Catholic Health
Laboratory Services

MEMORANDUM

TO: Catholic Health Practitioners
CH Health Emergency Departments
CH Clinics
CH Infection Control
CH Supply Chain

FROM: James J Jarnot, MBA, MT (ASCP), SC; Technical Director, CH Laboratory

DATE: September 18, 2020

SUBJECT: **Shortage of Sexually Transmitted Infection Diagnostic Supplies**

CC: Hans Cassagnol M.D. Executive Vice President and Chief Physician
Michael Albert M.D. Medical Director, CH Laboratory @ Buffalo Mercy
John Severins, CH Director of Ancillary Services

This memo is being written to communicate a critical shortage of Sexually Transmitted Infection (STI) diagnostic test supplies. There are three bacterial STIs (chlamydia, gonorrhoea and syphilis) and one parasitic STI (trichomoniasis) that are generally characterized as causing STI. As of today, the shortage of testing supplies affects the components of specimen collection and testing for chlamydia and gonorrhea nucleic acid testing. Syphilis testing is NOT affected.

You may have noticed that your testing supply orders have taken longer to be delivered and the quantities received are less than what was ordered. Also, the test reports are probably taking longer as well. These observations are all part of the ramifications of the shortages affecting diagnostic laboratories.

The laboratory is suggesting that we utilize the "urine/unisex" inventory (yellow vial) for male patients and the "multitest" inventory (orange vial) for female patients.

The Centers for Disease Control (CDC) has published a communique that provides guidance for prioritizing testing in different patient populations or risk categories. These categories include:

- Chlamydia and gonorrhea screening of asymptomatic individuals
- Men with symptomatic urethritis
- Women with cervicitis or pelvic inflammatory disease
- Individuals with proctitis syndrome
- Individuals taking Pre Exposure Prophylaxis (PrEP)
- Contacts to chlamydia and/or gonorrhea

Although it was not specifically identified by the CDC, trichomonas diagnostic testing is also affected by this shortage.

A copy of the CDC publication is attached for your review. Additionally, the hyperlink to the CDC website is provided:
https://www.cdc.gov/std/prevention/disruptionGuidance.htm

Please distribute as you see appropriate.

Thank you

Attachment: Department of Health and Human Services-CDC 9/3/2020

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control and Prevention

September 8, 2020

Dear Colleagues,

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. 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.

Previous Dear Colleague Letters (DCLs) provided guidance for clinical management of STIs in jurisdictions experiencing disruption in clinical services (April 6th DCL and May 13th DCL). This letter offers 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. Since the magnitude of the STI diagnostic test shortages is likely to differ across the country, the potential approaches listed below and in Table 1 should be tailored by local jurisdictions. 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.

Considerations for prioritizing STI testing if test kits are in short supply:

• **Chlamydia and gonorrhea screening of asymptomatic individuals.** Prioritize populations recommended by the U.S. Preventive Services Task Force (USPSTF) and 2015 CDC STD Treatment Guidelines for screening as outlined below:

- Asymptomatic women, especially pregnant women, <25 years of age or women > 25 years of age at risk (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). Genital CT/GC NAAT testing should be prioritized with a vaginal swab, the preferred specimen. Extra-genital CT/GC screening is not recommended for women.
- Asymptomatic men who have sex with men (MSM): Rectal and pharyngeal CT/GC NAAT testing for men with exposure at these anatomic sites should be prioritized above urethral (or urine-based) testing in order to maximize the detection of infection per below. If test kits are severely limited, consider prioritizing rectal testing over pharyngeal testing.

- CT/GC screening is not recommended for asymptomatic men who have sex only with women.
- Extended screening intervals for whom screening is recommended every 3 months (i.e. high-risk MSM and MSM on pre-exposure prophylaxis (PrEP)) may need to be considered in order to provide access to testing for other populations (listed above) while test kits are in shortage.

