Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2281004	06/09/2026
Name of Provider or Supplier	**Street Address, City, State**	
Vitality Plus Urology, Llc	140 Hwy 201 North, Mountain Home, AR	

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
D3005	FACILITIES CFR(s): 493.1101(a)(3) (a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: Based upon observations made during a tour of facilities and interview with laboratory staff, the laboratory failed to establish a uni-directional workflow for molecular amplification procedures in which amplified specimens were transported back to the specimen preparation area. Findings follow: A) During a tour of the laboratory testing facilities on 6/10/26 at 01:30 p.m. the surveyor observed the room in which molecular amplification procedures were performed. The room is rectangular with longer sides (side "A" and side "B") and shorter sides (side "C" and side "D"). Entry is via a door in side "A" at the corner formed at conjuction with side "D". Side "A" had a workbench and sink. Side "C" had a work bench. On side "B" was a Thermo Fisher Scientific QuantStudio instrument used for analyzing samples after amplification and a centrifuge used for specimen preparation. Side "D" had a door to another testing area and nothing used in the molecular amplification process. B) During an interview on 6/10/26 at 03:30 p.m., the testing personnel (# 2 on the form CMS 209) described the testing process workflow as specimens entering from the door on side "A", proceeding to side "C" for preparation , moving to side"B" for centrifugation, moving to side "A" for amplification, and moving to side "B" for final analysis on the QuantStudio instrument. C) In an interview on 6/10/26 at 3:35 p.m., the testing personnel (# 2 on the form CMS 209) confirmed that the testing flow was not uni-directional, that testing was halted in May for a temporary period when reagents became contaminated through "user error".

D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based upon review of policy and procedure, observation, and interview, the laboratory failed to establish and follow policies that ensure patient identification through the testing and reporting process. Findings follow: A) Review of policy and procedure revealed that the laboratory would maintain two unique patient identifiers through the specimen collection and testing porcess. B) During a tour of the laboratory on 6/10/26 at 04:45 p.m., The surveyor observed urine specimens that were labeled with patient first and last names and patient dates of birth, and test tubes to be placed on the AUA 450 urine analyzer that were labeled with patient first and last names and a specimen number. C) In an interview on 6/10/26 at 04:45 p.m., the testing personnel (# 2 on the form CMS 209) stated that urine samples were poured from the original containers labeled with patient names and dates of birth in to test tubes to be placed on the analyzer labeled with patient names and specimen numbers and confirmed that two unique identifiers were not used in common throughout the testing process.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based upon a review of an email with the header of "AutoUA 2026 Quant A Survey RESULTS", a report "2026 AutoUA Quant A Survey Graded Results", lack of documentation, and interview with laboratory staff, the laboratory failed to assess and provide corrective action when elements of the "AutoUA 2026 Quant A Survey Results" failed to meet crieria of acceptability. Findings follow: A) Review of an email regarding "AutoUA Quant A Survey Results" revealed "after reviewing the quantitative results, we averaged data from all particpating labs. Grades were determined based on the accuracy of each lab's reported results compared to overall average, with a margin of plus or minus 20%". B) Review of "AutoUA Quant A Survey Graded Results" revealed that the laboratory's results were graded as unacceptable for sample "AUA-1" for the analyte Urobilinogen and sample "AUA-5" for analytes Ketone, and Urobilinogen. C) Upon request, the laboratory could not provide the assessment of the unacceptable result identified above. D) In an interview on 6/10/26 at 03:45 p.m., the testing personnel (# 2 on the form CMS 209) confirmed that the lab accepted an overall passing grade and did not assess the cause or determine possible corrective action for the unsuccessful proficiency testing results identified above
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Through observation and interview with laboratory staff the laboratory failed to label the contents of one of one containers of liquid stored in the laboratory refirgerator.. findings follow: A) During a tour of the laboratory on 6/10/26 at 04:15 PM a plastic container containing a yellow colored liquid substance was observed in the laboratory refrigerator without a label of contents. B) When asked during an interview on 6/10 /26 at 04:15 PM what the identity of the contents of the container were, the laboratory staff member, (# 2 on the CMS 209 form) said the container held material used as substrate in the instrument validation process and confirmed the container was not labeled as to contents.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: . Based upon review of personnel files for testing personnel listed on the form CMS-209, lack of documentation, and interviews with laboratory staff, the laboratory director failed to authorize one of one testing personnel that performs highly complex molecular amplification testing to perform testing without direct supervision. Survey findings include: A) Review of personnel files for two testing personnel revealed testing personnel (# 2 as listed on the form CMS 209) lacked written authorization from the laboratory director to perform highly complex molecular amplification testing without direct supervision. B) Upon request, the laboratory was unable to provide the laboratory director's written authorization for the testing personnel (# 2 on the form CMS 209) to perform and report highly complex molecular amplification tests. C) In an interview, at 02:17 on 6/10/26, laboratory staff member #2 (as listed on the form CMS 209) confirmed the lack of written authorization to perform tests for the testing personnel identified above and that testing personnel (#2 on the form CMS 209) was the only personnel that performs and reports molecular amplification tests.