Using Quality Management Methods to Compare the Operational Characteristics of Mid-Volume CT/GC Molecular Lab Automation:

Siemens VERSANT® kPCR / Abbott m2000® / BD ProbeTec®

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Introduction

Molecular testing techniques are becoming more and more commonplace within the clinical diagnostics laboratory. This is due in part to the increasing availability of molecular lab automation that is both operationally practical and effective. As molecular testing continues to expand and grow, so too grows the complexity in making the "best" acquisition decisions as it pertains to integrating molecular technology into the clinical laboratory.

One such area where there is an abundance of molecular automation choices is Chlamydia and Gonorrhea (CT/GC) testing. Testing systems range from small bench-top, lower volume platforms that rely principally upon manual processes to large, highly automated, high throughput systems. For most hospital based, mid-volume laboratories, smaller systems with limited automation are simply too labor intensive to consider while the large, ultra high throughput systems don't provide a practical choice in terms of operating costs and space requirements. Mid-volume labs are generally looking for solutions that significantly automate the testing process, provide adequate turn-around times, consume minimal lab space, and are cost effective. This article examines three available solutions in the mid-volume molecular market.

Conducting this analysis for Siemens Healthcare Diagnostics was Nexus Global Solutions, Inc. (Nexus), an independent, third-party consulting firm that specializes in diagnostic product research as well as providing consulting services to both laboratory suppliers (diagnostic companies) and clinical end-users (laboratories).*

A study protocol, based upon Quality Management Methodology (i.e., Lean / Six Sigma), was utilized to objectively evaluate the operational characteristics of three mid-volume CT/GC molecular systems. The systems included the VERSANT® kPCR (kPCR) distributed by Siemens Healthcare Diagnostics; the Abbott m2000® (m2000), distributed by Abbott Laboratories; and the BD ProbeTec® (ProbeTec), distributed by Becton Dickinson Diagnostics. The performance of the automation under the study protocol should serve as a proxy for the overall operational effectiveness of the three molecular systems.

Study Methodology

To compare the strengths and weaknesses of each of the three systems, comparison data was collected through direct observations and targeted interviews at commercial laboratories throughout the U.S. Direct observations are essential because they ensure accurate and realistic data is captured. Site interviews make certain that no outliers are utilized in the data. After completing the studies and interviewing managers and medical technologists, the following operational attributes or metrics were developed for comparison purposes:

1. Workflow: Number and complexity of process steps required to obtain accurate test results
2. Cycle Time (C/T): Total time to include both manual and automation time
3. Workflow Breakdown: Workflow percentage details for automation, vigilant, and manual elements
4. Manual / Hands-on time: Direct operator involvement in sample prep, reagent prep, and system loading
5. Throughput: Total number of resulted tests over defined period of time
6. Space Requirements: Instrument(s) footprint, supplies and operator area required for testing

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Results

Metric #1: Workflow / Process Steps

Graph 1 summarizes the metrics from the Workflow/Process steps analysis.

