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Performance Evaluation of the LabGenius C-CT/NG-BMX Assay for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Detection

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The LabGenius C-CT/NG-BMX assay (LabGenius CT/NG; BIOMEDUX, Gyeonggi, Republic of Korea) is a recently developed real-time PCR assay that can simultaneously detect the sexually transmitted pathogens *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) in genitourinary specimens. We evaluated the analytical performance of this assay in comparison with BD MAX CT/GC/TV (Becton Dickinson, Franklin Lakes, NJ, USA). The results of both assays were in nearly perfect agreement for the detection of CT and NG. LabGenius CT/NG demonstrated acceptable analytical performance, comparable with that of another commercially available kit, and provides a cost-effective option for detecting sexually transmitted pathogens in routine and follow-up testing.

Key Words: *Chlamydia trachomatis*, Diagnostic tests, Evaluation, *Neisseria gonorrhoeae*, PCR, Sexually transmitted pathogens

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Chlamydia trachomatis (CT) and *Neisseria gonorrhoeae* (NG) cause preventable and curable sexually transmitted infections (STIs), particularly among female commercial sex workers [1]. The absolute incidence of STI increased between 1990 and 2019 [2], and in 2020, approximately 128.5 and 82.4 million new CT and NG infections, respectively, occurred among adults globally, according to the WHO [3, 4]. Therefore, STIs represent a global public health challenge in developing as well as developed countries.

Severe CT and/or NG infections cause life-threatening pelvic inflammatory disease [5]; however, a substantial proportion of patients infected with these pathogens develop no or only mild symptoms and are unlikely to seek treatment. Therefore, patients with asymptomatic CT and/or NG infection may have long-term infection and may pose an infection risk to their sexual partners [6].

Early STI diagnosis and rapid intervention are essential for preventing STI transmission to others, particularly in developing countries. Therefore, rapid and cost-effective diagnostic tests for STI pathogens are required in clinical laboratories. Real-time PCR-based diagnostic tests are preferable because they have higher sensitivity and specificity than other tests.

The LabGenius C-CT/NG-BMX assay (LabGenius CT/NG; BIOMEDUX, Gyeonggi, Republic of Korea) was recently developed as a point-of-care real-time PCR assay that can simultaneously detect CT and NG in the clinic. We compared the analytical performance of LabGenius CT/NG with that of BD MAX CT/GC/TV (BD MAX CT/GC/TV; Becton Dickinson, Franklin Lakes, NJ, USA), which is a similar automated real-time PCR assay, using 343 vaginal swabs and 167 urinary specimens. In addition, the limits of detection (LoDs), repeatability, and cross-reactivity of the assays were evaluated.

We collected a total of 510 specimens (343 vaginal swabs from women and 167 urinary specimens from men) between January and March 2021 to evaluate the efficacy of C-CT/NG-BMX. Among these, 197 and 132 specimens tested positive for CT and NG, respectively, in routine STI screening PCR assays. The specimens were anonymized, and only the test results were made available. Vaginal swabs and urinary specimens were collected using sexually transmitted disease/human papillomavirus (STD/HPV) collection kits (Noble Biosciences, Gyeonggi, Republic of Korea) and urine collection cups (SPL Life Sciences, Gyeonggi, Republic of Korea), respectively. All specimens were stored at −20°C until evaluation. This study was approved by the Institutional Review Board of Chung-Ang University Hospital (Seoul, Republic of Korea; approval No.: 2111-007-450).

LabGenius CT/NG is a real-time PCR assay for detecting CT and NG in genitourinary specimens and is supplied as a cartridge (Supplemental Data Fig. S1). The clinical samples were loaded directly into the sample inlet holes in the cartridge, which was placed in the LabGenius PCR system (BIOMEDUX). Sample extraction, PCR amplification, and fluorescence detection were performed automatically in the closed cartridge. The system reports the PCR results in approximately 90 mins and is suitable for point-of-care testing as it is portable and fully automated.

