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To: Kansas Health Care Providers Offering STI Testing Services

RE: Shortage of STI Test Kits and Laboratory Supplies – CT/GC NAAT

The Centers for Disease Control and Prevention (CDC) recently issued a Dear Colleague Letter (DCL) alerting of shortages of sexually transmitted infection (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 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.

KDHE is issuing this Health Alert Network notice to ensure that providers are aware of the shortages and are familiar with the guidance issued by CDC for clinical management of STIs in jurisdictions experiencing disruptions in clinical services (April 6th DCL and May 13th DCL). Their most recent letter outlines recommendations 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 state, 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.

Kansas has experienced sustained increases in gonorrhea and chlamydia infections for more than five years, so appropriate testing and treatment of these infections remains vital. 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. Conducting a complete sexual history with patients is an important step in determining appropriate testing. The complete guidance from CDC may be found on their website at https://www.cdc.gov/std/prevention/disruptionGuidance.htm.

Special considerations for Local Health Departments (LHDs), rural healthcare providers and other clinics operating under low or limited physician availability:

- **Ensure that your Standing Orders related to management of STIs will permit these recommended practices or update them where necessary.** Many clinics providing STI clinical services operate under Standing Orders from a local medical officer or other physician that is not often on site to directly examine patients. Clinics operating under Standing Orders are advised to consult their authorizing physician when current orders do not address the following situations:
    - Syndromic management of patients (Table 1) will likely be necessary for continuity of services while testing kits are unavailable or in short supply; particularly for patients that are not part of a

prioritized population.
    - Empirical/presumptive treatment of exposed partners (rather than confirming infection via testing) is recommended to conserve test kits.

Considerations for prioritizing STI testing <u>when test kits are in short supply</u>:

- **Chlamydia and gonorrhea screening of asymptomatic individuals.** Prioritize screening for populations recommended by the U.S. Preventive Services Task Force (USPSTF) and 2015 CDC STD Treatment Guidelines as outlined below:
    - Asymptomatic women, especially pregnant women, < 25 years of age or women ≥ 25 years of age with increased 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 yet recommended for women.
    - Asymptomatic men who have sex with men (MSM): Rectal and pharyngeal CT/GC NAAT testing for men <u>with exposure at these anatomic sites</u> 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 those whom screening is recommended every 3 months (i.e. high-risk MSM and MSM on pre-exposure prophylaxis (PrEP)). Less-frequent screening for these patients should be considered in order to provide access to testing for other populations (listed above) while test kits are in shortage.

- **Men with symptomatic urethritis:**
    - For clinical sites with the capacity to conduct Gram stain (GS) or methylene blue (MB) stain examinations of urethral specimens should perform these diagnostic tests on symptomatic men to conserve available test kits.
    - Clinics without this capacity may consider contacting local hospitals with microbiology labs to determine whether it would be feasible to send urethral specimens to their 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. 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. Therapy for herpes simplex virus may be considered if pain or

mucocutaneous lesions are present (see Table 1 below). However, any evaluation of genital, anal, or perianal ulcers should also include 1) syphilis serology, darkfield examination, or PCR testing if available; 2) culture or PCR testing for genital herpes; 3) serologic testing for type-specific HSV antibody; and 4) HIV testing for persons not known to have HIV infection.

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

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

- **Exposed Partners of suspected or confirmed cases of chlamydia and/or gonorrhea:**
  - Empirically treat the partner(s) for the appropriate organism. If CT/GC NAAT test kits are in short supply, consider forgoing testing of the partners as a condition of treatment.

Providers are strongly encouraged to check with the laboratory that they normally submit specimens to for chlamydia/gonorrhea testing to determine the extent of the shortages and the impact upon your clinic and patients. If the laboratory you work with is experiencing shortages, we encourage you to work closely with them to determine how best to conserve resources and prioritize testing.

If clinical services have not been disrupted, or as the clinical environment normalizes, providers should continue to follow recommendations from the current CDC guidelines and the Recommendations for Providing Quality STD Clinical Services, 2020 with appropriate precautions to prevent COVID-19 transmission to patients and providers (see KDHE Guidance for Healthcare Providers).

