ForPatients
*by Roche*

Neisseria Gonorrhoeae InfectionChlamydia Trachomatis InfectionInfectious DiseasesMycoplasma Genitalium Infection

# A Study of the Cobas® Liat CT/NG/MG Test Versus Current Standard Practice for Managing Participants at Increased Risk of Sexually Transmitted Infections

| Trial Status | Trial Runs In | Trial Identifier |
|---|---|---|
| Completed | 1 Country | NCT06369220 RD006616 LIA-STI-542 |

*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:*

A Study of the Clinical Utility of Point of Care Cobas® Liat CT/NG/MG Nucleic Acid Test Versus Current Standard Practice

## *Trial Summary:*

This study is designed to assess the comparative clinical utility of the point of care cobas® liat CT/NG/MG to current standard practices in the diagnosis and treatment of urogenital infections with Chlamydia trachomatis (CT), Neisseria gonorrhoeae (NG), and Mycoplasma genitalium (MG).

| Hoffmann-La Roche | N/A |
|---|---|
| Sponsor | Phase |

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Trial Identifiers

## *Eligibility Criteria:*

| Gender | Age | Healthy Volunteers |
|---|---|---|
| All | #18 Years | No |

## *Inclusion Criteria:*

- Sexually active people
- People seeking medical services for symptoms consistent with a sexually transmitted infection (STI) and/or known exposure to an STI

## *Exclusion Criteria:*

- Previously enrolled in the study
- Unable to provide informed consent
- Currently pregnant
- Declines POC testing
- Presents for routine STI screening (asymptomatic)
- Use of antimicrobial agents active against CT, NG, or MG during the 21 days before sample collection. Example of such antimicrobial agents include the following: Macrolides (e.g., azithromycin and erythromycin); Penicillins (e.g., amoxicillin); Tetracyclines (e.g., doxycycline); Fluoroquinolones (e.g., ciprofloxacin, ofloxacin, levofloxacin, and moxifloxacin); Cephalosporins (e.g., ceftriaxone and cefixime)
- Use of phenazopyridine-containing urinary pain relief medicines (ie, Azo or Pyridium) within 2 days prior to sample collection
- Use of any over-the-counter feminine hygiene products (internally or externally), such as vaginal moisturizers, lubricants (e.g., Replens, RepHresh, etc.), and feminine washes/vaginal douches, etc. within the 3 days prior to sample collection. The use of tampons or pads during menses is not an exclusionary criterion.
- Contraindication to vaginal swab sampling where vaginal swab sampling is the only option available
- Urination within 1 hour prior to sample collection (for subjects providing urine sample)