Implementation and Cost Benefit Analysis of the fully automated Idylla system in a large laboratory setting

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Geisinger
Disclaimers

Speaker:
Biocartis
Cepheid
The Cost Effective Laboratory: Right-sizing Your Instrumentation and Test Menus

A cost/benefit analysis of:

- Comparison of in-house testing with reference laboratory charges and turn-around-time
- Cost: Instrument, reagent, storage requirement, QC, PT, facility, calibration and maintenance
- Instrument capacity and present or proposed test menu
- Tests run singularly or in batch mode
- Staffing requirements: number, training, qualifications
New Test Request Process

1. First Question

<table>
<thead>
<tr>
<th>Is this request for:</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Technology</td>
</tr>
<tr>
<td>New Test</td>
</tr>
<tr>
<td>New Point of Care Testing</td>
</tr>
<tr>
<td>New Service</td>
</tr>
</tbody>
</table>

2. Requestor Information
3. Tech Assessment Questions
4. Costing Sheet
5. Evaluation
How to decide which tests to perform in-house?
How to decide which tests to perform in-house?

<table>
<thead>
<tr>
<th>Impact</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Home run</td>
<td>Oak trees</td>
</tr>
<tr>
<td>Easy win</td>
<td>Non-starter</td>
</tr>
</tbody>
</table>
How to decide which tests to perform in-house?

Impact

Cost

Idylla based oncology tests

Viral load

NGS-based tests

Esoteric tests
But it took us a long way to get here……

[Graph showing the transition from single gene mutation testing to NGS-based panel testing over the years]
Molecular Testing Workflow Analysis for CRC

Sample sent to pathology

1 day

Specimen FFPE.
Slides prepared in-house

1-4 days

Pathology Diagnosis (AP)

2-7 days (mean 4.6 days)

In house single gene molecular testing

Samples sent to reference lab for Single gene* or NGS based panel testing

Results sent to/received by pathology

5-21 days

Results signed out by Molecular pathologists

same day

Results entered into EMR/LIMS

same day

* Extended RAS panel for CRC

Geisinger
New Molecular Testing Workflow Analysis for CRC

Sample sent to pathology → 1 day

Specimen FFPE. Slides prepared in-house → 1-4 days

Pathology Diagnosis (AP) → In house single gene molecular testing (Idylla platform) → 1 day

NGS based panel testing → Results sent to/received by pathology → 10-21 days

Results signed out by Molecular pathologists → same day

Results entered into EMR/LIMS → same day
Informatic Solution for MolDx Quality Management

Real-time pending test data
Informatic Solution for MolDx Quality Management

Molecular Testing

KRASMU

Month August 2019 Year 2019

Avg TAT: 1 Days
Non Compliant Results

<table>
<thead>
<tr>
<th>Accession Number</th>
<th>Results</th>
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<tbody>
<tr>
<td>% Day 1</td>
<td>93.4%</td>
</tr>
<tr>
<td>% Day 2</td>
<td>100%</td>
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</table>

<table>
<thead>
<tr>
<th>Month</th>
<th># All KRASMU</th>
<th># N</th>
<th># POS</th>
<th># INDET</th>
<th># INS</th>
<th># CR</th>
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</thead>
<tbody>
<tr>
<td>38 August</td>
<td>43.00</td>
<td>24.00</td>
<td>19.00</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>43.00</td>
<td>24.00</td>
<td>19.00</td>
<td></td>
<td></td>
<td></td>
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</table>
# The Idylla solution

<table>
<thead>
<tr>
<th>Features</th>
<th>Impact to Geisinger Laboratory Medicine</th>
</tr>
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<tbody>
<tr>
<td>Fully automated walk-away system</td>
<td>• ~ 2 mins hands-on time</td>
</tr>
<tr>
<td></td>
<td>• 1.0 FTE reduction</td>
</tr>
<tr>
<td>Fast assay Turn-around-time (TAT)</td>
<td>TAT decreases from 4-7 days to 1-2 days</td>
</tr>
<tr>
<td>Assay menu</td>
<td>• Expand our test menu</td>
</tr>
<tr>
<td></td>
<td>• Excellent bridge to NGS based panel testing</td>
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