For comparison with another commercially available kit, all specimens were simultaneously tested using the BD MAX CT/GC/TV assay. The positive percent agreement (PPA), negative percent agreement (NPA), and overall percent agreement (OPA) for CT and NG detection were calculated. When results were discordant between the two PCR assays, nucleic acid was extracted from the specimens using NucliSENS easyMAG (bioMérieux, Marcy l'Étoile, France), and additional real-time PCR tests were run using the Allplex STI Essential assay (Seegene, Seoul, Republic of Korea). In cases where the results of two or more tests were positive, the result was considered positive by consensus, and *vice versa*. The LabGenius CT/NG assay results were compared with the consensus results.

To evaluate the LoDs for CT and NG, we prepared pooled vaginal swabs and urinary specimens with confirmed negative results using the BD MAX CT/GC/TV and Allplex STI Essential assays. Then, we extracted genomic DNA from CT (ATCC VR-901BD; American Type Culture Collection (ATCC), Manassas, VA, USA) and NG (ATCC 53420D-5; ATCC), and spiked the pathogen DNA into pooled specimens. Using these pooled specimens, we prepared five levels of vaginal swabs and urinary samples (0, 5, 10, 20, and 50 copies/μL) and repeated the tests 45 times (five replicates per run and three lots per day for 3 days).

To account for various factors in clinical laboratories, we evaluated the precision profiles of cycle threshold (Ct) values, including repeatability, within-laboratory precision, and site-to-site variability. We prepared three specimens (10, 30, and 100 copies/μL) for each pathogen, and precision analysis was performed by repeating the test using these specimens in three replicate measurements per run and three runs per day for 20 days (3×3×20) in two laboratories (Chung-Ang University Hospital and BIOMEDUX).

To evaluate the cross-reactivity and interference from other pathogens and interfering substances, CT- and NG-negative specimens were spiked with DNA from microorganisms and interferents (Supplemental Data Table S1). We tested these specimens thrice daily for 3 days using LabGenius CT/NG.

PPA, NPA, and OPA were calculated according to CLSI guideline EP12-A2 [7], and the precision of Ct values was analyzed in accordance with CLSI guideline EP05-A3 [8]. Cohen's kappa coefficient (κ) was used to measure the agreement between the two assays [9]. Binomial logistic regression analysis was performed to evaluate the LoD of the LabGenius CT/NG. Logistic regression models were constructed based on the positive rates of LabGenius CT/NG and CT and NG DNA concentrations [7]. Using logistic regression analysis, we determined the function describing the relation between the LabGenius CT/NG results and bacterial DNA concentrations and estimated the DNA copy numbers at which 95% detection rates were achieved (LoD_{95}). All statistical analyses were performed using R version 4.3.2 (http://www.R-project.org/).

A comparison of the LabGenius CT/NG and BD MAX CT/GC/TV results is shown in Table 1 and Supplemental Data Fig. S2. The OPAs for CT and NG were 89.2%–93.3% and 97.7%–98.8%, respectively. Regarding the agreement between LabGenius CT/NG and BD MAX CT/GC/TV, Cohen's kappa coefficients for CT and NG were 0.78–0.91 and 0.92–0.95, respectively. These results were consistent, with nearly perfect agreement, except for CT detection in urinary specimens (κ=0.78). When compared

Table 1. Analytical performance of LabGenius CT/NG in comparison with BD MAX CT/GC/TV

