Work Flow Efficiencies and Operator Advantages Determined for the BD™ Viper ER and the BD™ ProbeTec

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REVISED ABSTRACT

BACKGROUND: From 2005 to 2007 the PPMM facility at San Jose, California, experienced a significant increase in the number of Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (GC) tests performed after the adoption of the BD Viper™ System in 2004. Interestingly, although one staff member left our facility at the same time, it was evident that there was no loss of productivity or increased work-burden per remaining staff. In fact, the opposite occurred. A study was initiated to quantify the productivity improvements.

METHOD: A retrospective analysis was conducted of archived records for the years 2005, 2006 and 2007. Data extracted for each of the 3 years included the number of tests performed, productivity per FTE, turnaround time to report results, QC records, and a qualitative assessment of personnel operational preferences.

RESULTS: The findings showed a 26.7% increase in test volume from 2005 to 2007. The addition of the Viper System allowed the lab to maintain reduced staffing at 3.5 FTE. The productivity per FTE jumped 77% from 65,000 tests in 2005 to 115,388 tests per FTE in 2007. The Viper System enabled completion of 360 patient samples at least one hour earlier compared to the previous method. We gained 2.75 hr/ day that allowed re-assignment of technologists to other tasks. Despite the increased work volume contamination events remained infrequent. In 2007, 1040 environmental swipes were tested. An external facilities maintenance procedure was directly related to 8 positive results (0.76%).

CONCLUSION: Adoption of the automated Viper ER system has enhanced operational effectiveness at PPMM. Successfully, we have increased the number of patient CT/GC tests processed daily, reduced staffing, improved the time to results, and improved personnel satisfaction by the reduction of repetitive transfer steps.

INTRODUCTION

In January, 2006, our facility upgraded to a BD Viper ER molecular platform for Chlamydia trachomatis and Neisseria gonorrhoeae testing. The Viper ER is an automated instrument that requires minimal hands-on time for large volume testing facilities. Viper uses Strand Displacement Technology, a molecular methodology used to detect DNA in patient samples. Our Planned Parenthood laboratory processes over 750 patient samples per day consisting of a mixture of female endocervical swabs and urines. Our facility shares the BD Viper with another laboratory facility that runs their daily collected specimens during separate evening test-runs. Overall, there are close to 1,000 patient specimens tested for CT and GC on an average day. For this poster presentation, we analyzed the overall testing volume increase over the three year period 2005-2007, the “hands-on” time necessary for operator interaction, “turnaround time” to results, and integration of test schedules and the emergence of all issues that would interfere with routine workflow efficacies.

METHODS

The following metrics were analyzed, compiled, and described
Before the BD Viper (BBDV) and After the BD Viper (ABDV) was installed:

1. Test volumes for 2005-2007; test volume per FTE.
3. Staffing requirements.
4. Turn-around time to results.
5. Contamination events.
Test volumes for each of three years are shown in Figure 1.

Figure 1: Increased Test Volume by Year

- There was a 23% increase in overall testing performed during 2006 compared to 2005, and a 26% increase when overall testing performed during 2007 was compared to 2005.
- The increase in test volume for 2007 compared to 2006 was 2.4% but seemingly leveled off when compared to the dramatic increase in test volume between 2006 and 2005.
- The successful absorption of the 23% volume increase is attributed to the use of the “high-throughput” mode of the instrument during the day, which allows for minimal technologist interaction.

RESULTS

- “Walkaway” mode is occasionally utilized for last run of the evening with acceptance of results the following morning.
- On a per FTE basis, before the BD Viper was implemented we staffed our facility operation at 4 FTEs, and due to the installation of the Viper we were able to decrease staffing to 3.5 FTEs after the BD Viper was implemented. Correspondingly, test productivity per FTE increased as shown in the Figure 2 below.

Figure 2

<table>
<thead>
<tr>
<th>Year</th>
<th>Test Volume</th>
<th>FTE</th>
<th>Per FTE</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>227,500</td>
<td>4</td>
<td>56,875.0</td>
</tr>
<tr>
<td>2006</td>
<td>280,000</td>
<td>4</td>
<td>70,000.0</td>
</tr>
<tr>
<td>2007</td>
<td>288,470</td>
<td>3.5</td>
<td>82,420.0</td>
</tr>
</tbody>
</table>

- Although test volume increased by 23%, test productivity per FTE increased by 34.3% by the end of 2006. Similarly, between 2006 and 2007, there was only a 2.4% increase in specimen volume, but test productivity per FTE increased by 12%. These are realized labor gains that were never seen with the previously utilized system.
RESULTS (continued)

- It is important to note that the Viper ER in High Throughput Mode does the work of two ProbeTec instruments in testing 360 patient specimens achieving completion of the daily testing at least one hour earlier than with the ProbeTec instruments.

