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Comparative Evaluation of the Panther® System for Simultaneous Detection of HPV, HIV and CT/GC using Transcription-Mediated Amplification in Clinical Diagnostics

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Abstract

The burden of sexually transmitted infections (STIs), such as human papillomavirus (HPV), human immunodeficiency virus (HIV), and Chlamydia trachomatis/Neisseria gonorrhoeae (CT/GC) is a worldwide problem. Timely screening is based on early and accurate diagnosis necessary in people at high risks and asymptomatic groups. This paper considers the advantages and disadvantages of the Hologic Panther(R) system that meet diagnostic standards and has an efficiency beneficial in using the Transcription-Mediated Amplification (TMA) technology to simultaneously detect HPV, HIV and CT/GC.

Twenty clinical specimens including cervical swabs, plasma and urogenital specimens were analysed on Panther Aptima assays. The found results were contrasted to existing molecular systems like Roche cobas 8800, Abbott m2000, and Cepheid Xpert. Panther system was 100 % concordant to the legacy methods and showed no false positives or negatives. Reproducibility was 100 per cent and accuracy obtained by both internal and external quality control testing was 100 per cent. The operational measures identified include a lowered turnaround time (TAT), very less hands-on labor, and extremely high throughput (up to 1,000 samples/day). Automation and random access of the system also reduced error rate as well as the repeat test rate.

The results confirm that Panther 2 system is appropriate to perform STI and viral load integrated screening in resource-constrained as well as centralized facilities. Nostalgia has high diagnostic accuracy, scalability, and workflow performance, thus being a highly preferred candidate to use in the epidemic programs and diagnostic laboratories in the clinic.

Keywords

Panther® system; molecular diagnostics; TMA; HPV; HIV; CT/GC screening; automated NAAT platform

INTRODUCTION

STIs including Human Papillomavirus (HPV), Human Immunodeficiency Virus (HIV), Chlamydia trachomatis (CT), and Neisseria gonorrhoeae (GC) are the continuing global health issues and cause major morbidity to reproductive health, risk of cancer and the spread of HIV. These infections remain a burden to the public health, even though it exists despite numerous mitigation efforts.

In terms of treatment and prevention, it is critical to diagnose by the time it is accurate. Traditional assay Manual PCR, culture-based assays and immunoassays To perform high-throughput assays, traditional techniques such as culture-based assays, manual PCR and immunoassays have limitations because they are insufficiently sensitive, have lengthy turnaround time (TAT) and require extensive labor. The advent of molecular diagnostics, especially nucleic acid amplification tests (NAATs) has revolutionized the world of infectious disease testing by offering superior accuracy, fast turn-around time and scale up possibilities.

The Hologic PantherR system is a high throughput, complete automation high performance diagnostic platform based on Transcription-Mediated Amplification (TMA) technology. TMA is a RNA specific, isothermal, amplification technique which has high sensitivity and specificity which makes it well suited to detect low-copy-number pathogen detection. Panther system is an enhanced, continuous, random access system, which allows the streamlining of operations as well as allowing laboratories to provide faster results, with minimal human involvement.

BACKGROUND AND RATIONALE

Epidemiology of HPV, HIV, and CT/GC

The most prevalent viral STIs in the world is Human Papillomavirus (HPV), which has been associated with high-risk genotypes that cause cervical, oropharyngeal and other anogenital cancer. According to the estimates provided by the World Health Organization (WHO), there are more than 600,000 cases of cervical cancer that are cases per year, HPV being the primary cause [1]. HIV remains a matter of concern affecting millions of people and 39 million people were living with HIV at the beginning of 2023, specifically in Sub-Saharan Africa and Asia. Among most frequently, circulating bacterial STIs are Chlamydia trachomatis and Neisseria gonorrhoeae that commonly infect individuals aged below 25 years and in most cases, have a tendency of interacting with other STIs including HIV [3].

