Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2107298	10/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Humboldt Family Walk-In Clinic	1600 Coleman Drive, Humboldt, 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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the validation records for the Beckman Coulter AcT Diff complete blood count (CBC) instrument, the laboratory's procedure and checklist for validation of new equipment and interview with the laboratory director, the laboratory failed to verify the manufacturer's patient normal ranges for the Beckman Coulter AcT Diff CBC instrument in 2017. 1. Observation of the laboratory on October 19, 2018 at 9:40 am revealed the Beckman Coulter AcT Diff CBC instrument (system id # 43043803) in use for patient testing. 2. Review of the validation records performed on October 19, 2017 for the Beckman Coulter AcT Diff CBC instrument revealed the manufacturer's patient normal ranges was not verified. 3. Review of the laboratory's procedure and checklist for validation of new equipment revealed that verification of the manufacturer's patient normal ranges is not part of the validation protocol. 4. Interview with the laboratory director on October 19, 2018 at 12:00 pm confirmed that the laboratory uses the manufacturer's patient normal ranges for the Beckman Coulter Act Diff CBC instrument and verification of manufacturer's patient normal range is not included as part of the validation protocol. The laboratory failed to verify the manufacturer's patient normal ranges for the Beckman Coulter AcT diff CBC instrument in 2017.