Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D1103190	01/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Acl Center For Advanced Care	1700 Luther Lane, Ste 1260, Park Ridge, IL	

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
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on the surveyor's direct observation, review of the laboratory's manuals, records and an interview with the technical consultant (TC), the laboratory failed to define a function check protocol for each equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. Findings: 1. On 01/25/2018 at 11:30 AM during a tour of the laboratory, the surveyor observed 2 electronic sensors in the reagent refrigerator. The surveyor inquired about the purpose of these sensors, the TC stated that the 2 sensors were given to the laboratory by the manufacturer to monitor the temperature in the refrigerator. TC further stated that the readings are sent directly to the manufacturer off-site. 2. The laboratory's manual does not include an establish procedure for checking the accuracy of the temperature reading sensors it now uses instead of thermometers. 3. No documentation was presented as evidence that the temperature of the reagent refrigerator has been monitored since the installation of the 2 sensors. 4. No documentation was provided as proof that the temperatures in the reagent refrigerator remain within the required manufacturer's temperature range for the Hematology

	stored reagents. 5. On a Recertification survey conducted on 01/25/2018 at 11:45 AM, the TC confirmed the above findings and stated that the laboratory does not receive a copy of the sensors' readings.