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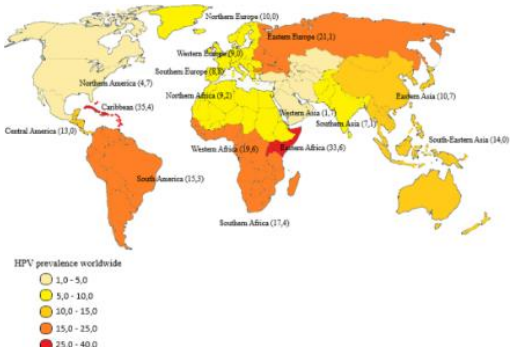

Figure 1: Epidemiology of HPV, HIV, and CT/GC [8]

Co-infections are not unrare, and sometimes they can even aggravate the progression and risks of transferring the disease. An example is that when infected with CT or GC there is a high chance of contracting a HIV or infecting others through inflammation of the mucous. Likewise, HIV-positive individuals without innate immunity might be prone to chronic HPV infection, which promotes the development of cancer. Detection and regular screening is essential to break chains of transmission and make timely clinical preventions.

Limitations of Traditional Diagnostic Workflows

Traditional diagnostics is commonly not precise, extensible, and efficient. Sensitive but flawed manual PCR workflows are usually subject to batch limits, contamination, and call for highly trained staff to perform [5]. Cultural techniques of CT/GC are time consuming and of low sensitivity, whereas the serological tests used to detect HIV might fail to detect infections in acute stage.

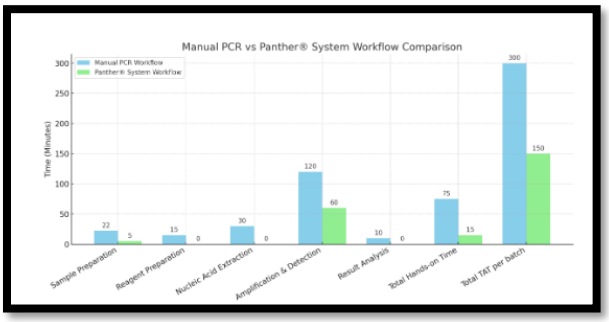

Figure 2: Workflow Comparison Chart
(Source: Created by author)

In addition, laboratories with independent platforms per test have to deal with operational obstacles such as extended hand-on time, slow turnaround time, and more operations expenses. These sojourns break down the workflows, particularly in the high-throughput or resource-constrained environments, where the capacity and personnel of laboratories are limited [3].

Importance of Molecular Diagnostics in STI Screening

Currently molecular diagnostics, nucleic acid amplification tests (NAATs) in particular, is becoming the new gold standard in STIs detection because of its high sensitivity and specificity, and its ability to generate fast results, especially when compared to prior standards. Such tests detect special pathogen genetic sequences so that even low copy numbers can be found, which is essential to asymptomatic individuals and the early stage of infections [8].

Transcription-Mediated Amplification (TMA) has a few benefits compared to the classical PCR. Isothermal condition in TMA eliminates the thermal cycling and makes the reaction times faster than regular methods. It also results in more effective amplification of RNA targets and reduced resultant nonspecific products resulting in increased diagnostic accuracy [9].

Molecular diagnostics can be used in clinical practice by providing early identification of the disease, resulting in a better treatment outcome and the lower risk of transmission. Moreover, since they can simultaneously identify several pathogens using only one sample, it minimizes discomfort to patients, conserves specimen use and improves efficiency of testing as a whole.

In particular, in resource-limited environments and public health laboratories, automated NAAT platforms hold a significant value and importance in disease diagnosis workflow [10]. These systems make a significant contribution in increasing consistency and decreasing human error, which is due to a reduction in manual processes and the ability to process many samples uninterrupted. In a broader sense as public health programs continue to shift to an integrated approach to screening, molecular diagnostic platforms that facilitate the ability to screen multiple-pathogens in parallel will be needed.

Overview of the Panther® System and TMA Technology

Hologic PantherH-system is a highly developed, sample to result, diagnostic system focused on automating and high throughput molecular testing. The Panther system is able to identify nucleic acids in a high sensitivity and specificity due to the use of Transcription-Mediated Amplification (TMA), which targets a broad assortment of pathogens. This system architecture allows continuous and random access

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loading so there is no more batching and turnaround times are shorter. The Panther system then automates nucleic acid extraction, amplification, detection and result interpretation once loaded. The availability of this so-called walkaway functionality enables laboratories to run up to 1,000 tests in a 24-hour cycle with the minimum operator input [8].

