DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

CENTERS FOR DISEASE CONTROL AND PREVENTION

August 15, 2002

Dear Colleague:

The August 15, 2002 issue of the *Weekly Morbidity and Mortality Report (MMWR)* contains a Notice to Readers entitled "Recall of LCx® *Neisseria gonorrhoeae* Assay and Implications for Laboratory Testing for *N. gonorrhoeae* (NG) and *Chlamydia trachomatis* (CT)." Abbott Laboratories initiated a voluntary recall of LCx® NG assays because during routine quality assurance testing several lots failed to meet the product insert claim of being able to detect at least 10 colony-forming units of the organism. The cause of the failure is under investigation by the company, and until resolved, delays in obtaining or receiving LCx® NG kits can be expected. Although there has been no recall of the LCx® CT assay, public health departments are reporting delays in the delivery of this assay.

This Notice to Readers provides information on the recall, the affected product list numbers, recommended actions concerning possible false-negative test results, and recommendations for options to test specimens in the absence of the LCx® assay.

The following are highlights of the recommendations included in the Notice to Readers:

- Abbott Laboratories recommends that all LCx® NG assay reagents with affected product list numbers be discarded.

- Laboratories that have tested specimens using the recalled lots should notify the health care providers/agencies that they serve about the increased risk of false-negative results.

- Clinicians should offer to retest patients who had a negative result from the recalled lots and who were not presumptively treated.

For laboratories unable to test specimens for CT and NG because of the unavailability of LCx® assay reagents, several testing options are available.

- Testing with the LCx® assays can be delayed. Urine specimens or endocervical or urethral swab specimens collected for LCx® testing can be stored at -4° F (-20° C) for up to 60 days before testing with the assay.

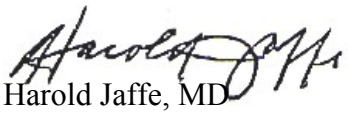
- For more timely patient management, the use of other FDA-cleared tests should be considered. Urine specimens that have not been processed for LCx® testing can be tested by using another FDA-cleared nucleic acid amplification test. Only nucleic acid amplification

tests are recommended for the direct detection of CT or NG in urine. Swab specimens collected from patients and placed in LCx® transport medium cannot be tested by using another FDA-cleared test. Health-care providers should consider recalling such patients to collect a new specimen for testing with another FDA-cleared test. If this is done, the laboratory should be consulted about procedures for proper swab collection. Laboratories also could consider culture as an option to test for NG.

- Laboratories may consider redirecting their consumers to other laboratories that can provide such screening services.

To download a complete copy of this *MMWR* Notice to Readers, please visit the *MMWR* Web site at http://www.cdc.gov/mmwr/. Also, additional information can be found on the Abbott Laboratories Web site at http://www.abbott.com/ or by calling Abbott Laboratories information services at (847) 937-6100.

Sincerely,



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