

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0698561	(X3) Date Survey Completed 05/11/2023
Name of Provider or Supplier Isbell Medical Group Pc	Street Address, City, State 550 Medical Center Drive Sw, Fort Payne, AL	
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	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the quality control (QC) records for the BD Affirm VP8, and interviews with Testing Personnel #1, the laboratory failed to ensure kit lot numbers were documented with the QC results, since before the previous survey on 11/17 /2021. The findings include: 1. During the entrance tour on 5/11/2023 at approximately 9:15 AM, Testing Personnel #1 stated the only non-waived instrument was the BD Affirm VP8, which tests for the presence of Trichomonas vaginalis, Candida species, and Gardnerella vaginalis. 2. A review of the BD Affirm VP8 QC records revealed the laboratory had implemented an IQCP (Individual Quality Control Plan) which specified external positive and negative quality controls should be performed for each new lot number of kits; Testing Personnel #1 stated she performed QC each time she opened a new box of kits. 3. A review of a BD Affirm VP8 form (not in use by the laboratory) revealed the following instructions, "Record the reactions of the BD Affirm VP8 external controls for each reagent lot # [number] tested". 4. A review of the BD Affirm VP8 QC records revealed the laboratory recorded the "DATE, LOT #, EXP [Expiration] DATE" of the external QC swabs, along with the QC reactions (Positive or Negative) each day of QC performance. However, there was no record of the BD Affirm VP8 kit lot # on which the QC was</p>

run since before the previous survey on 11/17/2021. 5. During an interview with Testing Personnel #1 on 5/11/2023 at 11:15 AM, the surveyor reviewed the kit lot numbers currently in use including Lot # 2327952 which had been used for patient testing since April 2023. The surveyor reviewed the QC records, and asked Testing Personnel #1 when she had performed QC on BD Affirm VPIII kit Lot # 2327952; Testing Personnel #1 stated she did not know. Testing Personnel #1 stated she only recorded the lot # and expiration date from the package of the Tri-valent Positive and Negative QC swabs. No one had instructed her in the requirement of recording the kit lot # when she performed the QC. .

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on a review of the quality control (QC) records for the BD Affirm VPIII, and interviews with Testing Personnel #1, the previous and current Laboratory Directors failed to ensure the laboratory documented the kit lot numbers with the QC results, since before the previous survey on 11/17/2021. The findings include: 1. Refer to D5445. SURVEYOR ID# 32558 Licensure and Certification Surveyor