Evaluation of a Microfluidic System for Performance of Fully Automated Companion Diagnostics for Personalized Medicine


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Rheonix has created a powerful microfluidic platform for the evolving molecular diagnostics industry. This system incorporates low cost disposable Rheonix CARD® technology to analyze single or multiple clinical raw samples. The Rheonix CARD® system provides multiplexed endpoint analysis and can be rapidly customized for a wide breadth of diagnostic applications.
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Creation of Microfluidic Networks

4 Diaphragms form 3 Bidirectional Pumps

Multiple diaphragm configurations can be customized to create simple or complex fluidic web networks.
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Sample Types/Volumes

• Sample Types
  – Whole Blood
  – Serum
  – Plasma
  – Saliva
  – Buccal Swabs
  – Vaginal Swab
  – Whole Tissue - Fresh & FFPE

• Volumes
  – 5 µl - 5 ml
Personalized Medicine Applications

Not 510(k) cleared for *in vitro* diagnostics (yet!!)

- **Warfarin sensitivity**
  - Cyp2C9*2, Cyp2C9*3, VKORC1
  - Whole blood or buccal swabs
- **Plavix sensitivity**
  - Cyp2C19*2, Cyp2C19*3
  - Whole blood or buccal swabs
- **EGFR inhibitors (Erbitux/Vectibix)**
  - Single nucleotide changes within Exon 2 at positions 34, 35, 37, 38 (G>A>C>T) - codons 12 and 13.
  - FFPE Tissue block

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Automated CARD Processes

- Introduce “raw” sample.
- Automatically process (“sample-to-results”)

Untreated “raw” Sample

- Lyse cells
- Extract/purify DNA
- Multiplex PCR with biotinylated primers
- Denature amplicons
- Detect amplicons on DNA Array using RDB

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Rheonix Warfarin PGx Assay

- Raw sample is 5 µl whole blood
- 3 SNPs evaluated
  - CYP2C9*2
  - CYP2C9*3
  - VKOR1
  - 3 possible genotypes at each loci
    - WT/WT
    - WT/Mut
    - Mut/Mut
- Genomic “calls” made by software
- Results have been confirmed against bi-directional sequencing.
- Will enter US clinical studies soon.
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Upcoming Clinical Studies

- Four clinical study sites
  - Mayo Clinic (Rochester, MN)
  - Strong Memorial Hospital (Rochester, NY)
  - Catholic Hospital System (Buffalo, NY)
  - Rheonix, Inc. (Ithaca, NY)
- Bi-directional DNA Sequencing lab
  - Center of Excellence (Buffalo, NY)
- Intend to submit clinical data in a 510(k) application to support claims for Rheonix Warfarin PGx Assay and EncompassMDX™ instrument.
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**FFPE/KRAS Detection**

<table>
<thead>
<tr>
<th>KRAS Filter Key</th>
<th>Raw Sample</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spotting Control</td>
<td><img src="image1.png" alt="Sample Image" /></td>
<td><img src="image2.png" alt="Results Image" /></td>
</tr>
<tr>
<td>34 WT</td>
<td>34 G&gt;A</td>
<td>34 G&gt;A</td>
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<tr>
<td>35 G&gt;A</td>
<td>35 G&gt;C</td>
<td>35 G&gt;C</td>
</tr>
<tr>
<td>35 G&gt;A</td>
<td>BRAFMUT1</td>
<td>BRAF WT</td>
</tr>
<tr>
<td>38 G&gt;A</td>
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#### Raw Sample Results

- **35 G>A**

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Rheonix CONFERENCE

Tomorrow’s Technology Today
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**Technical/Financial Benefits**

- **Rheonix CARD® Technology is fully automated**
  - Reduces training requirements and costs

- **Inexpensive Capital Equipment and Disposable costs**
  - No need for additional equipment
  - CARDs are produced by injection molding

- **Overall - technology will dramatically lower the cost per reportable result**
Thank you

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