Test Definition: CVRNA

Candida Vaginitis, Nucleic Acid Amplification RNA, Vaginal

Overview

Useful For

Aiding in the diagnosis of Candida vaginitis

This test is **not intended for use** in medico-legal applications.

Method Name

Transcription Mediated Amplification

NY State Available

Yes

Specimen

Specimen Type

Vaginal

Specimen Required

Specimen Type: Vaginal
Supplies: Aptima Multitest Swab Collection Kit (T584)
Container/Tube: Aptima Multitest Swab
Specimen Volume: Swab
Collection Instructions:
1. **Specimens must be collected using the Aptima Multitest Swab Collection Kit.**
2. Insert swab (pink shaft) about 5 cm past introitus and rotate gently for 30 seconds.
3. Place swab into transport tube provided in collection kit. Snap off swab at score line so swab fits into closed tube.
4. Cap tube securely, and label tube with patient's entire name and collection date and time.
5. Maintain swab container at 2 to 30 degrees C (refrigerate temperature is preferred) and transport within 30 days of collection. If longer storage is needed, freeze at -20 to -70 degrees C up to 60 days.

Specimen Minimum Volume

See Specimen Required

Reject Due To

Incorrect swab Transport tubes containing	Reject

more than one swab	

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Vaginal	Refrigerated (preferred)	30 days	APTIMA VIAL
	Ambient	30 days	APTIMA VIAL
	Frozen	60 days	APTIMA VIAL

Clinical & Interpretive

Clinical Information

This test is intended to aid in the diagnosis of vulvovaginal candidiasis from vaginal samples collected from symptomatic individuals. Vaginitis is characterized by a spectrum of signs and symptoms, including vaginal/vulvar irritation, odor, discharge, and pruritus. Vaginitis may develop as a result of mechanical and/or chemical irritants (eg, feminine hygiene products, contraceptive materials), or due to a dysbiosis of the microbiota in the vaginal tract. Up to 90% of vaginitis cases are infectious due to Bacterial vaginosis (BV), vulvovaginal candidiasis (*Candida* vaginitis, CV) and/or trichomoniasis (*Trichomonas vaginalis*, TV). BV, CV and TV individually account for 22% to 50%, 17% to 39%, and 4% to 35% of vaginitis cases, respectively.

Candida vaginitis, commonly known as a yeast infection, is the second most frequent cause of vaginitis. CV is characterized by an overgrowth of *Candida* species in the vaginal tract and is associated with development of inflammation, abnormal vaginal discharge, vaginal soreness, pruritus, dyspareunia, and external dysuria. Up to 89% of CV cases are caused by *C albicans*, while non-albicans species may be responsible for 11%. *C glabrata*, which is responsible for the majority of non-albicans CV in the U.S., has decreased susceptibility to standard antifungal regiments for CV as compared to *C albicans*, which is why *C glabrata* is specifically reported by this assay.

Reference Values

Candida glabrata
Negative

Candida species group (*C albicans, C tropicalis, C parapsilosis, C dubliniensis*)
Negative

Interpretation

Candida species group (C albicans, C tropicalis, C parapsilosis, C dubliniensis):
Positive: Candida albicans, C tropicalis, C parapsilosis and/or C dubliniensis RNA detected. Individual organisms are not identified or reported by this assay. Results should be interpreted alongside clinical presentation. Up to 21% of asymptomatic patients may be positive by this assay.

Negative: No RNA detected from Candida albicans, C tropicalis, C parapsilosis or C dubliniensis. A negative result does not exclude infection.

Inconclusive: Repeat testing on a new sample is recommended if clinically indicated.

Candida glabrata:
Positive: Candida glabrata RNA detected. Results should be interpreted alongside clinical presentation. Up to 9% of asymptomatic patients may be positive for C glabrata this assay.

Negative: No RNA detected from Candida glabrata. A negative result does not exclude infection.

Inconclusive: Repeat testing on a new sample is recommended if clinically indicated.

Cautions

The effects of tampon use, douching, and specimen collection variables have not been evaluated for their impact on assay performance.

This report is intended for clinical monitoring or management of patients; it is not intended for use in medico-legal applications.

Appropriate specimen collection and handling is necessary for optimal assay performance.

Therapeutic failure or success cannot be determined with this assay since nucleic acid may persist following appropriate antimicrobial therapy.

A negative result does not preclude a possible infection because results are dependent on adequate specimen collection. Test results may be affected by improper specimen collection, technical error, specimen mix-up, or low numbers of organisms in the specimen (target levels below the assay limit of detection).

Therapeutic failure or success cannot be determined since nucleic acid may persist following appropriate antimicrobial therapy.

Performance of the assay has not been evaluated in women younger than 14 years.

Collection and testing of patient-collected vaginal swab specimens with the assay is not intended to replace clinical examination. Vaginal infections may result from other causes or concurrent infections may occur.

Interference with the 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 following organism was observed to cross-react above the stated concentrations:
Candida famata at concentrations higher than 5x105 CFU/mL.

Competitive interference was observed in co-infected samples for the combination of low *C glabrata* (3X LoD) and high *T vaginalis* (1x105 or 1x104 cells/mL).

Clinical Reference

1. Workowski KA, Bachmann LH, Chan PA, et al. Sexually transmitted infections treatment guidelines, 2021. MMWR Recomm Rep. 2021;70(4):1-187. doi:10.15585/mmwr.rr7004a1
2. Huang SH, Hsu HC, Lee TF, et al. Prevalence, Associated Factors, and Appropriateness of Empirical Treatment of Trichomoniasis, Bacterial Vaginosis, and Vulvovaginal Candidiasis among Women with Vaginitis, 2023. American Society for Microbiology. 2023;11(3):e00161-23.doi:10.1128/spectrum.00161-23
3. Farr A, Effendy I, Frey Tirri B, Hof H, et al. Guideline: Vulvovaginal candidosis (AWMF 015/072, level S2k), 2021. Mycoses. 2021;64(6) 583-602. doi.org/10.1111/myc.13248

Performance

Method Description

The Aptima CV/TV kit is used for this testing, however only the CV result is reported. This assay is an *in vitro* nucleic acid amplification test for the detection of RNA from microorganisms associated with vulvovaginal candidiasis and trichomoniasis. The assay utilizes real time transcription-mediated amplification (TMA) to detect and qualitatively report results for the following organisms: *Candida* species group (*C albicans, C tropicalis, parapsilosis, C dubliniensis), Candida glabrata,* and *Trichomonas vaginalis* (TV). The Panther system detects and discriminates between four fluorescent signals corresponding to Candida species group, C glabrata, TV, and IC amplification products. The Panther system software uses an Aptima CV/TV assay-specific algorithm that interprets the amplification signal emergence times to generate a Positive or Negative status for each target organism in the sample. Note, the TV component of this kit is not reported. (Package insert: Aptima CV/TV Assay, AW-23713-001. Hologic, Inc; Rev 001, 03/2023)

PDF Report

No

Day(s) Performed

Monday through Sunday

Report Available

1 to 4 days

Specimen Retention Time

7 days

Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Superior Drive

Fees & Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification

This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information

87481

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
CVRNA	Candida vaginitis, Amplified RNA	92703-8

Result ID	Test Result Name	Result LOINC® Value
621517	Candida species, Amplified RNA	94422-3
621518	Candida glabrata, Amplified RNA	94421-5