Specimen type and target species	BD MAX CT/GC/TV Positive		BD MAX CT/GC/TV Negative		PPA (%)	NPA (%)	OPA (%)	Cohen's kappa
	LabGenius CT/NG Positive	LabGenius CT/NG Negative	LabGenius CT/NG Positive	LabGenius CT/NG Negative				
Vaginal swab (N=343)								
Chlamydia trachomatis	127	22	1	193	99.2 (95.7–99.9)	89.8 (85.0–93.1)	93.3 (90.1–95.5)	0.91 (0.88–0.95)
Neisseria gonorrhoeae	64	7	1	271	98.5 (91.8–99.7)	97.5 (94.9–98.8)	97.7 (95.5–98.8)	0.92 (0.87–0.98)
Urine (N=167)								
Chlamydia trachomatis	61	11	7	88	89.7 (80.2–94.9)	88.9 (81.2–93.7)	89.2 (83.6–93.1)	0.78 (0.68–0.88)
Neisseria gonorrhoeae	63	2	0	102	100 (94.3–100.0)	98.1 (93.3–99.5)	98.8 (95.7–99.7)	0.93 (0.88–0.98)
Total (N=510)								
Chlamydia trachomatis	188	33	8	281	95.9 (92.2–97.9)	89.5 (85.6–92.4)	92.0 (89.3–94.0)	0.83 (0.79–0.88)
Neisseria gonorrhoeae	127	9	1	373	99.2 (95.7–99.9)	97.6 (95.6–98.8)	98.0 (96.4–98.9)	0.95 (0.92–0.98)

Abbreviations: CT, *Chlamydia trachomatis*; NG, *Neisseria gonorrhoeae*; TV, *Trichomonas vaginalis*; PPA, positive percent agreement; NPA, negative percent agreement; OPA, overall percent agreement.

with the consensus results, the total OPAs for discordant specimens were 87.8% and 50.0% for CT and NG, respectively (Table 2 and Supplemental Table S2). The LoD_{95} for vaginal swabs and urinary specimens were 9.9 and 7.8 copies/μL for CT, and 7.6 and 5.1 copies/μL for NG, respectively (Fig. 1).

The precision results of LabGenius CT/NG are summarized in Supplemental Table S3. For the three different CT and NG concentrations, the pooled precision of the Ct values was within 1.5% for all specimens tested. In the cross-reactivity and interference evaluations, no changes from positive to negative results were observed (data not shown).

Early STI diagnosis reduces symptoms and complications and prevents transmission to sexual partners [3, 4, 10, 11]. Various PCR assays for rapid and accurate STI detection have been introduced [10, 12], which are beneficial for timely treatment decisions and effective infection prevention [10]. However, these assays are expensive in some countries and require skilled personnel for operation and analysis [13]. Therefore, inexpensive molecular assays that do not require molecular expertise are required. From this perspective, the new LabGenius CT/NG assay may be beneficial as a rapid, cost-effective (retail price approximately $15 per test), and easily accessible detection method for the two STI pathogens.

We evaluated the efficacy of LabGenius CT/NG for detecting CT and NG in genitourinary specimens. The agreement between LabGenius CT/NG and BD MAX CT/GC/TV for the detection of CT and NG in genitourinary specimens was nearly perfect, except for CT detection in urinary specimens. The LoDs of the LabGenius CT/NG for detecting pathogens in vaginal swabs and urinary specimens were excellent. Therefore, we conclude that the performance of LabGenius CT/NG is equivalent to that of BD MAX CT/GC/TV, a commercially available molecular assay. Furthermore, the repeatability, lot-to-lot variability, operator-to-operator variability, and site-to-site variability of the LabGenius CT/NG were stable and excellent, and no cross-reactivity with other pathogens or potential interferents was observed.

Although we attempted to minimize errors, this study had limitations. We collected only specimens with CT- and/or NG-positive PCR results; therefore, we could not assess the pathogen concentration distribution in samples. This may have introduced bias in sample selection, which could not be excluded. In addition, because this study was conducted with a single sample collection protocol for each sample type, the specimens were collected using vaginal swab and urine collection kits typically used for routine tests. However, the BD MAX CT/GC/TV assay requires the use of the BD MAX UVE Specimen Collection Kit, and

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Table 2. Comparison of LabGenius CT/NG results and consensus results

