

Certificate of exclusivity

The SiMoA SR-X Digital Benchtop Analyzer is a next generation disruptive technology that is differentiated in many ways:

- The SiMoA system has the ability to measure biomarkers (proteins/cytokines/metabolites) in biological samples at concentrations that are a 1000 fold (femtogram/ml) improvement over current methods (Meso Scale Discovery and Luminex).
- Capable of analyzing biological samples using single-molecule digital ELISA array technology.
- Utilizing magnetic beads to form immunocomplex's. This allows the enzyme bound to the capture antibody to produce sufficient fluorescence in each well to be detectable, even when just a single molecule is present.
- Discs with twenty four channels are used to load, seal, and image the proteins of interest. Each array contains approximately 239,000 wells for maximum sensitivity.
- The increase in sensitivity will allow for less sample to be used for sample processing. Sample volumes as low as 1ul.
- The SR-X system is semi-automated that requires only 1h30 to 2 hours hands-on work on the bench compared to 4 hours for others platforms.
- The SiMoA system has the capability of running Multiplex panels with up to 6 markers.
- Ability to measure DNA and miRNA in semi-automated fashion with little purification and no amplification.
- Digital signal which allows for greater sensitivity and reproducibility.
- Analytical reagents must include the use of paramagnetic beads of 2.7 microns in diameter to allow for high beadto sample molecule ratio (~10:1). Paramagnetic bead size must not exceed an average of 2.7 microns.
- The SiMoA system is an open platform (Homebrew Kit) which will allow for the adoption and development of markers that might be of commercial interest and not currently available.
- System must have open platform assay kits that allow end users to modify and develop and adapt unique, labspecific biomarkers, like the "homebrew" from Quanterix. Open assay kits must be available for purchase and mustcontain paramagnetic beads and buffers required for conjugation.
- System must be able to detect biomarkers, proteins and DNA in urine, blood, plasma, serum, stool, cell lysates,tissue homogenates, CSF and environmental water.
- System must not utilize glass slides, glass coverslips or lasers.

- Reaction volumes must be very small, equaling 50x10⁻¹⁵ L and must number equal to or greater than 5 million per testing array.
- Throughput must equal at least 68 tests per hour with results between 30 and 60 mins, run in batches or individually.
- Analytical precision must have a CV of less than 10% and a dynamic range of 4 to 5 logs.

The Simoa HD-1 Analyzer is covered by the following patents:

- Four issued US patents on core Simoa assay technology, 8222047, 8236574, 8415171, 8846415
- Four issued or allowed patents on core Simoa technology in Japan, EU, Canada and China, JP 5363663, CA 2791655, CA 2791654, JP 5551798
- Three divisional and continuation applications pending on core technology
- Nine other cases pending US and Worldwide

The Simoa HD-1 analyzer allows researchers to analyze proteins at levels never seen before to dramatically increase the speed of research that will lead to new discoveries. Some of the advantages are dramatic increases in sensitivity (up to 3000x), greatly reduced sample size, the ability to detect DNA, full automation, single molecule detection and a dynamic range up to five logs.

Quanterix was recently named (Feb. 2015) as a 2015 award finalist by the internationally renowned Edison Awards™, alongside past diagnostic winners, such as Thermo Scientific and GE Healthcare. The distinguished awards, inspired by Thomas Edison's persistence and inventiveness, recognize innovation, creativity and ingenuity in the global economy.

Sincerely yours,

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