

National Shortage of STI Test Kits and Laboratory Supplies

Summary

There is a current shortage of STI test kits and laboratory supplies, most notably for chlamydia and gonorrhea nucleic acid amplification tests (CT/GC NAAT). The shortages affect multiple diagnostic companies, public health and commercial laboratories and impact several components of the specimen collection and testing process. Healthcare providers and healthcare agencies are encouraged to communicate with their STD testing laboratory to determine if their laboratory is experiencing testing supply shortages. CDC provided guidance on approaches to prioritizing chlamydial and gonococcal testing when STI diagnostic test kits are in short supply.

Background

In September 2020, CDC communicated to state, local and territorial programs regarding a concern about a shortage of STI test kits and laboratory supplies. CDC is working with state, local and territorial STD programs, the Association of Public Health Laboratories (APHL) and other laboratories, manufacturers of STI diagnostic supplies, and the U.S. Food and Drug Administration (FDA) to understand the scope of the shortages and determine possible solutions. Currently, no information is available about the extent or timeline for the resolution of the supply shortage.

The NDDoH and CDC offer guidance to prevention programs, including clinics, on approaches to prioritizing chlamydial and gonococcal testing when STI diagnostic test kits are in short supply. The goal of this guidance is to maximize the number of infected individuals identified and treated while prioritizing individuals most likely to experience complications. The diagnostic strategies below pertain primarily to chlamydial and gonococcal testing. HIV and syphilis testing should continue to be performed per the CDC's 2015 STD Treatment Guidelines. Every effort should be made to reinstitute STI screening and testing recommendations per the 2015 CDC STD Treatment Guidelines once the diagnostic test kit shortage has resolved.

Recommendations

- **If you order STI screening, especially for chlamydia and gonorrhea, contact your laboratory to determine the extent of the shortage of STI test kits and laboratory supplies they might be experiencing.**
- **Refer to tables 2 and 3 below if your laboratory is experiencing supply shortages for recommendations in alternative approaches to STI screening.**
- **Refer to CDC guidance for clinical management of STIs in jurisdictions experiencing disruption in clinical services. There was guidance for issued on [April 6](#) and [May 13th](#).**

Table 1. Tier 1: Recommendations based on the 2015 CDC STD Treatment Guidelines and no CT/GC NAAT test shortages

Population	Recommendations
Asymptomatic individuals	<ul style="list-style-type: none"> • Screen women <25 years of age and women ≥25 years of age who are at risk at least annually for CT and GC • Screen pregnant women <25 years of age and pregnant women ≥ 25 years of age at risk for CT and GC at first prenatal visit. Screening should be repeated at third trimester for women <25 years of age and/or at high risk • Screen MSM by site of exposure for CT and GC at least annually and more often (every 3-6 mo) in individuals with persistent risk including MSM on HIV PrEP
Men with symptomatic urethritis syndrome	Test for CT and GC
Women with cervicitis syndrome	Test for CT, GC, Trichomonas vaginalis (TV) and bacterial vaginosis (BV)
Women with vaginitis syndrome	Test for TV, BV and Candida
Proctitis syndrome	Test for CT, GC, syphilis and herpes simplex virus
Complicated STD syndromes (PID)	Test for CT and GC
Contacts to GC and/or CT	Test for CT and GC

Table 2. Tier 2: Approaches to consider when STI diagnostic test kits are limited

Population	Recommendations
Asymptomatic individuals	<ul style="list-style-type: none"> • Prioritize women < 25 years of age; pregnant women < 25 years of age; women ≥ 25 years at risk*# ; pregnant women ≥ 25 years of age at risk*# and MSM • Vaginal testing (women), rectal and pharyngeal⁺ testing (MSM) for CT and GC
Men with symptomatic urethritis syndrome	<ul style="list-style-type: none"> • Gram or methylene blue stain to direct therapy; Urinalysis or urine leukocyte esterase testing can be considered to confirm urethritis but will not distinguish between GC and CT • Reserve urine-based testing for persistent urethritis
Women with cervicitis syndrome	Vaginal or endocervical testing for CT and GC; Wet prep for BV and TV testing**
Women with vaginitis syndrome	Perform wet mount for TV, BV and Candida
Proctitis syndrome	Rectal testing for CT and GC
Complicated STD syndromes (PID)	Vaginal or endocervical testing for CT and GC
Contacts to GC and/or CT	Treat for appropriate organism

Table 3. Tier 3: Approaches to take when STI diagnostic tests kits are severely limited or not available

Population	Recommendations
All Populations	<ul style="list-style-type: none">• No screening• See guidance regarding syndromic management

MSW = men who have sex only with women

MSM = men who have sex with men

*Prioritize rectal over pharyngeal testing in MSM if test kits are limited

*e.g. those who have a new sex partner, more than one sex partner, a sex partner with concurrent partners or a sex partner who has an STI

#Prioritize women (including pregnant women) <25 years of age if test kits are limited

**If CT/GC NAAT sent and TV can be performed using the same test kit, TV NAAT could be considered

For More Information

Further information is available here: www.cdc.gov/std/prevention/disruptionGuidance.htm. If you have questions, contact the Division of Sexually Transmitted and Bloodborne Diseases at 800.472.2180.

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