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Performance of a single-use, rapid, point-of-care PCR device for the detection of *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, and *Trichomonas vaginalis*: a cross-sectional study

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Summary

Background

Timely detection and treatment are important for the control of *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis*. The objective of this study was to measure the performance of the Visby Medical Sexual Health Test, a single-use, point-of-care PCR device.

Methods

Women aged 14 years and older who presented consecutively to ten clinical sites across seven US states were enrolled for a cross-sectional, single-visit study. Patients who consented to participate, and who had not used any exclusionary products in the genital area in the previous 48 h, provided self-collected vaginal swabs for testing with the investigational device. Untrained operators received the specimens and ran the device using the guide provided. Specimens had to be run within 2 h of collection to be considered valid. For comparison, patient-infected status was derived by testing clinician-collected vaginal specimens with the Hologic Aptima Combo 2 Assay and Aptima *Trichomonas vaginalis* Assay, as well as the BD ProbeTec CT/GC Q Amplified DNA Assay and BD ProbeTec *Trichomonas*

Background

The objective of this study was to measure the performance of the Visby Medical Sexual Health Click Test, a single-use, point-of-care PCR device for timely detection, treatment and control of *Neisseria gonorrhoeae*, *Chlamydia trachomatis* and *Trichomonas vaginalis*.

Methods

- The study included collaboration between the National Institute of Allergy and Infectious Diseases of the US National Institutes of Health (NIH), STAR STI Clinical Trial Group and Visby Medical
- Over 1500 participants - women aged 14 - 80 years old, tested at 10 clinical sites across 7 states
- Patients who met inclusion criteria provided self-collected vaginal swabs to be used in the Visby Medical Sexual Health Click Test
- Patients who used exclusionary products (such as vaginal washes, lubricants, etc) in the genital area 48 hours before enrollment were excluded
- Study type: Cross sectional, single-visit study
- Untrained operators ran the Visby Medical device within 2 hours of sample collection
- For comparison, patient infected status was also derived by testing clinician-collected vaginal specimens with:
    - Hologic Aptima Combo 2 assay
    - Hologic Aptima Trichomonas vaginalis assay
    - BD ProbeTec CT/GC Q Amplified DNA assay
- If results did not match, BD MAX CT/GC/TV was used as tiebreaker

Test workflow and technology

The device is meant to be used by any clinic personnel using the quick reference guide: input sample using a pipette to transfer 650 μL of the sample-containing media into the device input port. Activate the device by closing the sample port and pressing buttons 1, 2, and 3 in succession. After button 3 is pressed and the device is plugged in, a white LED light turns on indicating the reaction is in progress, and a visual-read colorimetric result appears in less than 30 min.

The results should be read within 2 hours. If the sample is positive, a colorimetric change (from white to purple) is visible in the appropriate spot for the pathogen.

The Sexual Health Test contains all the reagents and instrumentation required to run a single PCR-based test. The device stores buffers and reagents on board for release at the correct time. Printed circuit boards control temperature and time the movement of the motors and liquid flow. Sample processing occurs on the device using a combination of heat and chemical lysis to release pathogen DNA. The inactivated sample is mixed with lyophilised PCR reagents and then amplified by continuous-flow PCR using a serpentine-shaped, plastic-moulded, fluidic circuit that allows rapid heating and cooling. Biotin-labeled PCR primers specifically amplify *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, and *Trichomonas vaginalis* genes. A detection flow cell has oligonucleotide capture probes that hybridise to the amplified pathogenic target (appendix p 1). A colorimetric signal is generated on the flow cell when horseradish peroxidase-linked streptavidin binds biotin-labeled amplicon and capture-probe pairs and catalyzes the conversion of 3,3',5,5'-tetramethylbenzidine, resulting in a purple precipitate. The presence of target pathogen in the sample thus leads to a white-to-purple color change on the detection flow cell.

Findings

Between February 25, 2019 and January 6, 2020, 1585 female participants aged between 14 - 80 years were enrolled. 1532 participants had a valid result.

Chlamydia trachomatis
(n=1457) 1313 negative, 144 positive
Sensitivity 97·6% (95% CI 93·2–99·2)
Specificity 98·3% (97·5–98·9)

Neisseria gonorrhoeae
(n=1468) 1423 negative, 45 positive
Sensitivity 97·4% (86·5–99·5)
Specificity 99·4% (98·9–99·7)

Trichomonas vaginalis
(n=1449) 1287 negative, 162 positive
Sensitivity 99·2% (95·5–99·9)
Specificity 96·9% (95·8–97·7)

"The device is potentially the new gold standard for point of care tests for infectious diseases such as STIs and influenza and coronavirus infections, in which rapid turnaround is key."

Other comparative point of care systems show high similar sensitivity and specificity for CT, NG, TV. However, they use desktop instruments that have higher complexity of operation, require maintenance, can only run one test at a time and take longer than most patients are willing to wait for results.

Interpretation

The Visby Medical Sexual Health Click Test represents a major step forward for the detection of STIs that could result in more timely and accurate patient care, improved control of these infections, and a reduction in STI complications. Widespread use of the rapid device would allow for treatment decisions in real time. Such use has been shown to improve appropriate treatment and reduce unnecessary antibiotic exposure. The device is potentially the new gold standard for point of care tests for infectious diseases such as STIs and influenza and coronavirus infections, in which rapid turnaround is key.

The Visby Medical Sexual Health Click Test is the first device to apply the advances in molecular and microfluidic technology towards true point-of-care, highly accurate, and rapid testing that can be applied to many prevalent infectious diseases globally.

- The development of rapid point of care test for STIs and other infectious diseases represents an important need in medicine and public health. For the public health control of STIs, the implications for such device are an advancement to treating everyone who needs treatment avoiding unnecessary speculative treatment, as well as minimizing time to treatment, which will reduce transmission and complications.
- The Visby Medical Sexual Health Click Test is an innovative, single-use, rapid, nucleic acid-based diagnostic test for detection of *N gonorrhea*, *C trachomatis*, *T vaginalis* infections. This test can be done at the point of care without complex instrumentation and give a result in less than 30 minutes.
- The test showed excellent sensitivity and specificity, and could represent an important advance in the development of rapid diagnostics for sexually transmitted infections and other infectious diseases.
- Other point of care systems such as Cepheid GeneXpert and Binx io require samples to be placed in PCR desktop instrument and take 30-45 minutes longer compared to the Visby Medical Sexual Health Test which takes 28 minutes and does not require an instrument at all.
- The Visby Medical Sexual Health Click Test meets many of the desirable characteristics defined by WHO for a point of care device: sensitive, specific, user friendly, rapid, robust, equipment free and deliverable to end users.
- Operators in the study agree or strongly agree that: “It was easy to set up the device”, “Overall, it was easy to run the device”

In summary, this study evaluated a new, first-in-class diagnostic point of care device for the detection of STIs in women. The device has major potential for the rapid detection of STIs in CLIA-waived settings.