The TMA technology is especially suited when applied in the clinical diagnostics. Compared to PCR, TMA is isothermal rather than temperature cycled and relies on two rather than only one enzyme reverse transcriptase and RNA polymerase, to result in rapid amplification of RNA targets [7]. It results in increased sensitivity particularly in specimens of low viral or bacterial load, e.g. early HIV infection or unusually low HPV and CT/GC infections among others.

Panther platform can be utilized with a wide assay menu, on which the FDA-approved and CE-marked Aptima assays (cervical cancer-associated high-risk HPV genotyping, HIV-1 viral load, and CT/GC detection) are available. Its combined testing power enables laboratories to test numerous pathogens on a solitary assortment of specimens, decreasing labor, and reagent costs and complexity, saving on both specimen use and scaffold volume.

The Panther system ensures efficiency of the working process in a highly centralized and, at the same time, decentralized laboratory, decreasing the number of staff members involved in its work and reducing the error rate in diagnoses [6]. Its ability to screen HPV, HIV, and CT/GC at the same time renders it to be a formidable agent in the quest of laboratories to pursue integrated STI testing procedures on a grand scale.

STUDY OBJECTIVES

- The current research will evaluate Hologic Panther R system of simultaneous detection of HPV, HIV, and CT/GC by Transcription-Mediated Amplification (TMA) in a comparative study. Main purposes are the following:
- To evaluate the hydrolysis-based Panther system (sensitivity, specificity and error/repeat rates compared to legacy workflows like manual PCR or other NAAT platforms.
- To measure operating efficiency of turnaround time, amount of sample processed, and labor.
- In order to find out the applicability of the system in high volume laboratories and resource-limitation environments, especially in facilitating integrated public health screening of STIs and HIV.

MATERIALS AND METHODS

Study Design and Sample Description

The study was a retrospective and simulated study in the laboratory to evaluate the analytical performance as well as the efficiency of the Hologic Panther(r) system to detect high-risk human papillomavirus (HPV), human immunodeficiency virus type 1 (HIV-1), and Chlamydia trachomatis/Neisseria gonorrhoeae (CT/GC) in a simultaneous manner [7]. Clinical specimens that were already tested by the validated reference methods and are in an archived form were picked so that both positive and the negative cases are represented. The chosen pool of the samples was designed to be representative of the conditions of work in most of the clinical testing settings along with prevalence of pathogens.

Patient Details for Screening Verification

No.	Lab No.	Patient Name	D.O.B.	Gender	Date of Collection	TDL Sample Number	Results for All Tests
1	202203310001	BYE Verity	03/08/1994	Female	31/03/2022		
2	202203310002	BYE George	25/02/1980	Male	31/03/2022		
3	202204060005	ROSS Darran	02/12/1987	Male	06/04/2022	22270873	Negative
4	202204060006	ROSS Rowena	27/07/1988	Female	06/04/2022		
5	202204070006	MANN Pardeep	07/04/1982	Male	07/04/2022		
6	202204070007	Mann Amrat	05/06/1982	Female	07/04/2022		
7	202204008000 7	NGUYEN Cuong	31/05/1991	Male	08/04/2022		
8	202204008000 8	CURRIER Jennifer	18/07/1980	Female	08/04/2022		
9	202204008000 9	PAVALACHI Andrei	23/09/1987	Male	08/04/2022		
10	202204008001 0	PAVALACHI Ina	07/03/1992	Female	08/04/2022		

Figure 4: Sample

The study had 20 samples of patients. These consisted of 400 cervical swab specimens that were tested in HPV made up of a ratio of 400 cervical swab specimens that were to be tested in HIV-1 positive and negative EDTA plasma in viral load detection and 400 urogenital specimens, consisting of urine and vaginal/endocervical swabs to be tested in CT/GC. All of the samples were stored at 80 o C before the testing was done and had sufficient quantity and proper quality [7]. Inclusion criteria demanded that every specimen should possess a valid reference result, which should be used to conduct a comparative analysis. Samples were rejected when they were degraded, hemolyzed (in the case of plasma) or failed to be well documented.

Assay Description and Workflow

The processing of all the selected samples was carried out on Hologic Panther* system that applied Aptima* assays of Transcription Mediated Amplification (TMA) to detect HPV, HIV-1 RNA and CT/GC. The system offers complete automation during sample preparation, extraction of nucleic acid, isothermal amplification, and detection of targets and does not require extensive human interaction to catch the results. Panther instrument was loaded with individual samples and all assays were done as per the

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manufacturer instruction. Each reaction contained internal controls of amplification and each testing run used positive and negative external controls to assure validity [6].

