

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0286057	(X3) Date Survey Completed 03/17/2020
Name of Provider or Supplier Harvey S Kleiner Do, Llc	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A recertification survey was conducted on March 17, 2020. Kleiner & Fernandez MDs clinical laboratory was found not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed provide documentation of calibration verification every six months between 10/11/18 and 10/11/19 on the</p>

Abbott Diagnostic Cell Dyn 1800 Hematology analyzer. Findings: Review of calibration verification records for the hematology analyzer showed that calibration verifications were performed on 10/11/18 and 10/11/19 (12 months apart). During an interview on 3/17/16 at 2:22 PM, Testing Personnel A stated she was unable to locate the missing calibrations records.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory reported patient results on six days for 2 (lot #331803, #319030) out of 3 (lot #31712, #331803, #319030) lot numbers examined for the Abbott Diagnostic Cell Dyn 1800 Hematology analyzer when at least 2 out of 3 daily control values are in the acceptable range. Findings: The laboratory prints out a list of daily controls run per lot number for the low, normal and high controls. Review of two lot number of daily controls logs showed that the lymphocyte percentage was out of the acceptable range for at least 2 out of 3 controls for the following: 1. Lot number 31712 was used from 4/30/18 to 9/8/18 shows that the acceptable range for low is 28.3% - 38.3%, normal is 37.1% - 47.1%, and high is 49.2% - 59.2%. On 7/9/18 the hematology analyzer reported the normal control as 36.5%, and the high control as 48.2%. Three patient test results were reported. 2. Lot number 319030 was used from 4/17/19 to 7/11/19 shows that the acceptable range for low is 31.1% - 41.1%, normal is 40.2% - 50.2%, and high is 49.9% - 59.9%. On 6/1/19 the hematology analyzer reported the low control as 29.2, the normal control as 39.6%, and the high control as 48.4%. Two patient test results were reported. On 6/24/19 the hematology analyzer reported the normal control as 39.8% and the high control as 49.0%. One patient test result was reported. On 7/3/19 the hematology analyzer reported the normal control as 39.9% and the high control as 48.2%. Six patient test results were reported. On 7/5/19 the hematology analyzer reported the low control as 30.6%, the normal control as 39.3% and the high control as 47.8%. Two patient test results were reported. On 7/8/19 the hematology analyzer reported the low control as 29.5, and the normal control as 38.4%. Fifteen patient test results were reported. The Clinical Laboratory Improvement Amendments (CLIA) Application for Certificate signed and dated by the laboratory director on 3/12/19 states the total estimated annual test volume is 10,360. During an interview on 3/17/20 at 2:40 PM, the Office Manager stated the controls were out and that patients test results should not be reported until the controls are in.

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for

acceptability.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory's patient reports failed to list the name and address of the laboratory where the hematology testing was performed for for 3 out of 3 (#1 #2 #3) patient results. Findings: Review of the hematology test results showed the name and address of the location where the testing was done was not on the copy of the Abbott Diagnostic Cell Dyn 1800 Hematology analyzer printout that was given to patients upon request. The Clinical Laboratory Improvement Amendments (CLIA) Application for Certificate signed and dated by the laboratory director on 3/12/19 states the total estimated annual test volume is 10,360. During an interview on 3/17/20 at 2:30 PM, Testing Personnel A stated that they gave patients a copy of the hematology analyzers reports and that the reports did not contain the name and address of where the hematology tests were performed.