ForPatients
by Roche

Vulvovaginal candidiasisBacterial vaginosis

Performance Study of the Cobas® BV/CV Test on Samples From Participants With and Without Symptoms of Bacterial Vaginosis and Candida Vaginitis

Trial Status	Trial Runs In	Trial Identifier
Completed	3 Countries	NCT06975436 RD006770

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

Cobas® BV/CV Test for Use on the Cobas® 5800/6800/8800 Systems: Clinical Performance and Reproducibility

Trial Summary:

In the clinical performance part of this study, prospectively acquired clinician-collected and clinician-instructed, self-collected vaginal swab specimens collected in cobas® PCR Media will be taken from a minimum of 500 symptomatic individuals with a clinical presentation consistent with vaginitis, vaginosis, or both. Additionally, a minimum of 100 asymptomatic individuals will also be enrolled in the study. The cobas® BV/CV assay amplifies and detects the deoxyribonucleic acid (DNA) of pathogens associated with bacterial vaginosis (BV) and candida vaginitis (CV). The BV results will be compared with the patient infection status (PIS) established by using 3 Food and Drug Administration (FDA)-cleared commercial assays, and the CV results will be compared with the PIS established with the use of culture plus MALDI-TOF (matrix-assisted laser desorption/ ionization time-of-flight). The primary objective of the clinical performance study is to evaluate the performance (sensitivity and specificity) of cobas® BV/CV to determine the presence of BV and/or CV in the intended use patient population when being tested on cobas® 6800/8800 systems. The secondary objective is to evaluate the equivalency of cobas® BV/CV between the cobas® 5800 system and cobas® 6800/8800 systems.

Hoffmann-La Roche	N/A
Sponsor	Phase

NCT06975436 RD006770
Trial Identifiers

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Eligibility Criteria:

Gender	Age	Healthy Volunteers
Female	**#14 Years**	**Accepts Healthy Volunteers**

Inclusion Criteria:

Inclusion Criteria for Symptomatic Participants:

- Symptomatic participants with a clinical presentation consistent with vaginitis, vaginosis, or both; symptoms may include abnormal vaginal discharge, painful or frequent urination, vaginal itching or burning or irritation, painful or uncomfortable intercourse, and/or abnormal vaginal odor.
- Participants aged 14 years or older who are willing and able to provide written, informed consent; for pediatric participants, written assent and parent/legal guardian consent, as applicable by the institutional review board/ethics committee (IRB/EC).

Inclusion Criteria for Asymptomatic Participants:

- Apparently healthy participants aged 14 years or older who are willing and able to provide written, informed consent; for pediatric participants, written assent and parent/legal guardian consent, as applicable by the IRB/EC.

Exclusion Criteria:

Exclusion Criteria for Symptomatic Participants:

- Participants not meeting the above described inclusion criteria will be excluded from the study.
- Use of any azole-containing antimicrobial (oral or vaginal) within the 7 days prior to study enrollment.
- Prior enrollment in this study.
- Use of any lubricants (eg, Replens, RepHresh) within 3 days prior to sample collection
- Use of douches, vaginal deodorizers, or other intravaginal products within 3 days prior to sample collection. The use of tampons or pads during menses should not be considered exclusionary criteria.
- Contraindication to vaginal swab sampling.
- Asymptomatic participants who do not have any signs or symptoms consistent with vaginitis, vaginosis, or both, as described above.

Exclusion Criteria for Asymptomatic Participants:

- Prior enrollment in this study.
- Participants with a clinical presentation consistent with vaginitis, vaginosis, or both; symptoms may include abnormal vaginal discharge, painful or frequent urination, vaginal itching or burning or irritation, painful or uncomfortable intercourse, and/or abnormal vaginal odor.

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