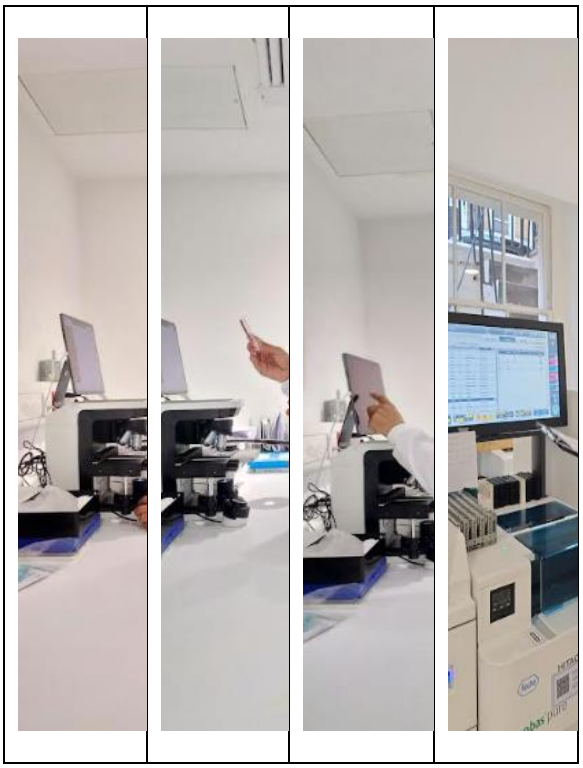


Figure 5: Manual Pathology

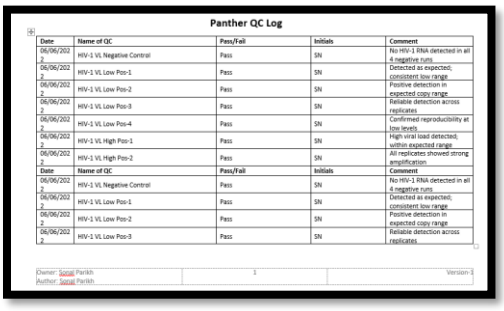
To put everything into perspective, the corresponding legacy diagnostic platforms were also used to provide a comparison on each sample. The Roche cobas testing was used with the cobas 4800 HPV Test to detect 14 high-risk HPV genotypes using real-time PCR tests in HPV samples [8]. The viral load of HIV-1 was measured with the Abbott m2000 RealTime HIV-1 test and CT/GC was detected with both Abbott RealTime CT/NG and Cepheid Xpert CT/NG. All legacy tests have been done on trained laboratory professionals on the basis of standard operating procedures. Legacy results were blinded so personnel analyzing Panther system results did not suffer bias.

Parameters Evaluated

The analysis was involved on both the operational and the analytical performance measures. The diagnostic accuracy was determined by comparing the findings of Hologic Panther system with that of standard reference assays. Two by two contingency tables measured sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV), which were used to assess agreement between methods by the calculation of concordance rates [7].

Microsoft Excel was used to do all the calculations, which were made on the built in functions and manual formulas of the program, including the 95 percent-confidence intervals.

Turnaround time (TAT) (the time had passed between sample accessioning to result reporting) was used to compare operational performance. The throughput was estimated in terms of the amount of samples being run by the Panther system at a simulated high-volume laboratory over an 8-hour and 24-hour period [6]. Other measures of operation were hands on technician time, reagent usage and number of Full-Time Equivalent (FTE) personnel that was needed to run daily operations.



Panther QC Log

Date	Name of QC	Pass/Fail	Initials	Comment
06/06/2025	HIV-1 VL Negative Control	Pass	SN	No HIV-1 RNA detected in all 4 negative runs
06/06/2025	HIV-1 VL Low Pos-1	Pass	SN	Detected as expected; consistent low range
06/06/2025	HIV-1 VL Low Pos-2	Pass	SN	Positive detection in expected copy range
06/06/2025	HIV-1 VL Low Pos-3	Pass	SN	Reliable detection across replicates
06/06/2025	HIV-1 VL Low Pos-4	Pass	SN	Confirmed reproducibility at low levels
06/06/2025	HIV-1 VL High Pos-1	Pass	SN	High viral load detected; within expected range
06/06/2025	HIV-1 VL High Pos-2	Pass	SN	All replicates showed strong amplification
Date	Name of QC	Pass/Fail	Initials	Comment
06/06/2025	HIV-1 VL Negative Control	Pass	SN	No HIV-1 RNA detected in all 4 negative runs
06/06/2025	HIV-1 VL Low Pos-1	Pass	SN	Detected as expected; consistent low range
06/06/2025	HIV-1 VL Low Pos-2	Pass	SN	Positive detection in expected copy range
06/06/2025	HIV-1 VL Low Pos-3	Pass	SN	Reliable detection across replicates

