Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0308958	(X3) Date Survey Completed 04/30/2019
Name of Provider or Supplier Heritage Medical Associates	**Street Address, City, State** 3901 Central Pike, Suite 251, Hermitage, TN	

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
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on record review of Horiba Complete Blood Count (CBC) analyzer verification of performance specifications and interview with the lead testing person the laboratory director failed to approve the verification of performance specifications prior to patient testing in 2018. The findings include: 1. Review of the Horiba CBC analyzer verification of performance specifications determined the laboratory director failed to verify the accuracy, precision, linearity, reference range and correlation specifications prior to patient testing in March 5, 2018. 2. Interview with the lead testing person on April 30, 2019 at 1:00 pm confirmed the laboratory director failed to verify the Horiba CBC analyzer verification of performance specifications for the accuracy, precision, linearity, reference range and correlation specifications prior to patient testing in March 5, 2018.