Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D2062566	09/03/2019
Name of Provider or Supplier	**Street Address, City, State**	
Accu Reference Medical Lab, Llc	677 Silver Ln, East Hartford, CT	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to follow quality control (QC) acceptance criteria in the specialty of hematology. Findings include: 1. Record review of the laboratory's procedure manual on 9/3/19 revealed: a. All three of levels of QC must be within acceptable limits before patient samples are tested. b. All QC results are reviewed on a monthly basis by the laboratory director (LD) or a qualified designee. 2. Record review of the laboratory's QC records on 9/3/19 revealed: a. The laboratory is accepting QC if two of three levels of QC are within acceptable limits and by using a code "O2I3". b. No documentation for monthly QC review by the LD or qualified designee. 3. Staff interview the technical consultant (TC) on 9/3/19 at 10:00 AM confirmed the above findings. The TC further stated QC data is being reviewed at the end of the QC expiration date which occurs approximately every 2 months.
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 record review and staff interview the laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer before testing patient samples. Findings include: 1. Record review on 9/3 /19 of the laboratory's validation records for Horiba Micros 60 (SN# 211CS92296) hematology analyzer revealed the values obtained from a reportable range study indicated the following expected values obtained by the reagent manufacturer (Verified Medical Research [VMR]) were not demonstrated by the laboratory analyzer. Analyte VMR expected values WBC 0.38 to 126.7 x 10^3/uL RBC 0.23 to 8.0 x 10^6/uL HGB 0.4 to 24.64 g/dL HCT 1.95 to 71.31 % PLT 11.92 to 5317.5 x 10^3/uL The above reportable ranges were reviewed and approved by the laboratory director on 5/22/19. 2. Record review on 9/3/19 of the raw data from the reportable range study revealed the the laboratory's analyzer was unable to obtain the above expected values provided by the reagent manufacturer as indicated below. Analyte Ranges from Reportable range study WBC 0.4 to 118.9 x 10^3/uL HGB 0.6 to 24.4 g /dL PLT 7 to 4913 x 10^3/uL 3. Record review on 9/3/19 of the laboratory's hematology procedure manual (HPM) revealed the following linearity ranges are in use. Analyte HPM linearity ranges WBC 0.5 to 122 x 10^3/uL RBC 0.2 to 8.7 x 10^6 /uL HGB 2 to 27 g/dL HCT 1.8 to 82.3 % PLT 25 to 4990 x 10^3/uL The above ranges listed are different from the reportable range study performed by the laboratory. 4. Staff interview with the laboratory director and the technical consultant on 9/3/19 at 10:30 AM confirmed the above findings. 5. The laboratory performs 2,600 complete blood count tests annually.