

Invalid Results: Possible causes for Vaginal and Sexual Transmitted Disease (STD) testing to be reported as invalid for the following Nucleic Acid Amplification Assays (NAA):

Vaginitis NAA Panel

- Candida species and Trichomonas (CV/TV)
 - Interference with the Aptima CV/TV assay was observed in the presence of the following substances: tioconazole 6.5% ointment (3% W/V, all analytes), vaginal moisturizing gel (1% W/V, C spp; 5% W/V, C. glabrata; 3% W/V, TV), and glacial acetic acid (5% V/V, C spp only).
 - The effects of other potential variables such as vaginal discharge, use of tampons, and specimen collection variables have not been determined.
- Gardnerella (BV)
 - Interference with the Aptima BV assay was observed in the presence of the following substances: mucus (1.5% V/V), vaginal moisturizing gel (0.5% W/V) and tioconazole (5% W/V).
 - The effects of other potential variables such as vaginal discharge, use of tampons, and specimen collection variables have not been determined.

References:

Aptima BV Assay Product Insert. AW-18811-001 Rev. 003; 2020-09. Hologic, Inc 10210 Genetic Center Drive San Diego, CA 92121 USA

Aptima CV/TV Assay Product Insert. AW-18812-001 Rev. 004; 2021-06. Hologic, Inc 10210 Genetic Center Drive San Diego, CA 92121 USA