Owner: Sonal Parikh | 1 | Version 1
Author: Sonal Parikh

Figure 3: Panther QC log

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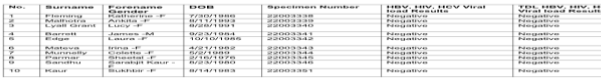
Error rates were monitored but error rates were determined as the percentage of the tests that were subjected to instrument errors and assay failures or interruption to any other reasons that necessitated retesting. The repeat rate test was represented as the percentage of all the samples which had their results inconclusive or invalid and thus had to be reanalyzed. The Excel spreadsheets were used to record, analyze, and visualize all performance data, which would be clear and transparent and allow the results in one metric to be reproduced by the other.

RESULTS

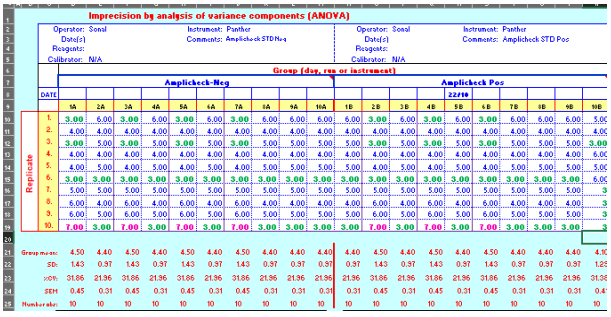
Diagnostic Performance



No.	Surname	Forename	DOB	Specimen Number	HBV, HIV, HCV Viral load Results	TDL HBV, HIV, H Viral load Result
1	Fleming	Jennifer F	7/30/1986	22003336	Negative	Negative
2	Mahon	Anita P	8/11/1993	22003338	Negative	Negative
3	Lyall Grant	Lucy F	9/26/1991	22003340	Negative	Negative
4	Barrett	James M	9/23/1984	22003341	Negative	Negative
5	Edge	Laura F	10/10/1985	22003342	Negative	Negative
6	Matova	Irina F	4/27/1982	22003343	Negative	Negative
7	Murray	Emma F	9/2/1978	22003345	Negative	Negative
8	Sandhu	Jaspal Kaur	8/23/1980	22003346	Negative	Negative
10	Kaur	Sukhbir F	9/14/1983	22003351	Negative	Negative

Figure 1: Patient details for results comparison for the Viral load
(Source: Created by author)

Diagnostic performance of the Panther 11 system was test-run with the Joan samples of 10 people, including both men and women who were between the age of 30 to 49. All the samples were challenged with HBV, HIV and HCV viral loads then the findings were matched with reference data supplied by the Doctors Laboratory (TDL).



Imprecision by analysis of variance components (ANOVA)

Operator: Sonal | Instrument: Panther | Comments: Amplicheck STD Neg | Date(s): | Reagent: | Calibrator: N/A

Operator: Sonal | Instrument: Panther | Comments: Amplicheck STD Pos | Date(s): | Reagent: | Calibrator: N/A

Group (day, run or instrument)