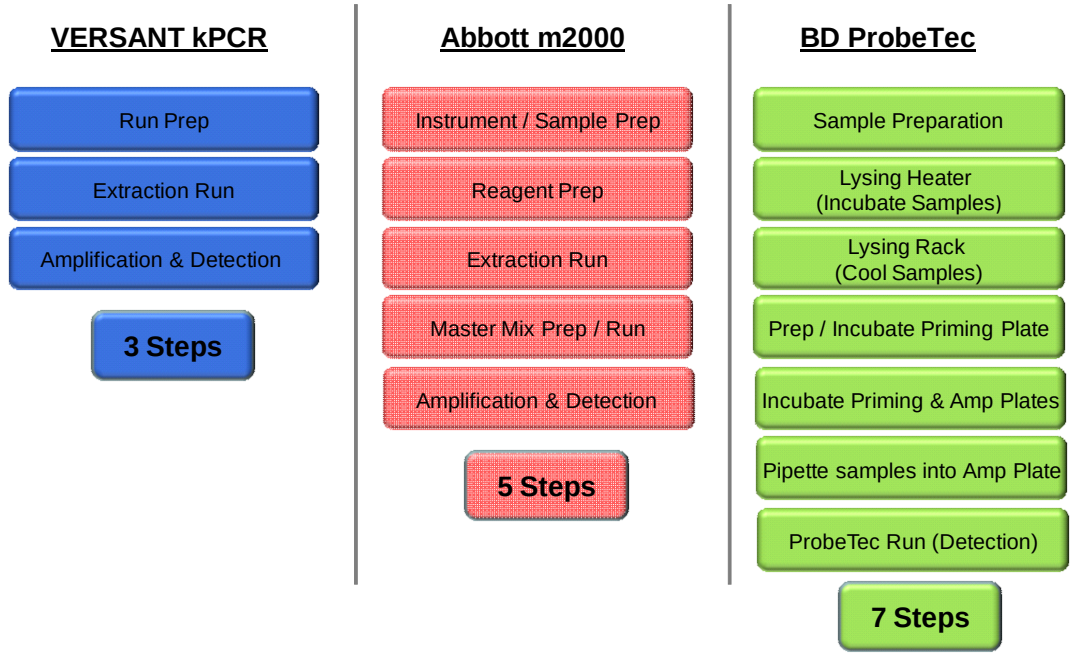
There are three specific workflow categories (series of process steps) involved in operating the kPCR. These include the initial run prep (reagent and sample preparation), the automated extraction run, and the automated amplification and detection run. Because the preparation of reagents and samples is essentially seamless, (no specific delay or manual "hand-off") it is consider one single workflow category.

The m2000 incorporates five separate workflow categories for CT/GC testing. These include instrument / sample preparation (loading of system components and sample preparation), manual reagent preparation, automated extraction run, master mix preparation (manual step) and automated run, and finally the automated amplification and detection run.

The ProbeTec has seven distinct process categories, much of which require on-going interaction and vigilance on the part of the operator. These include sample preparation (loading samples into racks /add diluent if required), heat / incubate samples and prepare priming plates, cool samples, pipette samples into priming plate and incubate at room temperature, heat priming and amplification plate, manually pipette samples into amplification plate, and finally the automated detection run.

The kPCR platform incorporates the fewest distinct process categories of the three systems. This is significant because fewer process categories results in a more user-friendly system that is simpler to operate and less prone to operator error.

Graph 1: Workflow



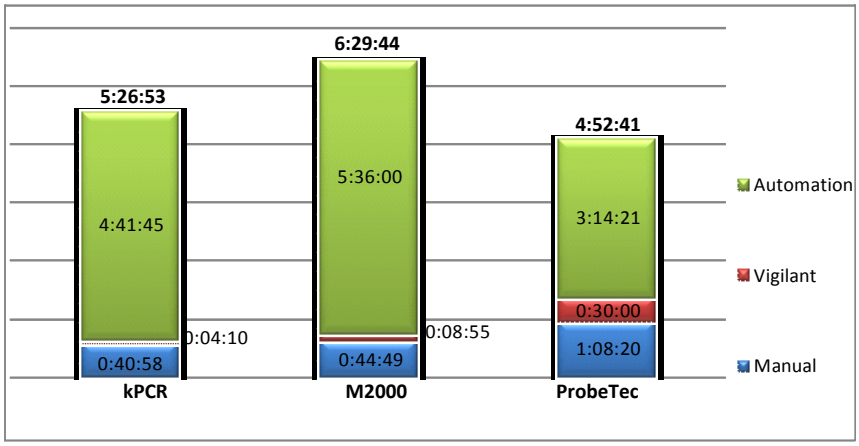
Metric #2: Cycle Time (96 Sample Run Size)

Graph 2 & 3 summarizes the metrics from the CT analysis for each system.

Cycle times for *wet swabs* ranged from a low of just under five (5) hours for the ProbeTec to a high of approximately 6.5 hours for the m2000. The kPCR cycle time was clocked at ~5.5 hours.

