Point of Care Diagnosis of Vaginal Infections to Ensure Accurate Treatment: (PAT Study)

NCT06438575

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Study Title	Point of Care Diagnosis of Vaginal Infections to Ensure Accurate Treatment: (PAT Study) Healthcare Provider Sub Study		
Consent Version	3.0 25Feb2025	**Protocol Version**	4.0 09Aug2024
Principal Investigator	Sharon Hillier, PhD		
Researcher's phone #	412-641-4242		
Funding agencies	Cepheid		

********************************KEY INFORMATION********************************

You are being invited to participate in a research study because one or more of your clinical patients has participated in the PAT study. Researchers are interested in better understanding how providers feel about using point of care (POC) testing for vaginitis. Your participation would involve answering an anonymous, brief (5 minute) questionnaire about your experience as a provider and your opinion about POC testing.

The PAT study is fully enrolled. The purpose of the study was to compare the standard of care for vaginitis among providers and the use of a POC test, called the Xpert® Xpress MVP (MVP) test. The MVP is an FDA-approved test to diagnose bacterial vaginosis (BV), yeast, and trichomonas in approximately one hour. Participants with vaginal complaints who agreed to participate were asked to self-collect vaginal swabs, with one of the swabs used to run the MVP test as detailed below. Participants were randomized at the time of their clinic visit to one of two arms:

Arm 1: Provider performed usual care to diagnose and provide treatment for vaginitis, if necessary. MVP results were delayed and provided approximately two weeks later.

Arm 2: MVP result was run immediately following self-collection. Provider was asked to use the results of the MVP test to diagnose and provide treatment for vaginitis.

In both arms, MVP results were made available to the provider/placed in the participant's electronic health record.

ENROLLMENT PROCEDURES

If you decide to participate, you would be asked questions to confirm eligibility and asked to complete a survey that would take approximately 5 minutes. You would be provided with a $50 gift card for your time.

RISKS/BENEFITS/ALTERNATIVES

The risks of participating in this study are minimal and include inconvenience and the potential for breach of confidentiality. Your confidentiality will be protected as your survey responses will not be connected to identifiable information. You may not receive any direct benefits from participating.

Participation is voluntary. You may choose not to take part in this study.
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

PROBLEMS OR QUESTIONS

If you have any questions about your rights as a research subject or wish to talk to someone other the research team, please call the University of Pittsburgh Human Subjects Protection Advocate toll-free at 866-212-2668.

VOLUNTARY CONSENT FOR PARTICIPANTS

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified member of the research team or by the Principal Investigator listed on the first page. I understand that I may always request that my questions, concerns or complaints be addressed by the Principal Investigator. At any time, I may also contact the Human Subjects Protection Advocate of the Human Research Protection office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable. By signing this form, I agree to participate in this research study for the purposes described above. A copy of this consent form will be offered to me.

_____

Printed Name of Participant

_____ _____ _____

Participant Signature Date Time (am/pm)

CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of this research to the above individual and I have discussed the potential benefits and possible risks of study participation. Any questions the individual has about the study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____

Printed name of Person Obtaining Consent Role in Research Study

_____ _____ _____

Signature of Person Obtaining Consent Date Time (am/pm)