



**FOR IMMEDIATE RELEASE**

## **Rheonix CARD™ Technology Demonstrates Utility in Multiple Molecular Diagnostic Applications at AACC Annual Meeting**

-- Fully Automated Analytic Platform Demonstrates Accuracy and Versatility in Viral Detection, Pathogen Identification and SNP Analysis --

**Ithaca, NY — July 27, 2010 —** [Rheonix, Inc.](#) today announced positive results from three separate studies of the [Rheonix CARD™ \(Chemistry And Reagent Device\) system](#) presented in poster sessions at the American Association for Clinical Chemistry (AACC) Annual Meeting held in Anaheim, CA, July 25-29, 2010. The data presented demonstrate the utility of the Rheonix CARD™ system as a powerful, analytic platform for the life science industry. In studies conducted by the Company, fully automated custom Rheonix CARD systems were successfully designed for three molecular diagnostic applications. In each case, the Rheonix CARD system's capacity to achieve highly reliable results was validated using comparator tests, control samples and/or DNA sequencing.

“The rapid advancement of the molecular diagnostics industry is driving the need for new, cost-efficient platforms that can be rapidly customized to perform single or multiplex diagnostic assays across a broad range of applications with minimal operator intervention,” said Tony Eisenhut, President of Rheonix. “Rheonix has built a platform that not only meets this need but, as demonstrated at AACC, can achieve industry gold standard accuracy in important clinical applications. Based on the success of pilot Rheonix CARD system programs, we are planning a 510(k) submission to the US FDA for our Warfarin sensitivity test by the end of 2010 and will seek to leverage partnerships to explore further development pathways.”

The Rheonix CARD system is a powerful microfluidic platform that miniaturizes and fully automates all the functions of a molecular biology lab on a small disposable chip. For each of the prototype tests presented, the only operator step required is the introduction of the sample onto the chip. Subsequent steps are customized based on the design of the assay and automated using Rheonix's advanced microfluidic design technology.

## **Study Results Presented at AACC:**

In the poster presentation entitled “Fully Integrated, Automatic, and Rapid Molecular Detection and Identification of 20 Clinically Relevant HPV types using the CARD™ Platform,” Rheonix reported successful results for the rapid and reliable detection of HPV using the Rheonix HPV CARD system. The study analyzed 69 clinical specimens for the presence of 20 clinically relevant HPV types. After the operator introduces a swab sample, the remaining operations, including all steps on multiplex PCR, DNA microarray and image analysis were performed on the fully automated Rheonix CARD system. Of the specimens analyzed, 48 were found to be HPV negative by both the Rheonix test and an FDA-approved comparison product. Fourteen were determined to be HPV positive by both tests, and six specimens, while negative on the comparison test, were positive on the Rheonix test. The presence of HPV in the discordant samples was confirmed by amplicon sequencing, confirming accuracy of the Rheonix technology.

In the poster presentation entitled “CARD™ Technology for Rapid and Automatic Determination of SNP Profile for Pharmacogenomics,” Rheonix presented results representing the successful genotyping of 21 individuals with previously unknown genotypes using the Rheonix Warfarin Genotyping CARD Assay. A buccal swab provided by an operator was applied to the assay, followed by fully automated multiplex PCR, biotinylated primer extension and image analysis to detect three SNPs associated with warfarin dosing sensitivity (VKOR1, CYP2C9\*2 and CYP2C9\*3). The assay achieved correct genotype results for all tested samples, as confirmed using bi-directional DNA sequencing.

In the poster presentation entitled “Rapid Molecular Detection of Sexually Transmitted Infections using a fully automated, microfluidic CARD™,” Rheonix demonstrated the capability of the Rheonix STI Card system to identify the presence of four STIs in a multiplex assay. 5 million C33A cells/ml were spiked with 10,000 copies/ml of genomic DNA from *N. gonorrhoeae*, *C. trachomatis*, *T. pallidum*, and *T. vaginalis* either singly or in combination. For each sample 1 µL (i.e., 10 copies) was applied to the assay chip by an operator followed by fully automated analysis using multiplex PCR and DNA reverse dot blot imaging. The Rheonix CARD system positively and correctly identified the STI genomic DNA present in each tested sample.

## **About the Rheonix CARD™ System**

The Rheonix CARD™ (Chemistry And Reagent Device) system allows sophisticated molecular and/or immunologic assays to be integrated into a simple, modular platform with unprecedented raw sample preparation capabilities and broad, multiplex analysis applications. This technology is extremely versatile and outperforms its labor-intensive

"bench-top" counterparts. Disposable Rheonix CARD technology can be customized for immunoassay, pathogen identification, gene sequence detection, cell based assays and other molecular diagnostic applications. Rheonix CARD system advantages include:

- Virtually no hands-on effort, resulting in significantly reduced labor costs
- Reduced sample volumes and reagent volumes, saving time and money
- Performance of sophisticated assays through a series of programmable, automatic steps
- Integrated biosensors, which enable a highly-sensitive assay with digital readout of results on the completely disposable microfluidic Rheonix CARD technology
- Low-cost, scalable, and reproducible manufacturing capabilities

To learn more about the Rheonix CARD system and its applications, please visit [www.rheonix.com](http://www.rheonix.com).

### **About Rheonix, Inc.**

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. [www.rheonix.com](http://www.rheonix.com)

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