• **Men with symptomatic urethritis:**
- A Gram stain (GS) or methylene blue (MB) stain should be performed as the diagnostic test on urethral specimens at clinical sites with this capacity. Clinics without this capacity should send a urethral GS or MB stain specimen to a laboratory to distinguish between gonococcal urethritis and non-gonococcal urethritis (NGU). The GS and MB stain are highly sensitive and specific in symptomatic urethritis. If the GS or MB stain is available at the time of the patient visit, therapy can be targeted appropriately, thus limiting unnecessary antibiotic exposure. If empiric treatment is administered, the GS or MB stain should still be obtained to confirm a GC or NGU diagnosis and to inform partner management and future management if symptoms persist or recur. If GS/MB is not available, treat men with symptomatic urethritis for both gonorrhea and chlamydia per the 2015 CDC STD Treatment Guidelines.

• **Women with cervicitis syndrome or pelvic inflammatory disease (PID):**
- Empirically treating these syndromes is a priority. If CT/GC NAAT kits are available for diagnostic testing, then vaginal swabs for chlamydia and gonorrhea NAAT test are the preferred specimen type. Endocervical swabs can also be considered. Tests should be prioritized for women < 25 years of age with cervicitis or PID.

• **Individuals with proctitis syndrome:**
- Empirically treating these syndromes is a priority. Therapy for herpes simplex virus may be considered if pain or mucocutaneous lesions are present (see April 6th Dear Colleague Letter). If rectal CT/GC NAAT test kits are available for diagnostic testing, then obtain a rectal specimen and treat empirically per the 2015 CDC STD Treatment Guidelines.

• **Individuals taking PrEP:**
- The frequency of extragenital CT/GC screening in MSM receiving PrEP should be in accord with the current CDC PrEP guidelines.
- If test kits are in short supply, extended extragenital screening intervals may be considered.
- For more general guidance on PrEP clinical services during the COVID-19 pandemic, please see the May 15 DCL.

• **Contacts to chlamydia and/or gonorrhea:**
- Empirically treat the contact for the appropriate organism. If CT/GC NAAT test kits are in short supply, consider forgoing testing.

• **If urine CT/GC NAAT test kits are in short supply:**
- Reserve test kits for men with persistent urethritis.

CDC values its relationships with all state, local and territorial programs and is appreciative of the effort invested daily to combat STIs, including HIV. The COVID-19 pandemic continues to offer new challenges requiring perseverance and creativity. CDC will prioritize communicating with STD programs as the pandemic evolves and the availability of STI clinical preventive services adapt accordingly.

Please let us know if you are having problems with availability of CT/GC NAAT test kits for your clients and take care while this new normal continues. As always, you can reach out to your assigned DSTDP Prevention Specialist for additional guidance or assistance.

Sincerely,

Laura Hinkle Bachmann, MD, MPH
Chief Medical Officer
Clinical Team Lead, Program Development and Quality Improvement Branch
Division of STD Prevention
National Center for HIV/AIDs, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention

Gail Bolan, MD
Director
Division of STD Prevention
National Center for HIV/AIDs, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention

Table 1. Recommendations for prioritization of STI diagnostic testing by population at times of diagnostic test kit shortage

	Asymptomatic individuals	**Men with symptomatic urethritis syndrome**	**Women with cervicitis syndrome**	**Women with vaginitis syndrome**	**Proctitis syndrome**	**Complicated STD syndromes (PID)**	**Contacts to GC and/or CT**
Tier 1: Recommendations based on the 2015 CDC STD Treatment Guidelines and no CT/GC NAAT test shortages	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	Test for CT and GC	Test for CT, GC, Trichomonas vaginalis (TV) and bacterial vaginosis (BV)	Test for TV, BV and Candida	Test for CT, GC, syphilis and herpes simplex virus	Test for CT and GC	Test for CT and GC

Tier 2: Approaches to consider when STI diagnostic test kits are limited	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	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	Vaginal or endocervical testing for CT and GC; Wet prep for BV and TV testing**	Perform wet mount for TV, BV and Candida	Rectal testing for CT and GC	Vaginal or endocervical testing for CT and GC	Treat for appropriate organism
Tier 3: Approaches to take when STI diagnostic tests kits are severely limited or not available	No screening	See guidance in DCLs 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