

OPPORTUNITIES AND CHALLENGES OF A RAPID SYPHILIS TEST (RST)

A RST that is treponemal-specific is now commercially available in the US.^v This test can be performed on whole blood from a finger stick as well as serum or plasma. Once treponemal antibody positive, RST will usually remain positive for a patient's entire life and therefore cannot distinguish past treated syphilis from syphilis requiring treatment. As a result, RST tests are less useful in populations with a high prevalence of past treated syphilis. In all cases, providers considering screening patients with a RST should first ask about a past history of syphilis. If they report a previous history of syphilis, a non-treponemal test (i.e., RPR or TRUST) should be obtained for evaluation.



The RST could be beneficial for individuals reporting no history of prior syphilis from the following venues or populations:

- HIV testing sites where venous blood draws are not performed such as non-traditional testing sites using oral or finger stick rapid HIV testing
- STD clinics, Emergency Departments, or urgent care centers with the important qualifier of suitability with patients being evaluated for genital lesions or signs/symptoms consistent with P&S syphilis
- Field screening for social contacts of Syphilis cases
- Sexually active gay men and other MSM

Several companies are in the process of developing a non-treponemal RST, but it is not yet available in the U.S.^{vi}

FURTHER RESOURCES

For additional information about syphilis and other STDs, please visit the following:

- **National Network of Prevention Training Centers (NNPTC)** at www.nnptc.org
 - The NNPTC is a premier resource providing up-to-date information to public and private clinicians who diagnose, treat, and manage patients with STDs.
- **The Centers of Disease Control and Prevention (CDC)** at <http://www.cdc.gov/std/syphilis/default.htm>
 - The CDC has many resources devoted to educating about syphilis and other STDs. Equally important, the CDC website has an excellent guide designed to assist healthcare providers in taking a sexual health history at <http://www.cdc.gov/std/see/HealthCareProviders/SexualHistory.pdf> and <http://www.medscape.com/viewarticle/743130>.
- Finally, your own **state, territorial, and city/county health departments** can be a vital resource.

Additional field testing in the coming year will shed further light on the use of RST. Please check NCSDDC's website (www.ncsddc.org) for updates on the RST.

Special thanks to Dr. Peter Leone, a Member of NCSDDC's Board of Directors and Professor of Medicine at the University of North Carolina, who authored and served as editor of this resource.

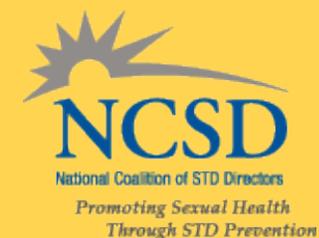
Thanks also to Trinity Biotech for its support to create this pamphlet.

- <http://www.cdc.gov/std/stats09/syphilis.htm>
- For a summary of treatment guidelines for all STDs, including syphilis, go to <http://www.ncsddc.org/resources/cdc-2010-std-treatment-guidelines-summary>
- <http://www.cdc.gov/std/stats09/syphilis.htm>
- <http://www.cdc.gov/std/stats09/syphilis.htm>
- As of the time of printing of this primer, November 2011, there is only one FDA-approved RST available in the United States, called Syphilis Health Check distributed by Trinity Biotech. A CLIA-waiver for this diagnostic was pending at the time of printing.
- For updates on the availability of next generation RSTs please visit NCSDDC's website at www.ncsddc.org

Rapid Testing for Syphilis:

A Primer for Clinicians and Other Healthcare Providers

NCSDDC promotes sexual health through focusing on STD prevention. Our members include the STD Programs in every state, territory, and seven large cities, as well as hundreds of additional health professionals and advocates working in public and private settings across the country.



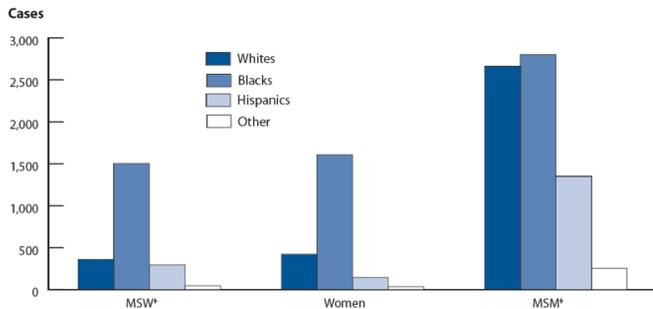
1029 Vermont Ave, NW Suite 500
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A RESURGENCE OF SYPHILIS

Between 1990 and 2000, rates of primary & secondary (P&S) syphilis in the U.S. declined by nearly 90% and in 2000, reached the lowest level since reporting began in 1941. However, since 2001, rates have again begun to climb, calling on all of us to help reverse this trend.ⁱ Syphilis is easily treated in most casesⁱⁱ, but screening and testing is the initial front line to ensuring we drive incidence lower.