- Additionally, the Viper ER allows reassignment of a staff technologist for a total of 5 hr 30 min per shift compared to the requirements of the ProbeTec, which allowed only 4 hr 10 min. It should be noted that the Viper ER allows PPM greater flexibility in choosing the length of the break points in the protocol prior to resumption of the automated procedural steps (middle chart).

- PPM has utilized a maximum throughput scenario for testing with measured additional overall time-savings for complete daily testing of 2 hr15 min. When using high throughput mode in practice, communication and coordination between staff personnel is important.

- Staffing has remained steady at 3.5 FTE dedicated to testing since 2007. As a result, the approximate number of specimens capable of being tested has increased proportionately as evidenced in Figure 2.

- Turnaround time to results has remained consistent at 24 h. Physicians have direct on-line access to results through our password protected secured laboratory information system. Positive and Negative results are batch approved and released for review upon demand. Low positive results (2,000-10,000 MOTA) are confirmed the following day. Concordant results are released at that time point. Discordant results are repeated as required by the State of California.

- Daily environmental monitoring consists of performing four environmental wipe tests per day for the presence of any DNA contamination by CT or GC.

- This is a greater threshold than required by the manufacturer but is a preferential option we choose to perform.

- PPM is conservative in our reporting based upon our relationships to our providers and our patient clientele.

- A five day schedule of twenty different sampling sites within the testing laboratory has been identified. We have detected the presence of DNA in only 8 eight of 1,040 monitoring samples during 2007 (Figure 5).

- Two recoveries in June, 2007, were related (Figure 4). We are confident that our environmental intake system was compromised by heavy smoke and vapors related to roof-tarring repairs on two separate occasions (Figure 5).

- A thorough decontamination of the entire laboratory testing facility was performed.

- Continuous environmental monitoring is our choice and allows us a cautious and conservative approach to testing and reporting.

- Our environmental monitoring procedures, in conjunction with our expected daily positivity rate, allows us to recognize immediately the presence of extraneous environmental DNA.

- The manufacturer’s suggested surveillance schedule to check for contamination is well advised given the very low occurrence of contamination events, as results from our testing facility demonstrate.

DISCUSSION

Technologist satisfaction was increased by:

- Diminished number of repetitive motions associated with microwell preparation and the elimination of visual inspections to assure adequate filling for all well levels.

- Before the upgrade to the Viper, processed specimens were transferred to the microtitre test plate by use of a manual multi-channel pipettor requiring adept hand and agile wrist strengths.

- Additionally, transferring of sample from Priming microwells to the Amplification microwells was another similar isometric exercise.

- Although we experienced minimal complaints of physical fatigue from our personnel, we recognize that complaints due to repetitive motion activity is highly individualized.

- The upgrade to the Viper reduced the number of repetitive motions and decreased the overall time it took for transfer of specimen to the Priming or Amplification microwells. Prior to the Viper upgrade it would take approximately ten minutes to manually pipette from the sample rack to two Amplification microwell plates. Now it takes five minutes for the Viper to complete that step. BBDV this step took about four minutes per plate, depending on CLS experience with the procedure, and then the plate was sealed and transferred to the ProbeTec. The Viper now takes 10 minutes to pipette two plates, with a total of 11.5 minutes if you include the automated plate sealing function in the timing. The sealed Amplification microwell plate automatically moves it into the reader.

- Automated microwell plate sealing results in a more consistent placement of the sealer on the amplification microwell plate, it is less tedious and far more precise than the manual operation.

2. The total number of FTEs decreased to 3.5 from 4 without loss of productivity, as evidenced by an increase in total work load per FTE.

3. PPMM uses 2 Vipers in the daily testing regimen. The comparisons shown reflect a parity situation for one Viper vs. two ProbeTec instruments.

4. PPMM chooses to utilize the flexibility of the Vipers such that PPMM can structure its working day to the most proficient and productive manner. The natural break points in the testing protocol are utilized fully. Maximal through-put performance would increase the overall “Hands-Off” time to 5 hrs 40 min from current 4 hrs 50 minutes.

5. TAT remained consistent at 24 hours.

6. During 2007, there were 8 samples that reflected environmental contamination. We correlated the contamination events to external maintenance being performed on the building which interfered with the laborotories air handling system.

7. The episode was not further characterized and there have been no additional contamination events.