A Study of Results Generated Using the Abbott LCx-GC Assay Fails to Reveal a Performance-Based Rationale for the 2002 Level 1 Recall

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Abstract

To establish the effect of a quality control failure on the performance of the LCx-GC nucleic-acid amplification assay for Neisseria gonorrhoeae (Abbott Laboratories, Abbott Park, IL) in the field, we conducted a retrospective analysis comparing the clinical and analytic performance of the recalled lots with those not implicated in the recall.

Our analysis revealed no statistically significant differences between recalled lots (n = 8,686 tests) and nonrecalled lots (n = 8,699 tests) with respect to multiple parameters of assay performance, including frequency distribution of patient results (P = .575), prevalence of indeterminate results (P = .245), mean positive control signals (P = .26), and within-run calibrator precision (P = .68). The LCx-GC system’s lack of an electronic data storage and retrieval capability prevented assessment of the impact of the quality control failure on the clinical performance of recalled lots, such as the one described herein, from being conducted in real time.

Detection of Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) in urogenital specimens using nucleic-acid amplification testing (NAT) has become firmly established as the standard of care for diagnosing infection with these organisms.1 The advantages of NAT in terms of clinical sensitivity and specificity have been well documented,2-4 as has its ability to enable testing of noninvasively collected specimens such as urine and self-collected vaginal samples,2,5,6 often in nontraditional health care settings.7 Given the overwhelming evidence of diagnostic superiority, and the prevalence of CT and NG infections in the United States,8 it is hardly surprising that NAT for these pathogens is the most widely performed and highest volume molecular diagnostic test.

Unfortunately, evidence of less than optimal performance of the US Food and Drug Administration (FDA)-approved NAT assays for CT and NG has appeared periodically in the peer-reviewed literature. Some of the causes of these performance problems have been applicable to all high-volume applications of NAT,9 whereas others have pertained only to specific assays.10-13 In addition, a number of product recall notices have been issued by manufacturers of NAT assays and the FDA, raising concerns about the manufacturability of NAT products for such a large-volume market.

One of the most significant of these recalls occurred in late August 2002, when Abbott Laboratories (Abbott Park, IL) issued a retroactive recall of 16 reagent lots distributed between April and June 2002 for use in their NAT assay for the detection of NG.14 Components of these kits had failed to meet predefined specifications in an in-house reagent stability test, with a downward trend in assay signal being observed over time in the affected lots, possibly resulting in false-negative test results. This finding suggested that the affected lots
may not meet package insert claims for clinical sensitivity, and, thus, the recall was initiated. The recall notice recommended that, in addition to discontinuing use of kits from recalled lot numbers, laboratories performing LCx-GC (Abbott) testing should identify potentially affected patients (ie, patients whose samples had been tested using the recalled lots), notify their care providers, and recommend retesting as appropriate. Owing to the large number of reagent lots implicated in the recall and the extended time during which recalled lots were released to customers, efforts to elucidate which patients could have been affected were incredibly complicated and labor-intensive.

It is important to note that the absolute risk of a false-negative result occurring with the recalled reagent lots was not established before the issuance of the recall, precluding objective discussion among laboratorians and providers of the likelihood of an erroneous result leading to any of the adverse outcomes associated with untreated NG infection. Indeed, what the testing abnormality observed at Abbott Laboratories meant for assay performance in the clinical laboratory, if anything, was never established, largely because of the inability to expeditiously retrieve and analyze LCx-GC data sets from clinical laboratories.

In an effort to elucidate whether there was any demonstrable loss of assay performance in our laboratory during the period when recalled reagent lots were in use, we conducted a retrospective, comparative analysis of various parameters of LCx-GC assay performance with matched lots of recalled and nonrecalled reagents. In addition, we sought to use this investigation to demonstrate how equipping molecular diagnostic assay systems with technology for automatically capturing and analyzing data in real time could benefit those involved in the manufacture, regulatory oversight, and use of NAT assays.

**Materials and Methods**

**Study Institution**

Hennepin County Medical Center (HCMC), Minneapolis, MN, is a 450-bed public teaching facility, averaging 20,000 patient admissions and 400,000 outpatient visits annually. In 2002, the HCMC laboratory analyzed 32,680 urogenital specimens for the presence of CT and NG using the LCx-GC platform. Of these, 2,308 (7.062%) were positive for CT and 1,102 (3.372%) were positive for NG.

