

# FACT SHEET FOR END USERS

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## Multiplo® Complete Syphilis (TP/nTP) Antibody Test

MedMira Inc.

This fact sheet is intended for end users and informs them of the significant known and potential benefits and risks associated with the use of Multiplo® Complete Syphilis (TP/nTP) Antibody Test.

**Intended use:** Multiplo® Complete Syphilis (TP/nTP) Antibody Test (Multiplo® TP/nTP) is a single use, manually performed, visually interpreted, qualitative immunoassay based on Rapid Vertical Flow Technology®, to detect antibodies to *Treponema pallidum* (TP), the causative agent of syphilis, and nontreponemal (nTP) antigens in human serum, plasma, or fingerstick whole blood specimens. Multiplo® TP/nTP is intended for use by healthcare professionals as an aid in the diagnosis of active syphilis infection.

**What is syphilis?** Syphilis is among most common sexually transmitted diseases (STDs) worldwide and is caused by the *Treponema pallidum* (TP) bacterium that spreads through direct contact with active lesions during vaginal, oral, or anal sexual contact with someone who has the infection. It can also be transmitted vertically when the infection is passed on from a pregnant person to their baby.

Syphilis is an easily treatable and preventable STD when diagnosed during early infections, however, when left untreated, it can result in serious complications for the patient such as severe heart disease, brain damage, spinal cord damage, blindness, and death. It is referred to as "the great imitator" since many of the early signs and symptoms are indistinguishable from those of other diseases.

**What are the symptoms of syphilis?** The first sign of syphilis is a small, usually painless sore, called a chancre (SHANG-kur). The sore forms at the spot of initial contact with bacteria and usually heals on its own within three to six weeks. After the original chancre heals, a rash that spreads to your entire body may appear (including the palms of your hands and the soles of your feet). These signs and symptoms eventually disappear with occasional re-appearances. About 15% to 30% of people infected with syphilis who don't get treatment will progress to tertiary syphilis. This stage is considered the most destructive stage, affecting multiple organs and systems including the heart, blood vessels, eyes (ocular syphilis), ears (otosyphilis), and the nervous system (neurosyphilis) and can result in death.\*

**What are syphilis tests and why are they important?** Syphilis tests are used for screening and diagnosis of infection with TP. Since syphilis is easy to cure during the early stages of infection, early detection and treatment of syphilis are necessary to prevent its progression to tertiary syphilis. Early diagnosis and intervention can also prevent the spread to others.

According to the Center for Diseases Control and Prevention (CDC), syphilis is the third most common STD in North America. Even though it is so common and easily preventable, due to the low prevalence of diagnostic testing, syphilis is one of the three STDs that required nearly 1.1 billion dollars in direct medical costs towards treatments in 2019 alone. The European Center of Disease Prevention and Control (ecdc) reported a steady increase of syphilis rate across Europe of approximately



50% each year. Taking just the congenital cases in consideration, the World Health Organization (WHO) estimated that nearly 1 million pregnant women are infected with syphilis annually, a number supported by the CDC, which reported an increase in congenital syphilis cases of around 291% between 2015 and 2019.

**What do the test measure?** Most syphilis test target various types of antibodies generated against the TP bacterium. Generally, these tests fall into two major types: Treponemal antibody tests and Nontreponemal antibody tests.

**Treponemal antibody tests (TP)** detect antibodies that are produced after syphilis infections. Since these antibodies remain even after treatment, they cannot be used to distinguish between current or past syphilis infection.

**Nontreponemal antibody tests (nTP)** detect nonspecific antibodies against biomarkers that are released during the cellular damage caused by a syphilis infection. Since these biomarkers can also be produced in response to other conditions and infections (i.e., not specific to TP), they are regarded as screening tests.

**Why Multiplo® TP/nTP?** Rising syphilis rates call for an urgent scale-up of global testing strategies. Our Multiplo® Complete Syphilis (TP/nTP) Antibody Test is a rapid test that combines both the screening (nTP) and the confirmation (TP) tests into a single device. It is ideally suited for point of patient care settings that require a portable and all-in-one testing solution.

On the Multiplo® TP/nTP test, a reactive TP result indicates previous exposure to the TP bacteria, while a reactive nTP result indicates the presence of antibodies produced during an active infection. Thus, the innovative dual detection offered by Multiplo® TP/nTP not only identifies exposure to TP but can also determine the current infection status. In a recent evaluation, Multiplo® TP/nTP displayed excellent performance, showing 100.00% sensitivity and specificity for the detection of active syphilis infections.

**About MedMira:** MedMira's patented Rapid Vertical Flow Technology® delivers fast, accurate results in a range of applications. Our products help care providers and their patients know more, instantly. MedMira rapid tests are manufactured in a cGMP facility with a quality management system registered to ISO 9001 and ISO 13485. In addition, MedMira's facility is MDSAP and CE certified. For more information about our products visit [medmira.com](http://medmira.com). For support contact us at +1 902 450 1588 or [support@medmira.com](mailto:support@medmira.com).

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\* This is for information purposes only. DO NOT diagnose or treat yourself and seek professional help if you suspect you may have been exposed to syphilis.