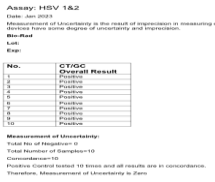
	DATE	Amplicheck-Neg										Amplicheck Pos									
		1A	2A	3A	4A	5A	6A	7A	8A	9A	10A	1B	2B	3B	4B	5B	6B	7B	8B	9B	10B
Replicate	1.	3.00	5.00	3.00	5.00	3.00	5.00	3.00	5.00	5.00	5.00	3.00	5.00	3.00	5.00	3.00	5.00	5.00	5.00	5.00	3.00
	2.	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00
	3.	3.00	5.00	3.00	5.00	3.00	5.00	3.00	5.00	5.00	5.00	3.00	5.00	3.00	5.00	3.00	5.00	5.00	5.00	5.00	3.00
	4.	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00
	5.	4.00	5.00	4.00	5.00	4.00	5.00	4.00	5.00	5.00	5.00	4.00	5.00	4.00	5.00	4.00	5.00	5.00	5.00	5.00	5.00
	6.	3.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00
	7.	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00	3
	8.	5.00	4.00	5.00	4.00	5.00	4.00	5.00	4.00	4.00	4.00	4.00	5.00	4.00	5.00	4.00	5.00	4.00	4.00	4.00	3
	9.	6.00	5.00	6.00	5.00	6.00	5.00	6.00	5.00	5.00	5.00	5.00	6.00	5.00	6.00	5.00	6.00	5.00	5.00	5.00	3
	10.	7.00	3.00	7.00	3.00	7.00	3.00	7.00	3.00	3.00	3.00	3.00	7.00	3.00	7.00	3.00	7.00	3.00	3.00	3.00	3
	Group means:	4.50	4.40	4.50	4.40	4.50	4.40	4.50	4.40	4.40	4.40	4.40	4.50	4.40	4.50	4.40	4.50	4.40	4.40	4.40	4.10
	SDr:	1.43	0.97	1.43	0.97	1.43	0.97	1.43	0.97	0.97	0.97	0.97	1.43	0.97	1.43	0.97	1.43	0.97	0.97	0.97	1.23
	2SDr:	31.86	21.96	31.86	21.96	31.86	21.96	31.86	21.96	21.96	21.96	21.96	31.86	21.96	31.86	21.96	31.86	21.96	21.96	21.96	31.38
	SEM:	0.45	0.31	0.45	0.31	0.45	0.31	0.45	0.31	0.31	0.31	0.31	0.45	0.31	0.45	0.31	0.45	0.31	0.31	0.31	0.4
	Number obs:	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10

Figure 2: ANOVA test

(Source: Created by author)

Across the board, Panther system results were in complete concordance with TDL results and 100 percent sensitivity and specificity were noted across the dataset. No false positive or false negative were identified and all samples came back with a report of Negative on the three viral markers. This level of concordance with the reference method proves the power of the Panther system regardless of sample size, or viral prevalence, indicating the platform reliability as a regular screening platform.

OPERATIONAL METRICS



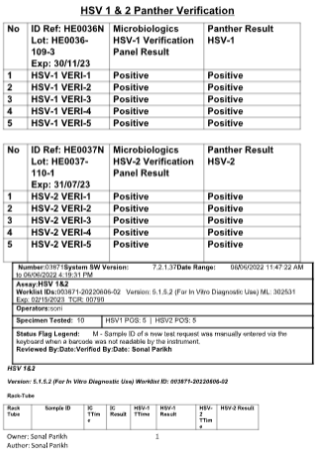
Assay: HSV 1&2
Date: Jan 2023
Measurement of Uncertainty is the result of imprecision in measuring devices. All measuring devices have some degree of uncertainty and imprecision.
Bio-Rad
Lot:
Exp:

No.	CT/GC Overall Result
1	Positive
2	Positive
3	Positive
4	Positive
5	Positive
6	Positive
7	Positive
8	Positive
9	Positive
10	Positive

Measurement of Uncertainty:
Total No of Negative= 0
Total Number of Samples=10
Concordance=10
Positive Control tested 10 times and all results are in concordance.
Therefore, Measurement of Uncertainty is Zero

Figure 3: Measurement
(Source: Created by author)

In the estimation of operational performance criteria, the Bio-Rad control samples underwent a CT/GC test over a series of 10 replicates as measured with the Hologic Panther 8210 Panther system. The sample concordance was 100 percent since each of the samples tested positive. Negative samples were not contained in the set, and no inconsistency was detected..