**LCx-GC Assay**

All LCx-GC assays were performed using the manufacturer’s recommended procedure on endocervical swabs, urethral swabs, and first-void urine samples. The technical details and performance characteristics of the LCx-GC assay have been described thoroughly elsewhere. Each sample run consisted of 20 processed patient samples, 2 negative control samples, and 2 positive calibrators. Each calibrator and negative control pair represent duplicate analyses of the same reagent. In addition to the positive calibrators, an external positive control sample (Gonotrol, Blackhawk BioSystems, San Ramon, CA) was included in one of the sample runs each day to verify assay performance.

From the signal generated in the assay by the positive calibrators, a parameter called the cutoff (CO) is calculated for each run by multiplying the mean fluorescence rate for the paired positive calibrators by 0.25. The signals generated in the negative control and patient samples then are normalized by dividing the obtained fluorescence rate by the CO, generating so-called S/CO ratios. For a run to be valid, negative control samples have to generate S/CO ratios of less than 0.2. Clinical samples that generate S/CO ratios of less than 0.8 are reported as negative, 1.2 or more as positive, and 0.8 to 1.19 as equivocal. The manufacturer recommends that testing be repeated for samples with S/CO ratios in the equivocal range. If the S/CO values in repeated testing are 1.0 or more, the sample is considered positive, and if the S/CO values in repeated testing are less than 1.0, the sample is considered negative.

Before the period covered in the recall, our laboratory had expanded the equivocal range to include all samples generating initial S/CO ratios in the LCx-GC assay of between 0.2 and 3.0. This expansion of the equivocal range was initiated when results of our in-house tracking of calibrators suggested a drift that might cause increased rates of false-positive results in our laboratory.

On completion of each run, a hard copy of the results, including the calibrator signals, the negative control signals, the CO, and the S/CO ratio of each sample, is printed by the LCx-GC analyzer. No electronic record of the results is maintained. As required by the Clinical Laboratory Improvement Act of 1988 and the College of American Pathologists, these hard copy records were stored in the laboratory for 2 years.

**Data Collection and Analysis**

Hard copies of all runs performed in the laboratory using the lots implicated in the product recall were retrieved from storage, and the following data elements were transcribed into a Microsoft Excel (Microsoft, Redmond, WA) spreadsheet: lot number, date of run, value of calibrator signals, value of negative control signals, value of external positive control signals, counts of clinical sample S/CO results per 0.5 S/CO interval, and counts of patient results in the equivocal range listed in the package insert (0.8-1.2). The specimen type is not recorded on the LCx-GC data printout, so this information was not available for tabulation. To enable a comparative assessment of assay performance, a data set also
was compiled that contained results from all runs performed with nonrecalled lots of reagents during the same period, April to August 2002, inclusive. Because considerably more results were generated using recalled rather than nonrecalled lots during this period, data obtained using nonrecalled reagent lots from the 2 months before the recall also were included. Table 1 gives a complete list of the lot numbers of reagents from which the data analyzed in this study were obtained.

No identifiable, private data that could be traced to an individual were used in the study. Therefore, the study is not considered “human research” by the institutional review board for the protection of human subjects and did not require approval from this board.18

A number of analyses were performed on the compiled data. Frequency distributions of S/CO ratios for patient sample results obtained using recalled and nonrecalled lots were constructed, and a $\chi^2$ test subsequently was performed to determine whether the 2 resultant distributions were significantly different. Tests for the significance of the difference between proportions were performed to determine whether the proportion of patient results falling into the manufacturer’s S/CO equivocal range differed between recalled and nonrecalled lots. Results for calibrators and control samples were tabulated for recalled and nonrecalled lots, and statistical tests for differences were performed. To discern whether within-lot variability was greater with recalled lot reagents, within-lot control charts19 were created using 3 SD control limit values. All statistical tests were performed using the Statistical Analysis Software for Windows package (SAS Institute, Cary, NC), and the data analysis tool set included in the Microsoft Excel spreadsheet program (Microsoft Office 2000, Microsoft).