Specimen type and target species	Positive consensus		Negative consensus		OPA (%)
	LabGenius CT/NG Positive	LabGenius CT/NG Negative	LabGenius CT/NG Positive	LabGenius CT/NG Negative	
Chlamydia trachomatis (N=41)					
Vaginal swab	0	1	1	21	91.3 (73.2–97.6)
Urine	6	1	2	9	83.3 (60.8–94.2)
Total	6	2	3	30	87.8 (74.5–94.7)
Neisseria gonorrhoeae (N=10)					
Vaginal swab	1	0	3	4	62.5 (30.6–86.3)
Urine	0	0	2	0	0 (0–65.8)
Total	1	0	5	4	50.0 (23.7–76.3)

Abbreviations: CT, *Chlamydia trachomatis*; NG, *Neisseria gonorrhoeae*; OPA, overall percent agreement.

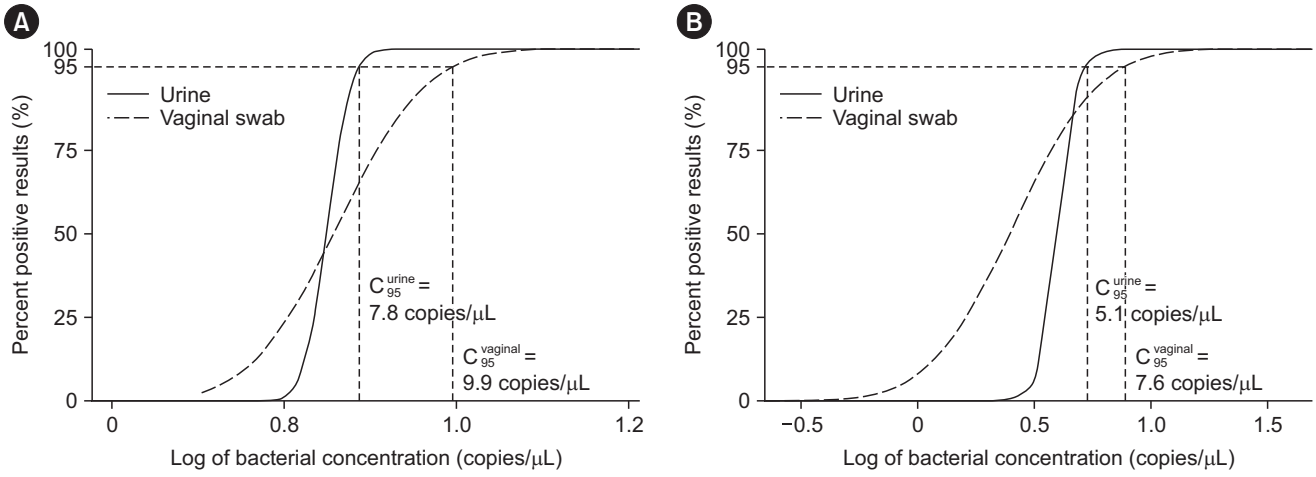

Fig. 1. Binomial logistic regression analysis of the percent positive results of LabGenius CT/NG according to (A) *Chlamydia trachomatis* (CT) and (B) *Neisseria gonorrhoeae* (NG) DNA concentrations.

this discrepancy may have impacted the assay performance.

In conclusion, we evaluated a recently developed point-of-care real-time PCR assay for the rapid detection of two of four major sexually transmitted pathogens [11]. LabGenius CT/NG had excellent performance in diagnosing CT and NG infections in genitourinary specimens. We expect that this assay will offer clinical laboratories and point-of-care clinics a valuable option for the rapid diagnosis and improved clinical management of patients with STIs.

SUPPLEMENTARY MATERIALS

Supplementary materials can be found via https://doi.org/10.3343/alm.2024.0118

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AUTHOR CONTRIBUTIONS

Lee MK conceived the idea and supervised the study; Kim HK, Yoon SM, Park AJ, and Kim TH performed the calculations and prepared the figures; Lim YK and Kweon OJ wrote the first draft of the manuscript. All authors have read and approved the final manuscript.

CONFLICTS OF INTEREST

None declared.

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