Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D0703107	(X3) Date Survey Completed 05/16/2024
Name of Provider or Supplier Cheyenne Obstetrics And Gynecology, Inc Pc	**Street Address, City, State** 2301 House Avenue Suite 400, Cheyenne, WY	

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
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of patient testing records, review of quality control (QC) records, review of the laboratory's individualized quality control plan (IQCP), and staff interview, the laboratory failed to ensure QC was performed with every new lot number or shipment of the Affirm VP III Gardnerella vaginalis, Candida species, and Trichomonas vaginalis testing cartridges prior to testing patient samples for 23 out of 35 patient test records reviewed between 1/8/24 and 1/24/24. The laboratory performed approximately 960 patient tests per year. The findings were: 1. Review of the QC log showed the Affirm VP III test cartridge lot #3261538 was received by the laboratory on 1/8/24 and QC was performed on 1/18/24. The following concerns were identified: a. Review of the patient testing log showed 1 patient sample was tested on 1/8/24; 7 patient samples were tested on 1/10/24; 3 patient samples were tested on 1/11/24; 3 patient samples were tested on 1/12/24; 3 patient samples were tested on 1/15/24; 2 patient samples were tested on 1/16/24; and 4 patient samples were tested on 1/17/24 using lot #3261538. 2. Review of the laboratory's IQCP, approved by the laboratory director on 9/5/23, showed external QC must be performed with each new lot number, each new shipment, after system maintenance and software upgrades, if the storage temperature of reagents fell outside of the acceptable range, or to verify

	device or reagent function before retesting questionable patient results. 3. Interview with the laboratory manager on 5/16/24 at 11:29 AM confirmed QC had not been performed on lot #3261538 prior to patient testing.