### Results

A total of 473 runs containing the LCx-GC assay results for 8,686 clinical samples performed in the HCMC laboratory using recalled lots of reagents were compared with 468 runs containing the results for 8,699 clinical samples performed using nonrecalled lots of reagents. The lot numbers used and the total numbers of clinical samples analyzed with each lot of reagents are shown in Table 1. The results of statistical analyses performed on these data sets are detailed subsequently.

### S/CO Frequency Distributions

The frequency distributions of S/CO ratios for clinical samples analyzed with recalled vs nonrecalled reagent lots are shown in Figure 1A. No obvious difference in the distribution of assay signals was discernible. To enable a statistical comparison of these distributions, all ranges in the higher end of the frequency distribution were collapsed into a single range (S/CO, >3.0) Figure 1B, resulting in a data set in which each discrete S/CO range was populated by results obtained with recalled and nonrecalled reagents. A $\chi^2$ test of significance then was performed on the modified data set, confirming the lack of significant difference in the

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**Table 1**

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<th>No. of Samples</th>
<th>No. of Runs</th>
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Skeate et al / LCX-GC ASSAY SHOWS NEED FOR ELECTRONIC DATA RECORDING

S/CO frequency distributions obtained with recalled and non-recalled reagent lots \((P = .575)\).

**Frequency of Equivocal Results**

A total of 11 samples of the 8,686 analyzed with reagents from recalled lots produced S/CO ratios within the manufacturer's equivocal zone \((0.8-1.20)\) compared with 8 of 8,699 samples analyzed using nonrecalled reagents. This difference was not statistically significant \((P = .245, \text{data not shown})\).

Because samples generating S/CO ratios in the manufacturer's equivocal range occurred extremely infrequently, we performed an additional comparison of results in a broader equivocal range. This consisted of samples generating S/CO values between 0.2 and 3.0, a range containing 2 groups of samples in addition to those falling within the manufacturer's equivocal zone, namely “high-negative” samples, with S/CO ratios between 0.2 and 0.8, and “low-positive” samples, with S/CO ratios between 1.2 and 3.0. This analysis was performed based on the hypothesis that a decline in assay performance of a magnitude sufficient to result in clinical false-negative results would almost certainly lead to an increased number of samples with signals close to the cutoff for positivity (ie, in the high-negative or low-positive range). Although 73 samples tested with recalled reagents fell into this range, compared with 61 samples tested with nonrecalled reagents, this difference was statistically insignificant \((P = .152)\) Figure 2B.

**Analysis of Control Values**

A summation of results obtained with control analytes (negative controls, positive calibrators, and external positive controls) is listed in Table 2. The mean signal (expressed in fluorescence counts/second/second \([\text{c/s/s}]\)) obtained with negative controls for recalled lot assay runs was significantly lower than that obtained with controls for nonrecalled lot runs \((13.40 \text{ c/s/s} \text{ and } 16.29 \text{ c/s/s}, \text{respectively}; \text{ } P < .01)\). In addition, and potentially more significantly, the mean fluorescent signal generated by the calibrators for recalled lot runs was significantly higher than that generated by the calibrators in runs performed using nonrecalled reagents \((1,089 \text{ c/s/s} \text{ and } 1,062 \text{ c/s/s}, \text{respectively}; \text{ } P < .01)\). Although the magnitude of this difference is too small to have had an impact on clinical performance, the finding that recalled lots of reagents generated higher average calibrator signals than nonrecalled lots is inconsistent with the contention that these lots contained reagents prone to produce falsely low signals.

The mean S/CO ratios for the external positive controls also were calculated (Table 2), and, as with the calibrators, the ratios generated by positive controls tested using recalled reagents were somewhat higher (mean S/CO, 3.97) than those tested using nonrecalled reagents (mean S/CO, 3.88). This difference, although not statistically significant \((P = .26)\), again...
is surprising and inconsistent with the hypothesis that the recalled reagent lots were performing suboptimally.

If the recalled lots contained defective reagents prone to causing outright amplification failure or suboptimal amplification efficiency, one might also expect a decrease in reproducibility of calibrator signals when recalled vs nonrecalled reagents were used. The overall between-run reproducibility of calibrator signals, however, was not meaningfully different between recalled (coefficient of variation, 13.63%) and nonrecalled (coefficient of variation, 13.08%) reagents.

