

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2203385	(X3) Date Survey Completed 08/02/2023
Name of Provider or Supplier Unified Women's Healthcare Texas, Pllc	Street Address, City, State 8282 El Rio St Suite 140, Houston, TX	
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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the manufacturer's package inserts, the laboratory's client manual, the laboratory's temperature records in 2022, CMS 116 application, and confirmed in an interview, the laboratory failed to ensure specimen temperature during transportation was maintained and followed manufacturer's instructions. for 7 of 7 microbiology assays performed on the Hologic Panther analyzer for 12 of 12 months reviewed. a. Aptima Mycoplasma genitalium Assay b. Aptima CV/TV Assay c. Aptima HPV Assay d. Aptima HPV 16 18/45 Genotype Assay e. Aptima BV Assay f. Aptima Trichomonas vaginalis Assay g. Aptima Combo 2 Assay (for Chlamydia trachomatis and Neisseria gonorrhoeae) The findings were: 1. Review of the laboratory's client manual titled 146428.107 LCS-005 Attachment TX Quick Reference Guide revealed three of three types of specimen types: Specimen types: ThinPrep Swabs Urine 2. Further review of the laboratory's client manual titled 146428.107 LCS-005 Attachment TX Quick Reference Guide revealed "PARTNERSHIP: UWH of TX Laboratory has partnered with BioReference Laboratories (BRL) for courier services to UWH of TX Laboratory." 3. Review of the</p>

laboratory's client manual titled GENLAB-010 SPECIMEN COLLECTION MANUAL under Specimen Transport revealed "Each primary collection container (i. e. Aptima collection device) should be placed in a properly labeled 6x9 specimen transport bag." 4. An interview with the technical supervisor on 8/2/2023 at 1:30 pm in the Lab Admin Entrance confirmed the laboratory used BRL courier service. The technical supervisor confirmed the laboratory received specimens in 6x9 biohazard bags and did not have records of temperature logs throughout transportation. 5. Review of the manufacturer's package insert titled Aptima Mycoplasma genitalium Assay (AW-17946 Rev. 001) under B. Specimen storage before testing revealed the following, "1. Swab specimens a. After collection, swab specimens in transport tube can be stored at 2C to 30C for up to 30 days. 2. Urine Specimens a. Before urine specimens can be tested, urine must be transferred to an Aptima urine transport tube in accordance with the instructions in the urine collection kit package insert." 6. Review of the Aptima Urine Specimen Transport Tubes package insert (502257 Rev. 002) under Specimen Transport and Storage revealed "After collection, transport the processed urine specimens in the Aptima urine specimen transport tube at 2C to 30C and store at 2C to 30C until tested." 7. Review of the manufacturer's package insert titled Aptima CV/TV Assay (AW-18812 Rev. 001) under B. Specimen transport and storage before testing revealed "1. Swab specimens a. After collection, swab specimens in transport tubes can be stored at 2C to 30C for up to 30 days." 8. Review of the manufacturer's package insert titled Aptima HPV Assay (AW-12820 Rev. 004) under B. Transport and storage before testing revealed "1. Transport the ThinPrep liquid cytology specimens at 2C to 30C." 9. Review of the manufacturer's package insert titled Aptima HPV 16 18/45 Genotype Assay (AW-12821 Rev. 005) under B. Transport and storage before testing revealed "1. Transport the ThinPrep liquid cytology specimens at 2C to 30C." 10. Review of the manufacturer's package insert titled Aptima BV Assay (AW-18811 Rev. 001) under B. Specimen transport and storage before testing revealed "1. Swab specimens a. After collection, swab specimens in transport tubes can be stored at 2C to 30C for up to 30 days..." 11. Review of the manufacturer's package insert titled Aptima Trichomonas vaginalis Assay (503684 Rev. 008) under B. Specimen transport and storage before testing revealed "1. Swab specimens a. After collection, transport and store the swab in the swab specimen transport tube at 2C to 30C until tested." 12. Review of the manufacturer's package insert titled Aptima Combo 2 Assay (502446 Rev. 010) under B. Specimen transport and storage before testing revealed "3. Urine specimens: ...b. After collection, transport the processed urine specimens in the Aptima urine specimen transport tube at 2C to 30C and store at 2C to 30C until tested." 13. Review of the laboratory's temperature logs in 2022 revealed no documentation for monitoring of specimen temperature during transportation for 12 of 12 months reviewed. 14. Review of the CMS 116 application, signed by the LD on 8/1/2023, revealed the laboratory performed 237,238 microbiology tests annually. 15. An interview with the technical supervisor on 8/2/2023 at 2:18 pm in the Lab Admin Entrance confirmed the above findings. Key: CMS=Center for Medicare and Medicaid Services CV /TV=Candida/Trichomonas BV=Bacterial vaginosis UWH=Unified Women's Healthcare C=Celsius LD=Laboratory Director