Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0226281	09/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Louisa Family Practice Plc	101 Woolfolk Street, Louisa, 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 Louisa Family Practice on September 21, 2021 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:
D2122	HEMATOLOGY CFR(s): 493.851(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services CASPER 0096D report form (CMS CASPER 96), proficiency testing (PT) records, and an interview, the laboratory failed to attain an overall score of at least eighty (80) percent (%) of acceptable responses for Hematology in one (1) out of three (3) PT testing events in calendar year 2020. Findings include: 1. During pre-survey duties, the inspector noted that the CMS CASPER 96 report included an overall unsatisfactory PT score for the speciality of Hematology. The pre-survey review revealed the laboratory received 50 % score for 2020 Event 2. 2. During the onsite survey on 09/21/21, the inspector reviewed the laboratory's College of American Pathologists (CAP) PT records (2020 Events 1-3, 2021 Events 1-2). The review revealed the following unsatisfactory scores: 2020 Event 2: Hematology overall scored at 50% (module breakdown Hematocrit scored 0%, Hemoglobin scored 0%, and Platelets scored 0%). 3. An exit interview with the lead nurse at approximately 3:30 PM confirmed the above findings.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented.

	This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, lack of documentation, and an interview, the laboratory failed to record evaluation of unsatisfactory scores for three (3) of 3 urine sediment examination and fifteen (15) of 15 hematology analyte challenges reported in calendar years 2020 and 2021. Findings include: 1. Review of the laboratory's College of American Pathologists (CAP) Clinical Microscopy (CM) and Full Hematology Auto Differential (FH) PT records (2020 Events 1-3, 2021 Events 1-2) revealed no evidence of evaluation for the following failed analyte challenge samples: 2020 CAP CM-A (Event 1): USP-01 scored unacceptable; 2020 CAP FH - 2 (Event 2): Hematocrit (HCT 06 - HCT 10 scored 0%), Hemoglobin (HGB 06 - HGB 10 scored 0%), and Platelets (PLT 06 - PLT 10 scored 0%); 2021 CAP CM-A (Event 1): USP-01 and USP-03 scored unacceptable. A total of eighteen (18) unsatisfactory challenges with no record of evaluation. The inspector requested to review documentation that the laboratory evaluated the 18 unacceptable challenge results outlined above. Documentation was not available for review. 2. An exit interview with the lead nurse on 09/21/21 at approximately 3:30 PM confirmed the above findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of policies and procedures, monthly quality control (QC) records, and an interview, the laboratory failed to follow their policy for QC statistics review in order to monitor, assess and correct problems with the hematology analyzer and complete blood count (CBC) QC materials for 4 of 8 months reviewed for calendar year 2021. Findings include: 1. Review of the laboratory's policies and procedures revealed a quality assurance (QA) plan to monitor, assess and correct problems with the Beckman Coulter AcTDiff hematology analyzer that outlined that the laboratory director (LD) was to review quarterly check lists that included Coulter 4C ES Cell QC data collected/reviewed on a monthly basis. 2. Review of the laboratory's monthly CBC QC records for calendar year 2021 (timeframe of January-August 2021) revealed that the laboratory participated with Beckman Coulter Interlaboratory Quality Assurance Program (IQAP). During the review, the inspector noted there was no LD signature of review for the AcTDiff Levey-Jennings (LJ) or IQAP reports for April, May, June, July. The inspector inquired regarding the lack of documentation of LD review for the 4 months outlined above. No Quarterly QA, IQAP or LJ data log report reviewed by the LD was available for the months requested. 3. An exit interview with the lead nurse on 09/21/21 at approximately 3:30 PM confirmed the above findings.