Poster 9

Abstract Submission

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Title: Automated flow cytometry for medical diagnostics

Presenter Name, Organization, and Contact Info:
Sharon Keren, Biomedical Engineer, LeukoDx Ltd.
3 Hamarpe St., Jerusalem, Israel
Cell: +972 (0)504 293 696 , Tel: +972 2 674 4422

Email: skeren@leukodx.com

Short Description:

Medical diagnostic flow cytometry is currently limited to high complexity laboratory settings because pre-analytical steps are time consuming, exacting and require highly trained and capable technologists to minimize variability. Individual instrument, and instrument-to-instrument variability limit broad acceptance of in-vitro diagnostic flow cytometry testing by users and regulatory bodies. Finally, interpretation of flow cytometry results requires highly trained flow cytometrists who are typically available only during normal work hours on weekdays.

The Accellix cartridge-based platform resolves each of these issues to provide 24/7 availability in a moderate complexity, & ultimately could be implemented in a CLIA waived setting. Once a sample is introduced into the closed Accellix cartridge all pre-analytical & analytical processing is performed in the cartridge without further user intervention. This has been enabled by the development of a unique one time use cartridge which includes onboard reagents and control material as well as an integrated flow cell. The compact Accellix Reader actuates the cartridge to perform automated sample preparation, aligns and focuses on the flow cell channel and flows the sample through the reading zone. It then performs post analytical processing of the flow cytometric data collected to produce the final medical diagnostic report.

The innovation inherent in the LeukoDx platform centers on:

- 15 minute target turnaround time for test results
  - Makes diagnosis and treatment possible during the doctors' checkup
  - Creates the option for real-time monitoring to track the effectiveness of treatment and enables adjustments
- The device is designed to minimize human involvement
  - Providing a disposable cartridge which will contain the blood, all the reagents and perform the biochemical reactions
  - Designed so that the person operating the test will not need any special training
- The cartridge can be designed to test many health issues
  - This includes the possibility of conducting multiple tests on one cartridge – a growing trend in point of care diagnostics

- The wide range of potential applications means there is an opportunity to capture a number of segments.

Unmet Need and Potential Impact:

Flow cytometry allows a quantitative look at blood and other cell populations, necessary for sophisticated diagnostic testing of all blood-related health issues. And yet, there is no cost effective, truly automated point of care flow cytometer on the market today.

The LeukoDx's compact platform will enable a shift of flow cytometry testing from complex and expensive laboratory equipment to affordable, easy to use (moderate, and later CLIA waived) compact table-top or portable equipment with disposable diagnostics cartridges. The smaller and less expensive LeukoDx flow cytometry equipment may be used in the central lab to free time of highly qualified lab technologists and offer 24/7 availability, and at the point of care in the hospital, in the clinics, and in the doctor's office.

For medium to high throughput settings, lab based testing can be cost effective. But, transport of whole blood samples is required; and return of results is typically slow and patients may be lost to follow up, with patients required to make multiple visits to health facilities to obtain a single test result. This results in travel time, travel costs and lost man hours. In addition, limited capacity and technologist shortage at central labs often leads to long patient backlogs and waiting periods between tests.

The expanded affordability and capability will provide faster and more accurate diagnostic and treatment decision making, as well as more cost effective use of flow cytometry diagnostics. Evolution to point of care use will dramatically expand the use of flow cytometry tools in the diagnostics field.

Innovation:

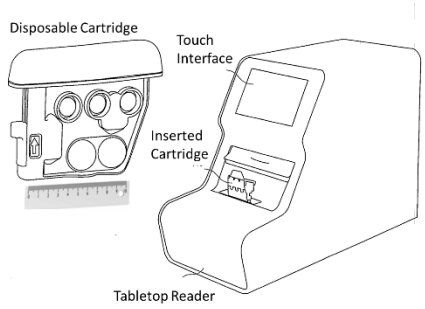
A critical part of what makes LeukoDx unique is its novel technology. Compared to conventional flow cytometer analysis, the cartridge based approach has the following innovative characteristics:

1. Single use microfluidic cartridges provide all pre-analytical & analytical functions, thereby simplifying instrument use to the point that it will be able to be CLIA waived.
2. The combination of biochemical reagents and microfluidic structures to promote rapid antibody conjugation in a homogenous assay.
3. Reagents contain a known concentration of fluorophore control such as standardized beads to provide self-calibrating volume measurement for each assay run in order to determine concentration results.
4. Multiple wavelength emission detection (up to 8 or more) allows a "cocktail assay" so that multiple markers can be evaluated in a single cartridge.

The innovative elements described above enable an instrument that provides actionable information in a near patient environment within 10 minutes from the start of the test using a single drop of whole blood.

Details of the novel microfluidic-based cartridge and its automatic operation controlled by the companion reader are presented. Results comparing the analytical performance of a CD64 assay using this instrument to that of conventional flow cytometry are presented showing an R2

exceeding 0.95. Also shown is the typical minimal user interaction required to run the instrument and obtain results. Thus, key moderate complexity requirements are demonstrated.



Development Stage:

We have finalized the platform validation phase and have started the clinical validation of the two initial applications – Sepsis and HIV monitoring. In parallel, the Company is developing of a dedicated solution for the monitoring of Minimal Residual Disease (MRD) for Leukemia & Lymphoma patients, focusing initially on Chronic Lymphocytic Leukemia (CLL).