
Max Chernesky, PhD, with a Panther® System customer review by Robyn Thon MT(ASCP)

Max Chernesky

St. Joseph’s Healthcare/McMaster University, Hamilton, ON
Making an Informed Decision

- Space Requirements
- Equipment Cost
- Labor Cost
- Consumable Cost
- Cost per Test
- Hands on Time
- Return Visits
- Test Capacity
- Time to Result
- Maintenance
Making an Informed Decision
Workflow studies give quantifiable and objective metrics
## Automated and Semi Automated Instruments

<table>
<thead>
<tr>
<th>Batching</th>
<th>m2000</th>
<th>Abbott</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Viper XTR</td>
<td>Becton Dickinson</td>
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<tr>
<td></td>
<td>cobas 4800</td>
<td>Roche</td>
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<tr>
<td></td>
<td>Tigris</td>
<td>Hologic</td>
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<tr>
<td>Continuous</td>
<td>Panther</td>
<td>Hologic</td>
</tr>
<tr>
<td>Random Access</td>
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</tbody>
</table>
m2000 (Abbott)

- Batching
- Separate units for specimen extraction (m2000sp) and detection (m2000rt)
- 93 specimens per run with return visits
Viper XTR (BD)

- Batching
- Single unit for specimen extraction and detection
- Max 92 specimens processed per batch without a return visit
cobas 4800 (Roche)

- Batching
- Separate units for specimen extraction (x480) and detection (z480)
- 94 specimens per batch
Tigris (Hologic)

• Batching
• Single unit for specimen extraction and detection
• Max 176 (9 racks x 20) specimens processed per batch
• Non-batch random access
• Single unit for specimen extraction and detection
• Max 118 (8 racks x 15) specimens initially with continuous feed

Panther (Hologic)
Methods

- 2 investigators travelled to each testing site for a 96-test run
- Second visit timed 192 tests
- Both vaginal and urine samples were tested for *C. trachomatis*
Study Parameters (96 and 192 tests)

1. **Total Hands-on Time**
   Total time required for manual interaction including daily maintenance

2. **Return Visits**
   Number of times operator is required to return to the instrument

3. **Time to Result**
   Time from start-up to first and final result

4. **Maintenance**
   Cumulative hands-on time required for daily, weekly, and monthly maintenance based on 20 testing days
Hands-on Time

1. Pre-analytical Interactions
2. Reagent Preparation and Loading
3. Sample Preparation and Loading
4. In-Process Interactions (Return Visits)
5. Post-analytical Interactions
6. Daily Maintenance
Normalization

- Some instruments are designed to process more than 96 or 192 tests
- e.g. pre-analytical waste management in Tigris took 7 min 12 sec for every 1000 tests

**Normalized time for 96 tests**

\[ \text{normalized time for 96 tests} = \frac{7 \text{ min 12 sec} \times 96}{1000} = 41.5 \text{ sec} \]
Total Hands-on Time for 96 and 192 tests

- m2000: 2:09 (Δ71)
- Viper XTR: 2:17 (Δ37)
- cobas 4800: 1:38 (Δ58)
- Tigris: 0:34 (Δ6)
- Panther: 0:33 (Δ12)

Total Hands-on Time for 96 tests:
- m2000: 0:58
- Viper XTR: 1:41
- cobas 4800: 1:30
- Tigris: 0:28
- Panther: 0:21
Time to Results for 96 and 192 Tests

- **m2000**: 6:11
- **Viper XTR**: 3:31
- **cobas 4800**: 4:23
- **Tigris**: 4:55
- **Panther**: 5:27

The time to first results is marked in orange, and the results are represented in green.
Cumulative Hands-on Time for Maintenance Based on 96 Tests Per Day, 20 Days Per Month

- **Daily maintenance**
- **Weekly maintenance**
- **Monthly maintenance**
575 Women (SCVS)

FVU x4 assays

RealTime

Qx

cobas 4800

Aptima

* spiked with *C. trachomatis*
Objectives

• Determine the analytical sensitivity of each assay for detection of *C. trachomatis* in vaginal swab samples and urine

• Test each sample with a CT spike to detect inhibitors

• Calculate sensitivities and specificities based on a Patient Infected Status (PIS)
## Determination of Analytical Sensitivity