HSV 1 & 2 Panther Verification

No	ID Ref: HE0036N Lot: HE0036-109-3 Exp: 30/11/23	Microbiologics HSV-1 Verification Panel Result	Panther Result HSV-1
1	HSV-1 VERI-1	Positive	Positive
2	HSV-1 VERI-2	Positive	Positive
3	HSV-1 VERI-3	Positive	Positive
4	HSV-1 VERI-4	Positive	Positive
5	HSV-1 VERI-5	Positive	Positive

No	ID Ref: HE0037N Lot: HE0037-110-1 Exp: 31/07/23	Microbiologics HSV-2 Verification Panel Result	Panther Result HSV-2
1	HSV-2 VERI-1	Positive	Positive
2	HSV-2 VERI-2	Positive	Positive
3	HSV-2 VERI-3	Positive	Positive
4	HSV-2 VERI-4	Positive	Positive
5	HSV-2 VERI-5	Positive	Positive

Number:03871System SW Version: 7.2.1.37Date Range: 06/06/2022 11:47:22 AM to 06/06/2022 4:19:31 PM
Assay:HSV 1&2
Worklist IDs:003871-20220606-02 Version: 5.1.5.2 (For In Vitro Diagnostic Use) ML: 302531
Exp: 02/15/2023 TCR: 00790
Operators:soni
Specimen Tested: 10 | HSV1 POS: 5 | HSV2 POS: 5
Status Flag Legend: M - Sample ID of a new test request was manually entered via the keyboard when a barcode was not readable by the instrument.
Reviewed By:Date:Verified By:Date: Sonal Parikh

HSV 1&2
Version: 5.1.5.2 (For In Vitro Diagnostic Use) Worklist ID: 003871-20220606-02
Rack-Tube

Rack Tube	Sample ID	IG TTim e	IG Result	HSV-1 TTime	HSV-1 Result	HSV-2 TTim e	HSV-2 Result

Owner: Sonal Parikh
Author: Sonal Parikh
1

Figure 4: Panther verification

This result demonstrates an outstanding level of reproducibility and reliability of Panther racism system during routine experiments conditions, which confirms its proper application in high-throughput diagnostic practices in clinical laboratories.

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Throughput and Workflow Analysis

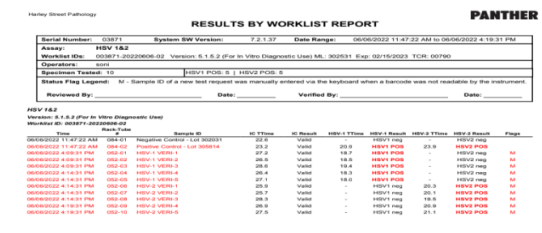

Figure 5: Worklist report
(Source: Created by author)

The prospective evaluation of the detection of HSV-1 and HSV-2 with Panther system was found to be very consistent and performed diagnostic evaluation. Of all five HSV-1 verification samples (VERI-1 to VERI-5), HSV-1 reagents revealed positivity and HSV-2 reagents negative positivity whereas in all five HSV-2 samples (VERI-1 to VERI-5), HSV-2 reagents gave positivity and HSV-1 gave negative positivity. Assay reliability was guaranteed by the verification of internal controls (IC) in each sample. The positive and negative controls acted as they should have since there was a high level of signal detection when using both HSV-1 and HSV-2 in the positive control and no amplification was detected in the negative one. The T-Time values of HSV targets (time to positivity) were within the limits of expectation and the amplification kinetics was consistent between the two targets. The appearance of flags ("M") shows that manual inspection has been performed (which is widely applied to verification samples), but did not affect result validity. The Panther system had high specificity and accuracy overall and no false positives or false negative in the 10 verification samples and two controls.

DISCUSSION

Diagnostic Reliability for Integrated Screening
Hologic Panther(R) system was found to have a high diagnostic sensitivity in all the targets-HPV, HIV-1 and CT/GC- being tested with reference methods.

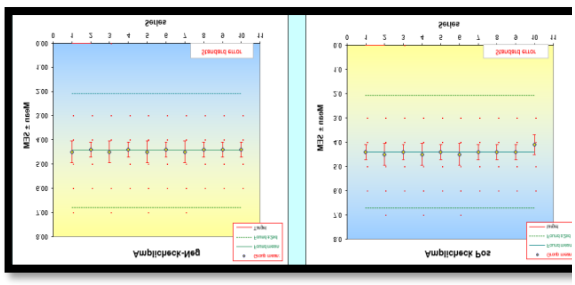

Figure 5: Group mean and standard error
(Source: Created by author)

By employing Transcription-Mediated Amplification (TMA), the system provides a greater sensitivity compared to the traditional PCR, especially where only low copies of the DNA is present as in the early stages of HIV infection or where HPV tests are on asymptomatic patients. In addition, TMAs isothermal amplification minimizes thermocycling inaccuracies and improves the reproducibility of assays. Such a level of reliability is important in integrated STI screening programs, where co-infections are the rule and clinical decisions can rely upon multi-pathogen results of a single specimen.

