Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0961491	01/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Chickahominy Family Practice- Central Lab	9010 Pocahontas Trail, Providence Forge, 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 Chickahominy Family Practice Central Lab on January 25, 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:
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of the laboratory's 2016 and 2017 chemistry proficiency testing (PT) documentation, policy manual, and an interview, the laboratory failed to retain copies of the attestation statements signed by the laboratory director and testing personnel for two (2) of six (6) PT testing events reviewed.. Findings include: 1. Review of the laboratory's 2016 and 2017 American Proficiency Institute (API) chemistry PT documentation, a total of six (6) events, revealed no signed attestation statements retained for: 2016 Chemistry Event 3, 2017 Chemistry Event 1. The inspector requested to review the attestation documentation. No documentation was available for review. 2. Review of the laboratory's policy manual revealed a written and approved Proficiency Testing policy that included the statement: "The Lab

	Director and testing personnel must sign the Attestation Statement." 3. In an interview with the primary testing personnel at approximately 2:30 PM on January 25, 2018, it was confirmed that the laboratory failed to retain copies of the PT attestation statements for the events listed above in calendar years 2016 and 2017
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 the laboratory's 2016 and 2017 proficiency testing (PT) records, policy manual, and an interview, the laboratory failed to document result evaluation of one (1) of six (6) PT events reviewed. Findings include: 1. Review of the laboratory's 2016 and 2017 American Proficiency Institute (API) PT documentation, a total of six (6) events, revealed no evidence of result evaluation for: 2016 Chemistry Event 3. The inspector requested to review evaluation documentation of the PT results for the event listed above. No documentation was available for review. 2. Review of the laboratory's policy manual revealed a written and approved Proficiency Testing policy that included the statement: "All proficiency testing results will be evaluated and reviewed by the laboratory director. A copy of the signed report form must be retained in the laboratory for a minimum of 2 years". 3. In an interview with the primary testing personnel at approximately 2:30 PM, it was confirmed that the laboratory failed to retain documentation of evaluation of the 2016 API Chemistry Event 3.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of the laboratory's procedures, calibration verification documentation, analyzer operations guide, a laboratory tour, patient test log review,

	and an interview, the laboratory failed to perform calibration validation studies for Sodium (Na), Potassium (K), and Chloride (CL) according to the laboratory's written policy in calendar year 2016. Findings include: 1. Review of the laboratory's procedures revealed a policy to perform calibration verification for the Siemens Dimension xPand Plus chemistry analyzer testing. The policy states: "calibration validation linearity studies are performed twice yearly for assays that have calibration curves of less than 3 points". 2. Review of the laboratory's 2016 Siemens Dimension xPand Plus chemistry analyzer calibration verification documentation revealed one (1) calibration verification performed and accepted by testing personnel and lab director for Sodium (Na), Potassium (K), and Chloride (CL) using Verichem calibration verifier material on 07/05/16. The inspector requested to review additional documentation of calibration verification for Na, K, and CL performed in calendar year 2016. The documentation was not available for review. 3. Review of the manufacturer's Siemens Dimension xPand Plus operator's guide revealed a two-point calibration for electrolytes Na, K, and CL. 4. During a laboratory tour at approximately 1:30 PM, the inspector asked the primary testing personnel to describe how the calibration verification policy is followed for the electrolytes assayed on the Siemens Dimension analyzer. The primary testing personnel stated "it is our policy to run the verification studies every 6 months but, I am unable to find the documentation at this time that it was performed twice in 2016 for the electrolytes." 5. Review of the laboratory's patient test logs revealed eight thousand eight hundred seventy-four (8,874) Na, K, and CL patient results were reported in calendar year 2016. 6. In an interview with the primary testing personnel at approximately 2:30 PM on January 25, 2018, it was confirmed that the laboratory failed to document performance of calibration validation studies according to the laboratory's written policy for the three (3) Siemens Dimension chemistry test reagents outlined above while reporting eight thousand eight hundred seventy-four (8,874) patient results in calendar year 2016.