Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 31D2228062	**(X3) Date Survey Completed** 05/17/2023
Name of Provider or Supplier Virtua - Midwifery Birth And Wellness Center	**Street Address, City, State** 165 Route 73, Voorhees, NJ	
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**
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to review and evaluate PT results obtained from the American Proficiency Institute (API) for Hematology/Coagulation 2nd event 2022 and 3rd event of 2021. The findings include: 1. The laboratory did not evaluate "Not Graded" response from API for the following: a. Vaginal Wet Mount Preparation sample VA-02 in event 2, 2022. b. Vaginal Wet Preparation (KOH) sample VKP-3 in event 3, 2021. 2. The TP confirmed on 5/17/23 at 10:30 am that the laboratory failed to evaluate the above mentioned coded results.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must

	document all control procedures performed. This STANDARD is not met as evidenced by: Based on the lack of Quality Control Verification (QCV) records and interview with the Testing Personnel (TP), the laboratory failed to verify QC material before use for Aminiotest tests performed with the Pro-Lab Diagnostics Nitrazine Yellow Swabs from 6/22/21 to the date of survey. The TP confirmed 5/17/23 at 11:15 am that QC material was not verified before putting in use.
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 surveyor review of the Procedure Manual and interview with Testing Personnel (TP) the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems from 6/22/21 to the date of survey. The finding includes: 1. The laboratory failed to have a procedure to verify new lots of controls before they were put in use. 2. The TP confirmed on 5/17/23 at 11:40 am that the laboratory failed to have a procedure to verify new lots of controls before they were put in use.