

alethia[®]

Chlamydia/Gonorrhea

Improves patient outcomes by providing accurate, actionable results for the detection of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoea* (NG)

Early and Accurate Results Matter

According to WHO, more than 1 million sexually transmitted infections (STIs) are acquired every day worldwide.^{1,2} In 2016 of all the STIs, 214 million new infections were caused by chlamydia (CT) or gonorrhea (NG).^{1,2}

Alethia[®] Chlamydia and Alethia[®] Gonorrhea provide healthcare systems easy access to appropriate CT and NG diagnosis to ensure the right treatment with a high-quality of care.

- Detect CT and/or NG infections easily from a wide range of samples (endocervical swabs, self-collected vaginal swabs and urine)
- Alethia[®] molecular platform reduces your laboratory's turnaround time to report results and eliminates the need for send-outs
- Fast, accurate, actionable results enable physicians to make informed decisions about the management and treatment of their patients

CT and NG infection can lead to complications such as Pelvic Inflammatory Disease (PID), ectopic pregnancy, infertility.

- With 50 - 70% of patients being asymptomatic for CT³, are you offering the best testing solution to your physicians to encourage diagnosis and avoid undertreatment?
- How would a test that enables timely and accurate results help support the use of appropriate therapy to control STIs?

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Results That Matter

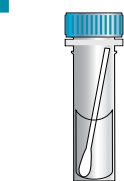
- The performance of NAATs with respect to overall sensitivity and specificity is better than that of any other test available for the diagnosis of chlamydial and gonococcal infections.⁵
- Simplify your workflow with Alethia[®] combined with our unique M-prep[™] simple sample preparation procedure.

Total Trusted Solution

- Adapt to your physician needs with Alethia[®]'s flexibility to test either CT alone, NG alone or CT + NG from one sample.
- The Alethia[®] instrument has 2 independent blocks with 5 positions each, providing flexibility to the lab to batch up to 10 patient samples or run the tests on demand.
- Meridian's flexible molecular platform allows your lab to add additional Alethia[®] assays, such as Alethia[®] HSV 1&2.

Alethia[®] Chlamydia and Gonorrhea Procedure Steps

1 Sample

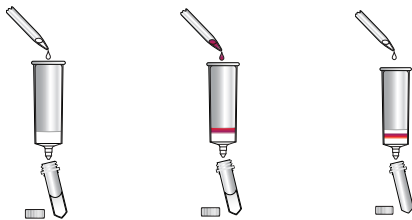


Swab Specimen



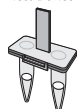
Urine Specimen

2 M-prep Procedure

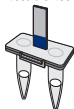


3 Load sample into Alethia[®] test devices and run

Alethia[®] Chlamydia Test Device



Alethia[®] Gonorrhea Test Device



Product Specifications

The Alethia[®] Chlamydia and Alethia[®] Gonorrhea assays are qualitative in vitro diagnostic tests for the direct detection of *Chlamydia trachomatis* and *Neisseria gonorrhoea* DNA in endocervical swabs, patient-collected vaginal swabs and male or female urine from patients suspected of having STI.

Turnaround Time

Approximately one hour

Shelf Life

18 months

Sample Type

Physician-collected endocervical swabs

Patient-collected vaginal swabs (from clinical settings)

Male urine and female urine

Sample Storage

Collected swab and urine specimens should be stored refrigerated (2-8 C) after collection for up to 7 days prior to testing

Kit Storage

Kit should be stored at 2-30C until expiration date indicated on kit label

Performance

Chlamydia trachomatis:

97.1% Sensitivity

97.9% Specificity

Neisseria gonorrhoea:

93.5% Sensitivity

98% Specificity

Catalog Number

Alethia[®] Chlamydia - 480450

Test Kit Size

50 tests per kit

Alethia[®] Gonorrhea - 480850

50 tests per kit

Materials provided separately

M-Swab[™] Collection, Preservation

and Transport System - 6E028N.MER

M-prep[™] DNA Sample Preparation Kit - 281110

M-prep[™] Workstation - 610165

References

1. Rowley J, Vander Hoorn S, Korenromp E, Low N, Unemo M, Abu-Raddad LJ, et al. Global and Regional Estimates of the Prevalence and Incidence of Four Curable Sexually Transmitted Infections in 2016. WHO Bulletin. June 2019. <https://www.who.int/bulletin/volumes/97/8/18-228486.pdf?ua=1>
2. Report on global sexually transmitted infection surveillance, 2018. Geneva: World Health Organization; 2018. Licence: CC BY-NC-SA 3.0 IGO] <https://www.who.int/reproductivehealth/publications/stis-surveillance-2018/en/>
3. <https://www.ecdc.europa.eu/en/chlamydia/facts>
4. Unemo M, Shafer WM. Antimicrobial resistance in *Neisseria gonorrhoeae* in the 21st century: past, evolution, and future. Clin Microbiol Rev. 2014;27(3):587–613.
5. United States Centers for Disease Control and Prevention. Recommendations for the Laboratory-Based Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* — 2014. March 2014/63(RR02); 1-19. <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6302a1.htm>

Ready to get a handle on CT/NG testing? Let's talk.

Contact a specialist at info@meridianbioscience.eu
meridianbioscience.com

meridian BIOSCIENCE[®]
LIFE DISCOVERED. LIFE DIAGNOSED.

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