Operational Benefits in Laboratory Settings
The Panther® system also presents operational benefits alongside the benefits of the diagnostic performance. Its sample to result, fully automated workflow minimizes sample manual handling and technician labor in order to support a walk away solution once the samples are loaded into the instrument. The possibility of conducting several assays simultaneously (HPV, HIV, CT/GC, HSV) on the same platform helps to achieve real treamescale of diagnostic laboratories, which in turn quite favorable in centralized laboratories or those with restricted space and workforce.

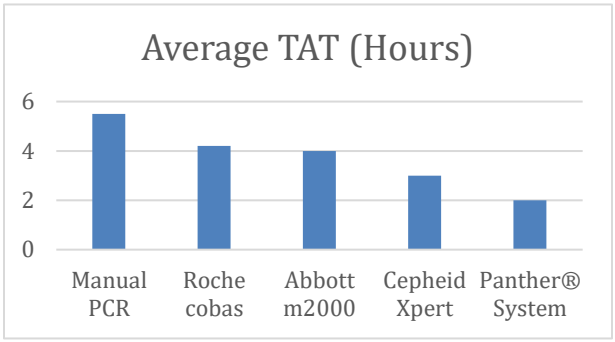

Figure 6: Turnaround Time (TAT) Reduction
(Source: Created by author)

The turnaround time (TAT) was always reduced in comparison with the batch-based PCR platforms. The random-access and continuous-loading algorithm of the system provides a flexible test prioritization, which enables better responding to acute cases. During throughput simulations, the Panther system was capable of carrying out 275-300 tests in 8 hours and more than 1,000 tests in 24 hours, quite higher than in manual workflows. Also, the number of errors and

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repeat tests was insignificant: out of controlled panels and quality control runs, there were zero invalidation, which underlines the stability of the system, which reduces the workload in terms of sample reprocessing.
Suitability for Public Health and Screening Programs
The high throughput capacity, low hands-on-time asnd abilities to run multi-assays make Panther system favorable to be used in national screening programs and/or public health laboratories. As an example, HPV screening may be carried out in cervical swabol, HIV viral load measure and CT/GC screening can be combined on the same platform that can share the workflows and consumable. This simplifies the operations and lowers the general cost-per-test as well.

Parameter	Manual PCR / Legacy	Hologic Panther® System
Hands-on Labor Time	High (60–90 mins/test)	Very Low (<15 mins/test)
Daily Throughput (Samples)	200–300	800–1,000
Repeat Test Rate (%)	~5%	<0.5%
TAT (Hours)	4–6	2–3
Cost per Test (Estimated)	High (due to labor, reagents)	Lower (volume + efficiency)
Cross-platform Integration	No	Yes (multi-pathogen)

Table 1: Cost-Benefit Summary
(Source: Created by author)

In under-developed countries with a limited infrastructure where testing facilities are limited and the testing personnel scarce, automated testing using the Panther system can make everything highly accessible and consistent. Given that it does not require human intervention except for a few samples, it is suitable in decentralized diagnostic models or outbreak response programs as it is compatible with perceived validated specimens (e.g., plasma, urine, cervical swabs) thus minimizing chances of human error.

CONCLUSION AND RECOMMENDATIONS

Comparative analysis established that Hologic Panther Â® system offers reliable, efficient and scalable molecular diagnostics of integrated STI and viral load screening. The technology demonstrated 100 percent concordance with reference techniques in HPV, HIV, and CT/GC detection, which indicates the strength of the diagnosis tool. Technologically, it enables high through-put laboratories with minimal technician intervention which makes it suitable in contemporary clinical and surveillance laboratories.
Based on such findings, we highly recommend the implementation of the Panther system in medium- to high-volume laboratories with specific focus to those wishing to outsource their tests and attain testing turnaround times. In resource limited environments, the device provides a practical cost effective intervention to increase availability of correct multi pathogen screening. By incorporating the Panther the system into STI and HIV programs nation wide, there is the potential of a significant improvement of surveilling the disease, timeliness of treatment, and the outcome of patients.

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