Because the calibrators are analyzed in duplicate in each run, we also evaluated within-run variability (Table 2). The average within-run difference in calibrator signals for runs using recalled reagents (48.76 c/s/s) was not significantly different (P = .68) from that observed with runs using nonrecalled reagents (47.27 c/s/s). These findings illustrate that use of the recalled reagents, in addition to not resulting in lower calibrator signals overall, also did not result in an increase in signal variability.

### Control Charts

Within-lot control charts were prepared for each lot number of reagent used in the study in an effort to detect a source of special-cause variation with the recalled lots that was not present with the nonrecalled lots. Representative examples of these control charts are shown in **Figure 3**. Negative control signals and calibrator signals were charted with 3 SDs above and below the lot mean used as control limits. A total of 7 (0.7%) of 946 data points fell outside the control limits for runs performed with recalled reagents (6 negative controls, 1 calibrator) compared with 5 (0.5%) of 936 data points for runs performed with nonrecalled reagents (3 negative controls and 2 calibrators). Neither recalled nor nonrecalled lots of reagents were free of special-cause variation, but the control charting revealed no compelling evidence for a novel source of such variation when runs were performed with reagents implicated in the recall.

### Discussion

The rationale put forth for the August 2002 recall of 16 lots of reagents for use in the Abbott LCx-GC NAT assay released during that year was that the failure of these reagent lots to meet internal stability testing specifications posed a risk that the assay would not meet package insert claims for clinical sensitivity when used in the field, and, thus, patients could remain undiagnosed and untreated. Under ideal circumstances, this hypothesis could have been tested (before any action being taken) by parallel testing of clinical samples using both reagents that had failed and reagents that had passed the release test.

Unfortunately, this approach was impractical for several reasons. First, the recall involved a large number of reagent lots and covered a prolonged period. At the time the recall was issued, therefore, many of the implicated lots were no longer in use in the field and could not be evaluated directly. Second, most laboratories do not retain clinical samples submitted for NAT for CT and GC after testing has been concluded, so samples were unavailable for reanalysis. Third, even if sufficient numbers of retained specimens were available from clinical laboratories for testing in the Abbott quality control laboratory, where archived batches of each implicated reagent lot would have been available, issues surrounding compliance with regulations governing patient confidentiality and consent would have to be addressed. For these reasons, direct comparative testing was not performed, and, consequently, the impact of the quality control failure on clinical performance
was never established. In the absence of any data directly demonstrating the magnitude, or lack thereof, of the effect on clinical test performance of using implicated lots of assay reagent, a least-risk approach was taken and an extensive recall notice issued.

In the absence of any external data with which to assess the risk of false-negative LCx-GC results occurring at HCMC during the recall period, we decided to conduct a retrospective, internal comparison of parameters of assay performance recorded during routine testing as an indirect means of comparing lots of reagents implicated in the recall with those that escaped indictment. The Abbott LCx-GC instrumentation, as with all other currently available NAT assays for CT and NG testing, has no capability for electronically storing or analyzing the data it generates. To perform the analyses described in this study, therefore, paper records for more than 6 months of testing and containing the results of assays performed on more than 17,000 clinical samples had to be retrieved manually and entered into a Microsoft Excel spreadsheet. Once this had been accomplished, it was possible to compare large populations of patient and control samples that had been analyzed with recalled or nonrecalled lots of reagents. We reasoned that a loss of analytic performance in the recalled lots of a magnitude sufficient to significantly impact clinical sensitivity and, thus, warrant a recall should be easily discernible on examination of data sets containing patient and control samples analyzed using recalled vs nonrecalled reagents. Irrespective of which particular parameter was examined, no such delineation between the performance of recalled and nonrecalled lots could be made.

The frequency distributions of assay signals (so-called S/CO ratios) obtained with clinical samples analyzed using recalled and nonrecalled lots of reagents were not meaningfully different. Although the LCx-GC assay is designed to be a purely qualitative test, nucleic-acid amplification is by its very nature at least a semiquantitative technique, and analyzing the frequency distribution of S/CO ratios of large populations of positive samples provided a somewhat quantifiable measure of assay performance.