While the ProbeTec had the best over-all cycle time for a wet swab run of 96 samples, it is important to note that a significant percentage of the over-all run time is consumed by manual processes that require on-going vigilance by the operator. In addition, ProbeTec cycle times are highly dependent upon the skill of the operator due to the system's heavy reliance on human interaction throughout the testing process. By contrast, both the kPCR and m2000 platforms require significantly less (~40 to 50 minutes) "hands-on" time by the operator.

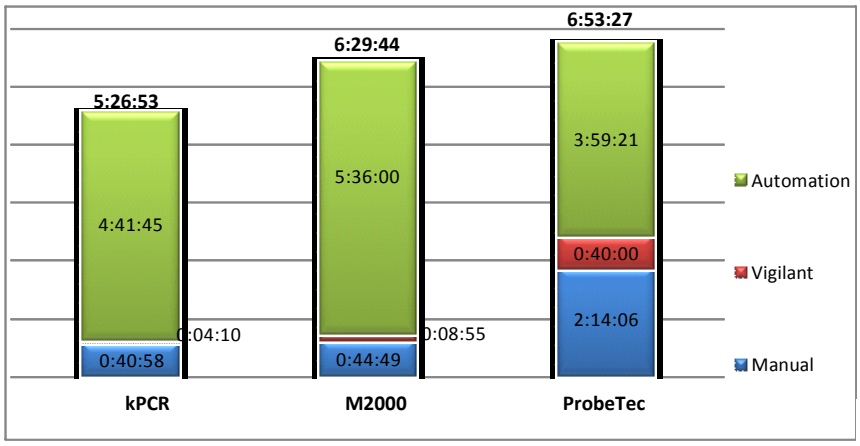
Graph 2: Cycle Time (*Wet Swab*)



Time Format (hh:mm:ss)

Cycle times for *urines* are identical to wet swabs for both the kPCR and m2000 platforms. However, ProbeTec cycle times increase to almost 7 hours for a run of 96 samples. This is due to the additional sample preparation steps that are required for ProbeTec urines. These steps include manual pipetting of urines into BD (ProbeTec) specific tubes, heating and cooling of samples, centrifugation of samples, and the addition of diluent into each sample tube. These additional process requirements add over two (2) hours of additional time.

Graph 3: Cycle Time (*Urines*)



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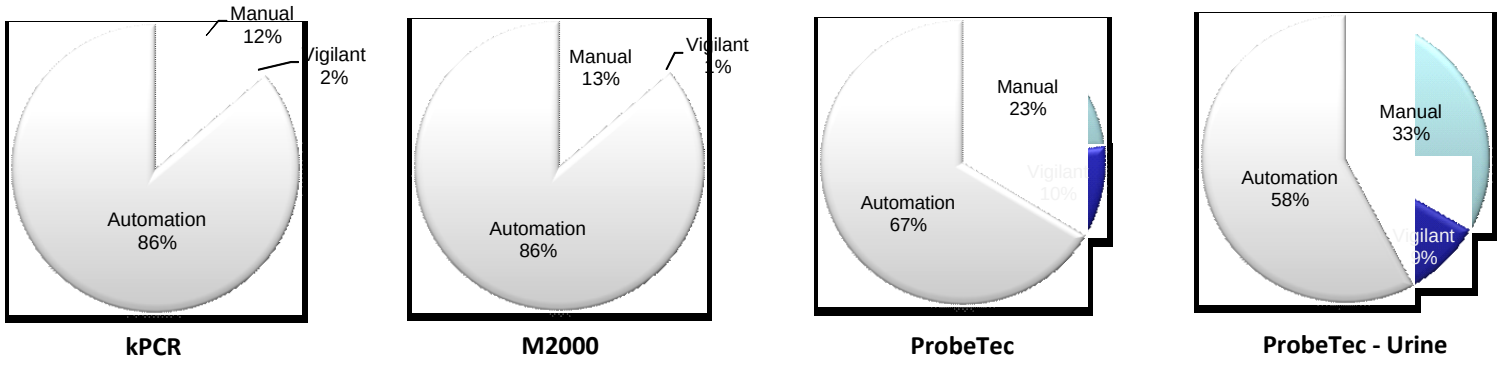
Metric #3: Workflow Breakdown

Workflow details (i.e., required process elements) for any analytical platform fall into three work or time categories. These include 1) Automation or instrument time that provides >10 minutes of "walk-away" time, 2) Manual or direct "hands-on" time by the operator, and 3) Vigilant time, defined as <10 minutes of automation / instrument time that does not afford the operator with adequate walk-away time to conduct other laboratory tasks.

