Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0233388	09/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Clinch Valley Physicians Associates, Llc	398 Clinic Road, Cedar Bluff, 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 the Clinch Valley Physicians Associates on September 4 and 5, 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:
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the package insert (PI) for the Quidel Quick Vue Heliobactor pylori (H. pylori) serum/whole blood test kit, patient data from the laboratory information system (LIS), and interviews, the laboratory failed to perform external positive and negative quality control materials each day of patient testing for the serum H. pylori tests from January 1, 2017 and up to the date of survey on September 5, 2018 while reporting four-hundred and twenty-eight (428) patients. Findings include: 1. Review of the H. pylori serum/plasma/whole blood test kit PI revealed that the use of serum samples for this test kit is categorized as moderate complexity testing. An interview with the primary testing personnel at approximately 3:30 PM on September 4, 2018 revealed that the laboratory utilizes serum samples to perform the H. pylori testing. The inspector requested to review the documentation of performing positive and negative external quality control materials each day of patient testing. The documentation was not available for review. 2. Review of the Merge LIS patient data report for the H. pylori test revealed that, from January 1, 2017 and up to the date of survey on September 5, 2018, the laboratory reported 428 patients. 3. An interview

	with the primary testing personnel, technical supervisor, and laboratory director at approximately 1:00 PM on August 5, 2018 confirmed that the laboratory failed to perform external quality control materials for the serum H. pylori tests each day of patient testing.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of one (1) patient blood gas test report from the electronic health record (EHR) and an interview, the e-Clinical EHR patient blood gas report failed to contain reference intervals or normal values for the total hemoglobin (tHbg) and fractionated hemoglobin (FO2Hb, FCO2Hb, FMetHb, FHHb) percentages at the date of survey on September 5, 2018. Findings include: 1. Review of 1 patient blood gas test report generated from the e-Clinical EHR revealed that the report lacked the tHbg and FO2Hb, FCO2Hb, FMetHb, FHHb percentage reference intervals or normal values. 2. An interview with the primary testing personnel and laboratory director at approximately 1:00 PM on August 5, 2018 confirmed that the e-Clinical EHR blood gas reports lacked the reference intervals or normal values for the above-specified blood gas parameters.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on the review of the CLIA Laboratory Personnel Report Form (CMS-209 Form), testing personnel (TP) records, and an interview, the technical supervisor (TS) failed to perform the semi-annual competency assessment for one (1) TP in 2017. Findings include: 1. Review of the CMS-209 Form revealed that TP A performs patient testing. (See attached personnel code sheet.) 2. Review of TP A records revealed training and initial assessment performed in December 2016. There was no documentation of the TS performing a semi-annual competency assessment for TP A in 2017. 2. Interviews with the laboratory director and technical supervisor on September 5, 2018 at approximately 1:00 PM confirmed that the TS failed to perform the semi-annual competency assessments for TP A in 2017.