

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0286057	<b>(X3) Date Survey Completed</b>  06/13/2018
<b>Name of Provider or Supplier</b>  Harvey S Kleiner Do, Llc	<b>Street Address, City, State</b>  8890 W Oakland Park Blvd Ste 100, Sunrise, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2121</b>	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to score at least 80% for platelet counts for the proficiency testing (PT) 1st event in 2017. Findings include: Review of the proficiency testing scores from the 2nd event in 2016 through the 1st event in 2018 showed that a score of 20% was reported by the PT company College of American Pathologist (CAP) for platelet counts for the 1st event of 2017. During an interview on 6/13/18 at approximately 3:30 PM, Laboratory Director acknowledged the proficiency testing failure.</p>
<b>D2128</b>	<p>HEMATOLOGY CFR(s): 493.851(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document remedial action for unsatisfactory proficiency testing (PT) in hematology for platelet counts.</p>

Findings include: Review of the proficiency testing scores from the 2nd event in 2016 through the 1st event in 2018 showed that a score of 20% was reported by the College of American Pathologist (CAP) for platelet counts for the first event of 2017. There was no documentation in the laboratory's PT records to show that remedial action was taken for this unsatisfactory score. During an interview on 6/13/18 at approximately 3:30 PM, Laboratory Director confirmed that the laboratory did not have documentation for remedial action taken for the platelet count score of 20% received on PT for the first testing event of 2017.

**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 interview, the laboratory failed to establish and follow a written quality assessment (QA) policy. Findings included: Record review of the laboratory procedure manual showed that there was no QA policy. During an interview on 6/13/18 at 4:20 PM, Office Manager stated they did not have a QA policy for the laboratory.