Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0492204	01/17/2023
Name of Provider or Supplier	**Street Address, City, State**	
Valdez Medical Md, Pa	5809 Airline Drive, Suite C, Houston, TX	

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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found in compliance with applicable CLIA Conditions, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the CMS Southern Operations Branch-Dallas for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 review of manufacturer operator's manual for the Sysmex KX hematology analyzer, review of the laboratory's Sysmex KX maintenance logs for 2022, review of laboratory's submitted Form 116 and staff interview, it was determined the laboratory failed to document two of four Sysmex KX manufacturer required periodic "Every 3-Month Maintenance" in 2022. Findings included: 1. Review of manufacturer operator's manual for the Sysmex KX hematology analyzer (Sysmex KX-21N Operator's Manual - Revised February 2000) revealed: "To ensure that the instrument can function in its best state, it is necessary to give scheduled maintenance. Perform maintenance according to the schedule below and record the result in the Maintenance Checklist." And, "Every 3-Month Maintenance (or Every 7500 Samples) Clean the

	sample rotor valve (SRV)." 2. Review of the laboratory's Sysmex KX analyzer maintenance logs for 2022 revealed there were only 2 instances of documented "Every 3-Month Maintenance" in 2022. These were: Date: 05/18/2022 08/15/2022 There was no documentation of SRV cleaning in February or November of 2022, the other 2 months "Every 3-Month Maintenance" was due. 3. Review of laboratory's submitted Form 116 revealed the laboratory performed 97 hematology tests annually. 4. In an interview on 01/17/2023 at 1220 hours in the office, the laboratory's Technical Consultant, after review of the data, confirmed the findings.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of the laboratory's temperature logs for September to December of 2022, review of laboratory's forms and policies, and staff interview it was determined the laboratory failed to document corrective action for 3 of 3 days the laboratory's room temperature was outside of laboratory's defined range. Findings included: 1. Review of the laboratory's temperature logs revealed the laboratory defined room temperature as 16-25C (Celsius) or 60.8 -77F (Fahrenheit). 2. Review of the laboratory's temperature logs for September to December of 2022 revealed the following days temperature was documented as outside of the above defined temperature range without documentation of corrective action: Date: Temperature: 10 /17/2022 79 12/20/2022 78 12/29/2022 78 3. Review of the laboratory's Form "TEMPERATURE/HUMIDITY/WEEKLY EYE WASH FLUSH STATION /WEEKLY MICROSCOPE CLEAN" revealed: "Personnel must document action taken to correct out of range reading and temperature MUST be re-read, a minimum of 30 minutes after adjustments." There was no other policy for corrective action for out of range temperatures. 4. In an interview on 01/17/2022 at 1230 hours in the office, the laboratory's Technical Consultant, after review of the data, confirmed the findings.