Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0883309	08/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
Gary M Kramer Md Pa	4950 Lejeune Rd Ste F, Coral Gables, 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
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 with laboratory director, the testing person and the laboratory director did not sign the American Proficiency Institute (API) attestation statements-1st and 3rd events of 2017 in the specialty of hematology. The findings include: API Proficiency testing record review on 8/8/18 at 2pm for two-year review period (8/2016 to 8/8/2018) showed that the testing person and the director did not sign Hematology/Coagulation 1st event and 3rdevent for year 2017 API proficiency testing attestation statements. During an interview on 8/8/18 at 4:00 PM, laboratory director confirmed that the testing person and the director did not sign the API proficiency testing attestation statements for Hematology/Coagulation- 1st event and 3rd event of year 2017.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory director, Hematology specialty laboratory failed to establish and follow written policies and procedures to access

	clinical consultant competency for the two year record review period (8/2016 - 8/8 /18). The findings include: Laboratory Procedures and policy records reviewed on 8/8 /18 at 2:30pm for two-year review period (8/2016 - 8/8/2018) did not show established policy to access clinical consultant competency. Personnel record review did not show the new hire competency assessment for the clinical consultant. During an interview on August 8, 2018, at 4:00pm, the laboratory director confirmed that the laboratory did not have the written policies and procedures to access clinical consultant competency and personnel records did not include the new hire competency assessment for the clinical consultant.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation, record review and interview with laboratory director, laboratory failed to have the manufacturer's instructions -operator's manual for the recommended maintenance and function checks for Quest Diagnostics Horizon centrifuge. The findings include: During a laboratory tour on 8/8/18 at 3:30 pm, surveyor observed a centrifuge; Quest Diagnostics Horizon model 642 E with no manufacturer's instructions or operator's manual for the recommended maintenance and function checks. During an interview on August 8, 2018, at 4:00pm, the laboratory director confirmed that the laboratory did not have manufacturer's instructions or operator's manual for the recommended maintenance and function checks for Quest Diagnostics Horizon model 642 E centrifuge.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) 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.

	This STANDARD is not met as evidenced by: Based on instrument calibration record review for two-year period (8/2016 to 8/8 /2018) and interview with the laboratory director, the laboratory failed to conduct and document the calibration verification for at least every six months for CDS Medonic M series hematology analyzer. The findings include: Calibration record review on 8/8 /18 at 3pm from two-year review period (8/2016-8/8/2018) showed that the laboratory did not perform the calibration verification for CDS Medonic M series hematology analyzer after November 2017 to August 8, 2018 and did not have the calibration verification records. During an interview on 8/8/18 at 4:00 PM, laboratory director confirmed that the laboratory did not perform the calibration verification for CDS Medonic M series hematology analyzer after November 2017 until August 8, 2018 and did not have the calibration verification records.