during the years of above-reference.</p>
D2123	<p>HEMATOLOGY CFR(s): 493.851(c)</p> <p>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)</p>

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 record review and interview with Testing personnel (TP) B, the laboratory failed to participate in proficiency testing (PT) that resulted in a score of zero (0) percent on the Hematology 3rd event in 2018. Findings: Review of the American Proficiency Institute (API) records for the 2018; Hematology 3rd event showed the laboratory received a score of 0% for all analytes to be tested. Notes on the API "Performance Summary" sheet stated "Failure to Participate". During an interview on 8/14/19 at 10:30 AM, TP B acknowledged that the laboratory failed to get the PT results.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory did not have a written Quality Assessment (QA) policy to monitor, assess the overall quality of laboratory activity. Findings include: Review of the procedure manual revealed that there was no QA policy for their Hematology laboratory. No documentation of the QA activity for the years 2017, 2018 and from January to July of 2019 found during the survey. During an interview on 08/14/2019 at 12:30 PM, with the LD, she confirmed that there were no records of QA activity for the years of above-reference.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on user manual review and interview with testing personnel (TP) B, the laboratory failed to document room temperature and humidity require to assure optimal operation of the Coulter ACo T diff 2 analyzer for a period of 2 out 2 years reviewed. Findings include: Review of Hematology analyzer Beckman Coulter ACT 2 diff installation guide manual revealed a room temperature requirement range of 16 to

35 C and a humidity not greater than 85 %. No documentation of the room temperature and humidity found for 2017, 2018 and 2019. During an interview on 08 /14/2018 at 11:30 a.m., the TP B confirmed that there was no record of room and humidity control check.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on record review and interview with staff, the laboratory director (LD) failed to ensure the laboratory had a Quality Assurance (QA) policy in the procedure manual. Findings include: Review of the procedure manual revealed that there was no QA policy. No documentation of the QA for years 2017, 2018 and from January to July 2019 found during the survey. During an interview on 08/14/2019 at 12:30 PM, with the LD, she confirmed that there were no records of QA activity for the years of reference.