

ABBOTT DIAGNOSTICS

Device Correction
LCx Chlamydia trachomatis
List Numbers 09B11/07A91
Lot 65731M300 or higher

February 12th 2001

Dear Abbott LCx Chlamydia trachomatis Customer:

This letter contains technical information regarding LCx Chlamydia trachomatis (List number 09B11/07A91). Your attention to this information is required. Please review the information carefully and follow the directions below.

BACKGROUND

Abbott Diagnostics Division has received customer complaints for LCx Chlamydia trachomatis for high negative control rates resulting in invalid runs for non-repeating positive patient specimen results. An investigation is underway at Abbott to identify the cause. To date, the investigation has demonstrated that specificity may be as low as 92% in some on-market lots. The cause of the specificity issue is unknown at this time. This issue is not related to patient or specimen type. Assay sensitivity has not changed.

Abbott Laboratories has implemented additional in-process specificity screening for all new LCx Chlamydia trachomatis lists being manufactured for distribution.

NECESSARY ACTIONS

As a precautionary measure until the investigation is complete, it is important that the following actions are taken:

- Interpret samples with S/CO ratio less than 0.80 as Negative. *C. trachomatis* plasmid DNA is not detected and the sample is presumed negative for *C. trachomatis* by LCR amplification and MELA detection.
- Repeat all patient samples that have S/CO ratios equal to or greater than 0.80:
 - If repeat test S/CO is equal to or above 1.00, then the sample is LCx Positive. *C. trachomatis* plasmid DNA is detected and the sample is presumed negative for *C. trachomatis* by LCR amplification and MELA detection.
 - If repeat test S/CO is less than 1.00, then the sample LCx Negative. Plasmid DNA is not detected and the sample is presumed negative for *C. trachomatis* by LCR amplification and MELA detection.

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The MDA have been made aware of this communication.

This repeat testing algorithm was developed to ensure package insert claims for specificity are met.

Please communicate this information to your medical professionals as you deem appropriate.

ADDITIONAL INFORMATION

For replacement tests resulting from this Device Correction, or if you have questions regarding this information, please contact the Customer Support Centre on 01628 784041. We anticipate learning more within the next month and will keep you updated on our investigation. We regret the inconvenience this has caused your laboratory. Thank you for your patience and co-operation.

Yours Sincerely

Christine Brooker
Quality Manager

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