<table>
<thead>
<tr>
<th>Dilution of CT</th>
<th>AC2 CT/GC</th>
<th>CT/NG RT m2000</th>
<th>CT/GC ProbeTec Qx</th>
<th>cobas 4800 CT/NG</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SCVS</td>
<td>FVU</td>
<td>SCVS</td>
<td>FVU</td>
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<tr>
<td>10^-5</td>
<td>10/10</td>
<td>10/10</td>
<td>10/10</td>
<td>10/10</td>
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<tr>
<td>10^-6</td>
<td>10/10</td>
<td>10/10</td>
<td>4/10</td>
<td>6/10</td>
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<tr>
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<td>4/10</td>
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<td>0/10</td>
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<tr>
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<td>0/10</td>
<td>0/10</td>
<td>0/10</td>
</tr>
<tr>
<td>Probit LOD_{50}</td>
<td>-8.1</td>
<td>-7.9</td>
<td>-5.9</td>
<td>-6.1</td>
</tr>
<tr>
<td>% Inhibitors</td>
<td>0.3</td>
<td>0.5</td>
<td>0.0</td>
<td>0.0</td>
</tr>
</tbody>
</table>
575 patients $\rightarrow$ 54 PIS $+$ve 53 VS $+$
48 FVU $+$

Patient Infected Status (PIS) = positive in at least 2 assays
Comparison of Sensitivity and Specificity of SCVS for *C. trachomatis*
Sensitivity and Specificity for *C. trachomatis* FVU Excluding 4 Urine-Negative Women (%)
• AC2 on Panther or Tigris identified more Chlamydia infections than the other assays
• Vaginal swabs were superior to urine
• Panther and Tigris had substantially less hands-on time for 96 and 192 tests
• All platforms produced 192 test results in a normal workday except for m2000, which were generated into the next work shift
• Viper had the shortest time to results (96/192 tests), but highest daily maintenance
• The “non-batching” Panther allowed continuous access to reagents and samples with greater workflow efficiency
We did it:
One Laboratory’s Experience

Robyn Thon, M.S., M(ASCP)
Columbia St. Mary’s – Milwaukee Hospital Laboratory
Decision

- Can we implement molecular testing at Columbia St. Mary’s?
Key Issues

• Space?
• Who?
• What?
• How?
• Price/Savings?
• Training?
Space

- Did we have the facilities at our disposal to even consider molecular testing?
- In the past, the recommendation was to have two separate rooms or areas available for work flow and cleanliness.
- Did we have the space?
- With the Panther, there is no need for separate work areas.
Molecular Laboratory of the PAST!

Sample handling
DNA preparation

Laboratory
Mixing site

Thermocycler
Amplification

Detection
Documentation

Clean room
Stock solutions
Who?

- Who would be involved in doing the testing?
- Did they have the level of expertise necessary or could they learn?
- Where does this testing fit the best?
- Could it be done without adding FTE’s?
What?

- What testing did we want to perform?
- Were there any that were high volume?
- Were there multiple tests on the same platform?
- Did any cross disciplines?
Current GC/Chlam Diagnostic Tests:

- Non-amplified
- Hologic/Gen-Probe *Aptima* (TMA)
- Qiagen *Hybrid Capture 2*
- Roche Cobas 4800 (PCR)
- B-D *ProbeTec Qx* (SDA)
- Culture
- Antigen Detection Tests: EIA, DFA
How (cont.)

- We determined it would be best to invite three vendors in for presentations.
  - quality (sensitivity/specificity)
  - functional ease
  - collection devices
Each of the three vendors presented an equally good product
- So we had to determine, which one we liked best.
- We involved the techs in the selection process.
- We went on site visits.
Price?

- We worked with each of the vendors to get their lowest price.
- Performing in house vs. send out testing
  - Approx cost $20/test in house vs. $40/test to send out.
  - Based on volume this would approximate a $80,000/year savings.
We chose the Panther
Training?

- We determined that we would train all staff.
  - Both first and second shift
  - Proficiency/Competency
  - Scheduling
Success?

- Test volume has increased generating greater savings.
- We have continued to bring in more testing.
- With our success, we felt comfortable bringing in additional platforms.
- Staff satisfaction with more testing knowledge.
Questions/Comments?

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