Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0227779	12/04/2020
Name of Provider or Supplier	**Street Address, City, State**	
New Market Medical Center	2660 New Market Road, Richmond, 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 on-site CLIA recertification survey was conducted at New Market Medical Center on December 4, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview and virtual record review conducted on 12/3/2020. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). 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 evaluate non-graded microscopy PT results for one (1) of three (3) events reviewed for calendar year 2019. Findings include: 1. Review of the laboratory's 2019 American Proficiency Institute (API) PT documentation (Events 1-3) revealed no evaluation or verification of accuracy for the non-graded responses of: 2019 Event 1 Urine Sediment - challenge sample US-02 -not graded due to lack of consensus, 2019 Event 1 Vaginal Wet Prep (KOH)- challenge sample VKP-01-not graded due to lack of consensus. The inspector requested to review evaluation documentation for the microscopy PT samples listed above. No additional documentation was available for review. 2. In an exit interview with the primary testing personnel on 12/4/20 at approximately 10:00 AM, the above findings were confirmed.
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 a review of the laboratory's policies and procedures, monthly hematology quality control (QC) records, lack of documentation, and an interview, the laboratory failed to follow their policy to monitor, assess/correct problems with the Abbott Cell Dyn analyzer with QC statistical review for three (3) of twelve (12) months reviewed in calendar year 2019. 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 Abbott Cell Dyn hematology analyzer via a monthly QA checklist with a review of printed Levy-Jennings (LJ) charts. 2. During a review of the laboratory's monthly QA reports from calendar year 2019, the inspector noted no hematology LJ charts were reviewed on the monthly reports during the timeframe of October 1, 2019 to December 31, 2019. The inspector requested to review the three month timeframe of LJ records. No additional hematology QC statistics were available for review. The primary testing personnel stated on 12/3/20 at approximately 3:30 PM: "I do not have those QC print outs. I am not sure where they are at this time." 3. In an exit interview with the primary testing personnel on 12/4/20 at approximately 10:00 AM, the above findings were confirmed.