Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0286057	03/17/2022
Name of Provider or Supplier	**Street Address, City, State**	
Harvey S Kleiner Do, Llc	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, 2022. Kleiner & Fernandez MDs clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to have documentation of the signing of the attestation form for proficiency testing (PT) for six of six (2020 1st, 2nd, 3rd & 2021 1st, 2nd, 3rd events) for the specialty of hematology. Findings: Review of the American Proficiency Institute (API) Attestation Statement noted "Signatures Required - Testing personnel and laboratory director must physically sign an attestation statement for PT results, and retain the signed statement (or a copy) for a minimum of 2 years." Review of the API PT records showed the attestation statement were signed by the Office Manager. On 03/17/2021 at 9:55 AM, the Office Manager acknowledge the attestations were not signed by the Laboratory Director.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

	This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to document the review and evaluation of proficiency testing (PT) for five (2020 2nd, 3rd & 2021 1st, 2nd, 3rd) of six (2020 1st, 2nd, 3rd & 2021 1st, 2nd, 3rd) events for the specialty of hematology. Findings: Review of the American Proficiency Institute (API) PT showed the Laboratory Director failed to sign the "Proficiency Testing Performance Evaluation" forms for 2nd and 3rd events in 2020, and the 1st, 2nd, and 3rd events in 2021. On 03/17/2021 at 9:55 AM, the Office Manager acknowledge the attestations were not signed by the Laboratory Director.
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 record review and interview, the laboratory failed to record the room temperature of rooms where testing was performed from 03/17/2020 to 03/17/2022. Findings: Review of the operation manual for the laboratory's Abbott Cell-Dyn 1800 hematology analyzer noted "To ensure the instrument and reagents function properly, it is important to maintain the temperature between 64 degrees F and 86 degrees F (18 degrees C and 30 degrees C)". No room temperature logs was available for review. On 03/17/2022 at 10:32 PM, Testing Personnel A stated they did not record the room temperature of the laboratory. Word Key F = Fahrenheit C = Celsius