This brief guide is designed as a primer to educate clinicians and other healthcare providers about the need for increased targeted screening and testing among high risk populations and to discuss the implications of the first ever rapid syphilis test (RST) approved by the Food and Drug Administration for use in the United States.

Primary and Secondary Syphilis—Reported Cases by Sex, Sexual Behavior, and Race/Ethnicity, United States, 2009



* Of the reported male cases of primary and secondary syphilis, 20% were missing sex of sex partner information; 1.7% of reported male cases with sex of sex partner data were missing race/ethnicity data.

† No imputation was done for race/ethnicity.

‡ MSW = men who have sex with women only; MSM = men who have sex with men.

Image Source: Sexually Transmitted Disease Surveillance, Division of STD Prevention, November 2010, Figure 43, page 42



WHERE MOST INFECTIONS ARE OCCURRING

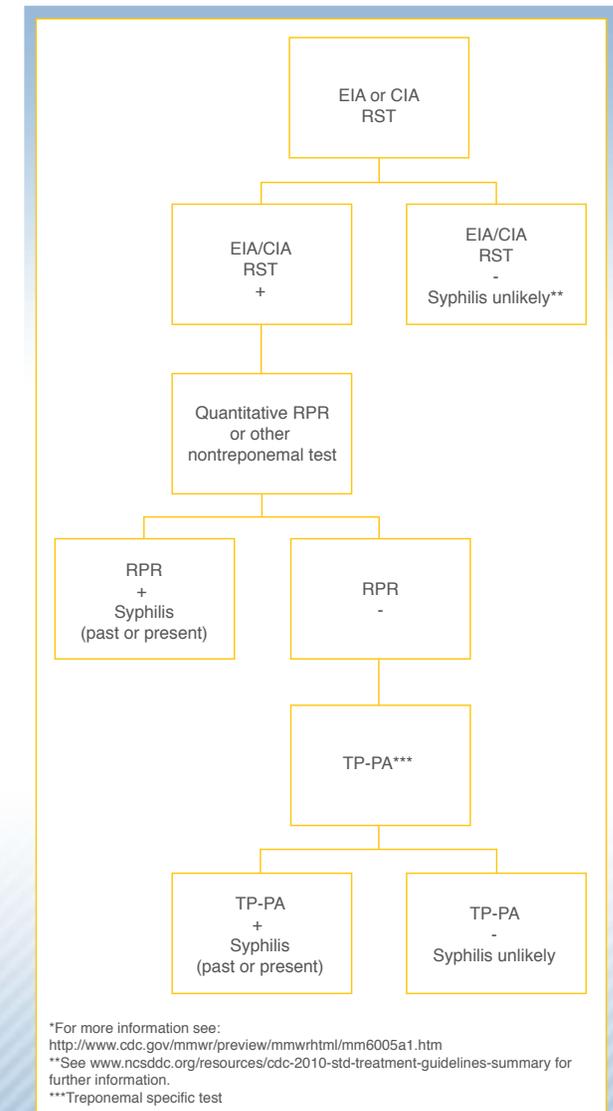
Recent data underscores the need for increased targeting testing for syphilis. According to the Centers for Disease Control and Prevention (CDC), in 2009 more than half of all P&S syphilis oddslot cases were reported from the South and between 2008 and 2009, rates in the South increased 10%.ⁱⁱⁱ

Also concerning is the increase of syphilis among gay men and other men who have sex with men (MSM). In 2000, 7% of P&S syphilis cases were among MSM. In 2009, it was 62%.^{iv} Equally disturbing is evidence of coinfection of HIV and syphilis among MSM and an estimated 2 to 5 fold increase of acquiring HIV if exposed to it while also coinfecting with syphilis. This syndemic, or overlapping epidemics of HIV and syphilis, is just beginning to be better understood, but highlights the need for increased screening and testing, particularly among MSM.

The newly approved Rapid Syphilis Test (RST) could present a unique opportunity to increase and simplify initial screening for syphilis in these key populations and within specific parameters.

SCREENING/TESTING ALGORITHM

A suggested RST algorithm and suggested treatment decision points for syphilis is shown below. RST is not recommended as a screening test in individuals with a past history of syphilis. The predictive value of the test is dependent on the prevalence of syphilis in the population being screened with discordant results higher in low risk populations than high risk populations.*



*For more information see: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6005a1.htm>

**See www.ncsddc.org/resources/odc-2010-std-treatment-guidelines-summary for further information.

***Treponemal specific test