For any questions or concerns related to these shortages or KDHE's recommendations, please contact the STI/HIV Surveillance & Intervention Section at 785-291-3610 or email Scott.Strobel@ks.gov.

Table 1. Therapeutic options to consider for symptomatic patients and their partners when clinical evaluation is not feasible (limited testing kits or reduced clinical capacity):

Syndrome	Preferred Treatments In clinic, or other location where injections can be given*	Alternative Treatments When only oral medications are available&	Follow-up
Male urethritis syndrome	Ceftriaxone 250mg intramuscular (IM) in a single dose **PLUS** Azithromycin 1g orally in a single dose (If azithromycin is not available and patient is not pregnant, then doxycycline 100 mg orally twice a day for 7 days is recommended). If cephalosporin allergy is reported, gentamicin 240 mg IM in a single dose **PLUS** azithromycin 2 g orally in single dose is recommended.	Cefixime 800 mg orally in a single dose **PLUS** Azithromycin 1g orally in a single dose (If azithromycin is not available and the patient is not pregnant, doxycycline 100 mg orally twice a day for 7 days is recommended). **OR** Cefpodoxime 400 mg orally q12 hours x 2 doses **PLUS** Azithromycin 1g orally in a single dose (If azithromycin is not available and the patient is not pregnant, doxycycline 100 mg orally twice a day for 7 days is recommended). If oral cephalosporin is not available or cephalosporin allergy is reported, azithromycin 2g orally in a single dose.	For alternative oral regimens, patients should be counseled that if their symptoms do not improve or resolve within 5-7 days, they should follow-up with the clinic or a medical provider. Patients should be counseled to be tested for STIs once clinical care is resumed in the jurisdiction. When possible, clinics are encouraged to schedule reminder calls for clients who were referred for oral treatment to return for comprehensive testing and screening or link them to services at that time. All patients receiving regimens other than Benzathine penicillin for syphilis treatment should have repeat serologic testing performed 3 months post-treatment.
Genital ulcer disease (GUD) Suspected primary or secondary syphilis++	Benzathine penicillin G, 2.4 million units IM in a single dose.	Males and non-pregnant females: Doxycycline 100 mg orally twice a day for 14 days.	
		Pregnant: Benzathine penicillin G, 2.4 million units IM in a single dose.	
Vaginal discharge syndrome in women without lower abdominal pain, dyspareunia or other signs concerning for pelvic inflammatory disease (PID)	Treatment guided by examination and laboratory results.	**Discharge suggestive of bacterial vaginosis or trichomoniasis (frothy, odor):** Metronidazole 500 mg orally twice a day for 7 days.	
		Discharge cottage cheese-like with genital itching: Therapy directed at candida.	
Proctitis syndrome#	Ceftriaxone 250mg IM in a single dose **PLUS** doxycycline 100 mg orally twice a day for 7 days. If doxycycline not available or the patient is pregnant, azithromycin 1g orally in single dose recommended.	Cefixime 800 mg orally in a single dose **PLUS** doxycycline 100 mg orally bid for 7 days (if doxycycline not available or the patient is pregnant, azithromycin 1g orally in single dose recommended). **OR** Cefpodoxime 400 mg orally q12 hours x 2 doses **PLUS** doxycycline 100 mg orally bid for 7 days (if doxycycline not available or the patient is pregnant, azithromycin 1g orally in single dose recommended).	

*When injections cannot be delivered directly, clinics should identify local pharmacies or other clinics that are still open and can give injections and establish a referral protocol for facilitating preferred treatments.

&Alternative regimens should be considered when recommended treatments from the 2015 CDC STD Treatment Guidelines are not available.

++All pregnant women with syphilis must receive Benzathine penicillin G. If clinical signs of neurosyphilis present (e.g. cranial nerve dysfunction, auditory or ophthalmic abnormalities, meningitis, stroke, acute or chronic altered mental status, loss of vibration sense), further evaluation is warranted.

#Consider adding therapy for herpes simplex virus if lesions are painful.