

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D1026042	(X3) Date Survey Completed 10/10/2018
Name of Provider or Supplier Palo Verde Hematology Oncology, Ltd	Street Address, City, State 7373 N Scottsdale Rd Bldg E-100, Scottsdale, AZ	
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
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 proficiency testing (PT) records from 2016, 2017 and 2018 and interview with the facility personnel, the laboratory failed to test PT samples by testing personnel who routinely perform patient testing in the laboratory. Findings include: 1. The laboratory participates in PT for the specialty of Hematology, which includes 3 testing events per calendar year consisting of 5 samples each. 2. The CMS-209, Laboratory Personnel Form presented during the survey conducted on October 10, 2018 listed eight testing personnel who routinely perform patient testing. 3. Review of the laboratory's PT records indicated that the same testing personnel tested all of the PT samples for the following events: 3rd event of 2016, 2nd event of 2017, and 1st and 2nd events of 2018. 4. The same testing personnel indicated above was listed as testing personnel for the 1st and 3rd event of 2017, in addition to two other testing personnel for each event. 5. The facility personnel confirmed that the same testing personnel had tested the PT samples as indicated above.</p>
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>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)(11) Ensure that prior to testing patients' specimens, all personnel</p>

have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on lack of education credentials and interview with the facility personnel, the laboratory director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience for the type and complexity of services offered. Findings include: 1. No evidence of education credentials was presented for review for one out of one testing personnel who began patient testing on the Sysmex XS i1000 analyzer in November 2017. 2. The facility personnel confirmed that the laboratory failed to provide a copy of the education credentials for the testing personnel indicated above.