Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0231191	08/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Kenbridge Family Medicine	306 East 6th Avenue, Kenbridge, VA	

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	An announced CLIA recertification survey was conducted at Kenbridge Family Medicine on August 28, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
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 a review of the Laboratory Personnel Report Form (CMS 209), procedure and policy manual, personnel files, and an interview, the laboratory did not establish and follow a policy for one (1) technical consultant's competency assessment in calendar years 2016, 2017 and up to the date of the survey on August 28, 2018. Findings include: 1. Review of the CMS 209 revealed that Testing Personnel E serves as Technical Consultant (TC). (See Personnel Code Sheet) 2. Review of the laboratory procedure and policy manual revealed no protocol outlining documentation of the competency assessment of the TC. 3. Review of the personnel files revealed that the laboratory director failed to document competency assessments in calendar years 2016, 2017, and year to date 2018 for Testing Personnel E in the role of TC. 4. In an interview with the TC and primary testing personnel at approximately 3:30 PM, it was confirmed that laboratory did not establish and follow a policy for documenting competency assessment for the duties of the TC for the timeframe outlined above.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)

	Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of policies and procedures, quality control (QC) records, and interviews, the laboratory failed to perform evaluations to verify eight (8) of eight (8) lot numbers of hematology QC materials used for monitoring accuracy of patient complete blood count (CBC) testing during the nineteen (19) months reviewed. Findings include: 1. Review of the laboratory's procedure manual revealed no Abbott Emerald hematology instrument procedure for the verification of new lot numbers of Cell Dyn 18 Plus QC assayed ranges. 2. Review of the laboratory's Abbott Emerald QC records from January 2017 to the date of the survey on August 28, 2018 revealed the following eight (8) Cell Dyn 18 Plus QC lot numbers were utilized to monitor patient CBC test results analyzed on the laboratory's Emerald instrument: 6326, 7044, 7128, 7212, 7296, 8015, 8099, 8183. The inspector requested to review the laboratory's documentation that each of the eight (8) new lot numbers of QC were confirmed (verified). No documentation was available. 3. In an interview with the technical consultant and primary testing personnel at approximately 3:30 PM, it was confirmed that the laboratory failed to verify eight (8) of eight (8) commercially assayed Cell Dyn 18 Plus QC lot numbered materials as outlined above.