Graph 4 summarizes the metrics from the Workflow Breakdown analysis. It is important to note that each chart illustrate the specific workflow breakdown for each platform as it relates to total cycle time (see Metric 2), which is unique for each instrument. As the graphs indicate, the kPCR and m2000 workflow breakdown is very similar as it relates to the percentage of time that falls into each time category. The ProbeTec workflow breakdown is considerably different with 33% of the over-all process elements falling into the manual and vigilant categories for wet swabs and 42% for urines.

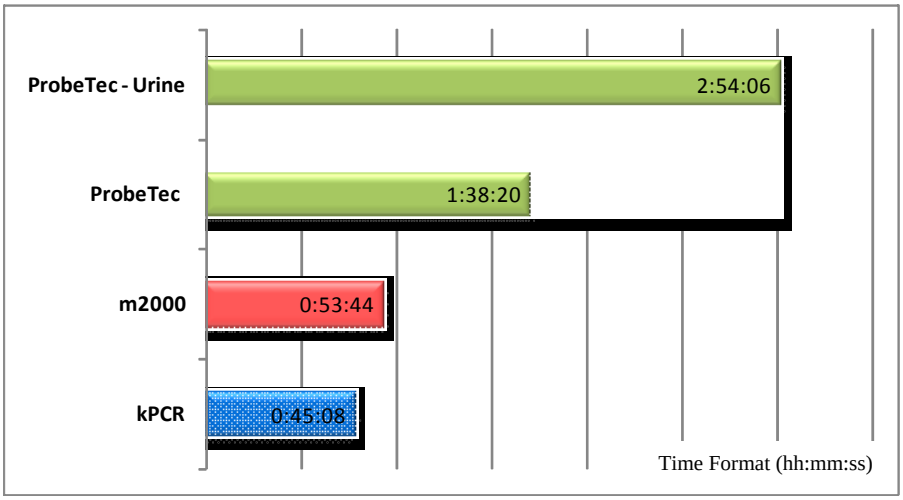
Graph 4: Workflow Breakdown



Metric #4: Manual / Hands-on time

The kPCR platform requires ~45 minutes of hands-on time (manual + vigilant) and the m2000 ~54 minutes. The ProbeTec needs more than 1.5 hours for wet swabs and almost three (3) hours for urines. Graph 5 summarizes the results for this metric.

Graph 5: Manual Time

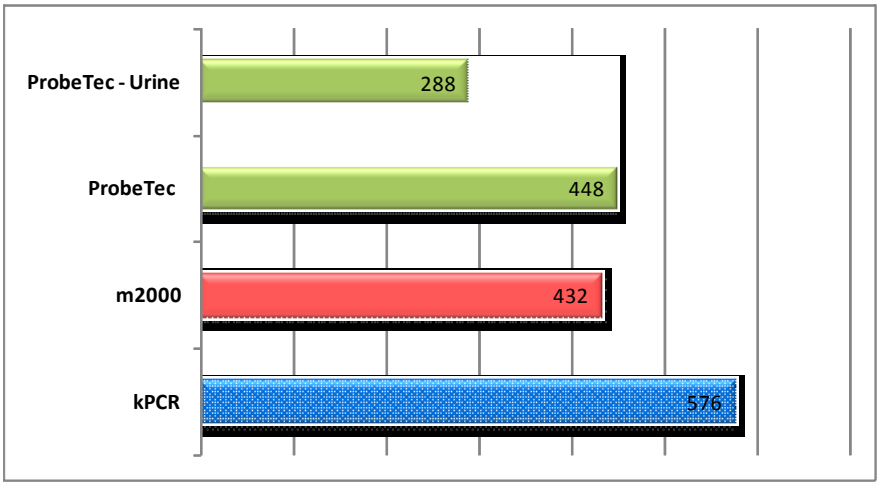


Metric #5: 24-hour Throughput

Graph 6 illustrates the potential 24-hour throughput associated with each system. The provided throughput data are theoretical and are based upon calculated values as none of the participating laboratory sites ran back-to-back runs over 24 hours. The throughput data is also predicated on a single automated system with all tests resulted with a single 24 hour period.