One would intuitively expect that if assay performance was impacted negatively by some deficiency in one or more assay components, the target nucleic acid would not amplify as efficiently, and, thus, less amplified product would be generated, ultimately resulting in lower assay signals. The overall distribution of S/CO ratios for positive samples analyzed using such defective reagents should, therefore, be shifted downward relative to those analyzed using unrecalled reagents. No such downward shift in S/CO ratios was observed.
In addition to examining the entire population of assay results obtained with clinical samples, we also examined the frequency with which samples fell in certain critical S/CO ranges. These included the manufacturer-defined equivocal range (S/CO, 0.8-1.2), an expanded equivocal range that captured samples yielding negative results with atypically elevated S/CO ratios (0.2-0.8), and samples yielding positive results with atypically low S/CO ratios (1.2-3.0). The basis for this analysis was the assumption that aberrantly performing reagents would be more likely to generate S/CO ratios from truly positive samples that fell into a somewhat ambiguous range between unequivocally negative and positive results. However, again there were no statistically significant differences in the frequency with which samples tested with recalled rather than nonrecalled reagents fell into this expanded equivocal range.

Each LCx-GC run contains duplicate negative controls and calibrators. It seems reasonable to assume that any significant deficiency in the performance of assay reagents would negatively impact the absolute signals generated by the calibrators or the within-run and between-run reproducibility of the calibrators or, more likely, all of these parameters. Although there were statistically significant differences between negative control and calibrator signals obtained with recalled vs nonrecalled reagents, these differences were not large enough to have had an impact on clinical performance. Indeed, somewhat ironically, the mean signal generated by calibrators analyzed with reagents from recalled lots was actually higher than that generated with reagents from nonrecalled lots. Furthermore, the between-run and within-run reproducibility of calibrator signals was essentially identical for recalled and nonrecalled reagents, and analysis of control charts failed to reveal any evidence for special-cause variation unique to any lot of recalled reagents in negative control or calibrator signals.

One weakness of this project is that the control chart evaluation was limited to 1 rule (ie, a data point was considered evidence of special-cause variation if it was beyond 3 SD above or below the mean for that lot). The evaluation of additional criteria, such as the presence of 2 of 3 successive points greater than 2 SD above the mean but not greater than 3 SD above the mean or the presence of 4 successive points greater than 1 SD above the mean, can provide additional evidence of special-cause variation. Owing to the large data set and the lack of even a rudimentary computerized data analysis tool set for the LCx-GC, testing these additional criteria would have been an onerous task. Given the overall lack of evidence of a performance difference between the recalled and nonrecalled lots, we think the more sophisticated analysis would be unlikely to yield findings that would have impacted the final conclusions of this study. Electronic recording and a set of basic data analysis tools would have permitted the efficient creation and the proper computer-assisted analysis of quality control charts for the LCx-GC data set.

We failed to discover any evidence of meaningful differences in assay performance between recalled and nonrecalled lots of reagents. Although it is not possible for us to state definitively that the internal quality control failure that initiated the LCx-GC recall had no relevance to the clinical performance of the assay, any decrease in assay performance that occurred during the period of the recall was of insufficient magnitude to be detectable in any of the parameters we measured. Our overall findings strongly suggest that the recall was, at a minimum, overly severe in scope and, indeed, might have been entirely unnecessary. Unfortunately, of course, data sets such as the one from the HCMC population used for the analysis described herein were not available from clinical laboratories in real time and, thus, could not be used to study assay performance before the issuance of the recall notice. Had an electronic data storage, retrieval, and analysis package been available for the Abbott LCx-GC instrument, it is entirely conceivable that a legitimate risk-based analysis could have been performed by Abbott Laboratories under the auspices of the FDA and the LCx-GC assay recall avoided or at least selectively applied.

A number of second-generation NAT assay platforms for CT and NG recently have been introduced to the marketplace to replace first-generation products such as the LCx-GC.¹³,²⁰,²¹ Although these new products typically have increased automation and higher sample throughput than earlier assays, they still conspicuously lack electronic data handling capability and quality control procedures. This stands in stark contrast with the sophisticated data analysis capabilities and quality control algorithms found on clinical chemistry and hematology instruments.¹⁹,²²,²³ It seems clear that the addition of such capabilities to instrumentation designed to perform high-volume molecular diagnostic assays should be a priority for manufacturers, because it not only would provide a value-added benefit for laboratorians interested in establishing meaningful quality assurance programs for such assays but also would enable manufacturers to more expeditiously investigate technical performance issues and potentially avoid costly and damaging product recalls.

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References