The kPCR platform has a calculated best in class throughput of 576 samples over 24 hours. This equates to six independent, 96 sample plate runs. The ProbeTec (wet swab) is calculated at 448 samples or 14 individual 32 specimen plate runs. The m2000 trails the ProbeTec only slightly with 432 samples, which equates to four (4) independent, 96 sample plate runs and one (1) run of 48 samples. Because of the additional sample preparation requirements for urine samples on the ProbeTec, throughput decreases to 288 samples or nine (9) independent runs.

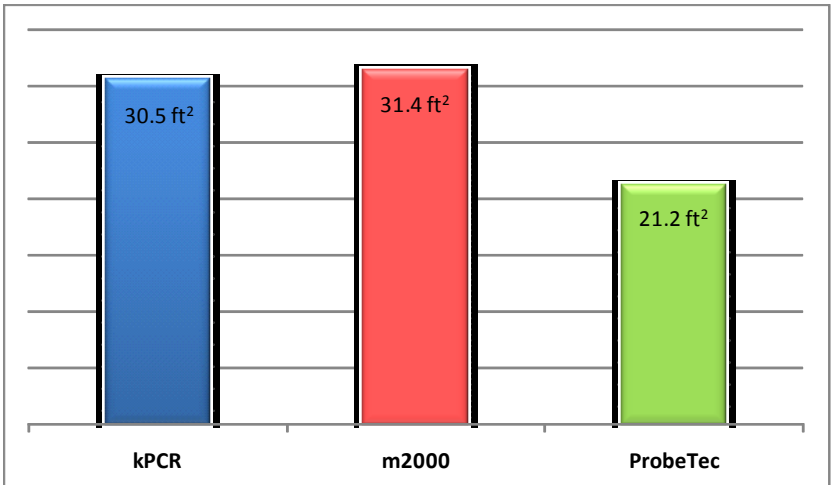
Graph 6: 24-hour Throughput (samples)



Metric #6: Space Requirements

Space requirements for the kPCR and m2000 are almost identical with the kPCR requiring approximately 30 ft^2 and the m2000 needing ~31.5 ft^2. These requirements take into account the actual footprint and clearance requirements for both of the system's sample preparation and amplification/detection platforms as well as any ancillary equipment and bench space requirements. The ProbeTec system requires ~21 ft^2, with bench space for manual preparation steps comprising 66% of the total requirements.

Graph 7: Footprint / Space Requirements



Summary

The Quality Management metrics used in this study provide an objective evaluation of the three systems from an operational perspective. While all of the molecular systems offer certain operational efficiencies, the VERSANT kPCR by Siemens Healthcare Diagnostics delivered best in class performance in four out of six operational categories. Table 1 provides a summary of the three platforms as they relate to the metrics detailed in this article.

Table 1: Operational Metrics Summary

Metric		kPCR	m2000	ProbeTec	ProbeTec - Urine
#1	Workflow / Process Steps	**3**	5	7	7
#2	Cycle Time	5:26:53	6:29:44	**4:52:41**	6:53:27
#3	Workflow Breakdown (Automation)	**86%**	**86%**	67%	58%
#4	Manual / Hands-on Time	**0:45:08**	0:53:44	1:38:20	2:32:04
#5	24-Hour Throughput (samples)	**576**	432	448	288
#6	Space Requirements (ft^2)	30.5	31.4	**21.2**	

Time Format (hh:mm:ss)

* Funding for this study was provided by Siemens Healthcare Diagnostics