

Simoa HD-1 Analyzer ™

The Simoa HD-1 Analyzer™ is a fully automated instrument for running immunoassays using Quanterix' proprietary single molecule array, or Simoa, platform. Simoa is a digital form of ELISA, trapping and

sealing individual immunocomplexes on paramagnetic beads in thousands of femtoliter sized wells in arrays found on the Simoa Discs.

This isolation of each beadimmunocomplex 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.

As a result, the analyzer produces a map of the array - each of which contains more than 200,000 wells - where each well can be digitally analyzed as either "on" (containing a target molecule) or "off". The proprietary Simoa algorithm converts then the measurement into a concentration which reaches femtomolar levels for most analytes. This revolutionary approach to digitalizing ELISA offers on average a 1000-fold improvement in sensitivity over current immunoassay techniques. In fact, Simoa has demonstrated sensitivity equivalent to PCR at a fraction of the cost and greater ease of use.



Sensitivity Means Knowing

What will you do with a 1000-fold improvement?

At the end of the day researchers and clinicians just want to know more. With Simoa's remarkable sensitivity comes the ability to see things more clearly than ever before. This advanced level of clarity puts answers in plain sight. It lets you count molecules. It tells you yes or no. It gives you the information and the confidence you need to make smart decisions. With Simoa, sensitivity means knowing.

Instrument Features and Benefits

• Sensitivity:

With an average of 1000x greater sensitivity than current immunoassays, analyte concentrations can be measured where they previously were not possible. Such a dramatic improvement in sensitivity opens new avenues of research and allows measurements of previously undetectable markers. Users with very low sample volumes can also pre-dilute samples to preserve samples and reduce matrix effects and still achieve greater sensitivity than ever before.

• Automation: Running immunoassays is a time consuming, largely manual technique. Users must either dedicate significant time to running assays or make use of expensive auxiliary automation systems. The Simoa HD-1 Analyzer performs all the steps of the assay, which both drives efficiencies but also provides more consistent, precise results by minimizing the variability of results common in manual approaches.

• Multiplexing:

The Simoa HD-1 Analyzer is capable of running up to 4-plex assays; providing the cost and sample preservation benefits researchers need without sacrificing sensitivity or precision.

• Walue:

The Simoa HD-1 Analyzer is remarkably affordable and is available to researchers on nearly any budget. Assays are also surprisingly cost-effective, especially given the savings obtained through automation and ability to use smaller sample volumes.

• Precision:

Thanks to the digital nature of Simoa and the consistency obtained through automation, CV's are below 10%.

• •Dynamic Range: The proprietary Simoa algorithm uses both digital measurements at low concentrations and analog measurements at higher concentrations, allowing a remarkable dynamic range of >4 logs.

• **Homebrew:** The Simoa HD-1 Analyzer helps users develop and optimize their own assays, leveraging all the benefits of Simoa on markers for which pre-packaged assay kits do not exist.



Simoa ™ Discs One Disc, Millions of Measurements

The Simoa Discs, manufacturedby Sony DADC, areat the heart of the operation of the Simoa HD-1 Analyzer. Each disc contains 24 arrays (enough for 24 samples), each with 216,000 microwells. In order to obtain accurate Simoa measurements, the microwells need to be manufactured on a miniature scale with extreme precision and consistency. The Simoa Disc provides just such extreme quality requirements and ensures the sensitivity and reproducibility of Simoa measurements.

Instrument Specifications

Assay Performance

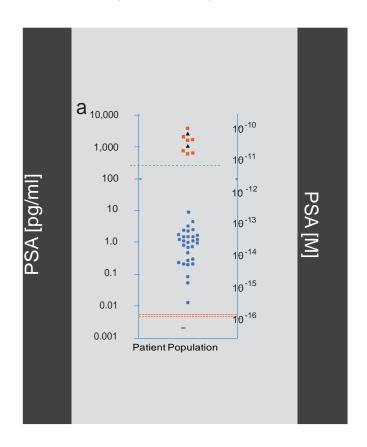
Metric	Simoa HD-1
Sensitivity	Average of 1000x improvement over leading assays available
Dynamic Range	>4 logs
Precision	<10% CVs

Instrument Performance

Metric	Simoa HD-1
Throughput	68 Tests/hour >500 data points per day
Workflow	Batch (plates or tubes)
Total Assay Time	<2.5 hours per 96-well plate
Hands on Time	Startup time <20 minutes
Automation	Full (sample in to data out)
Sample Input	96-well plate and tubes
Sample Volume	1 µl * - 100 µl
Instrument Footprint	135 x 60 x 160 cm (freestanding)
Multiplex Capability	up to 4-plex
Assay Flexibility	1, 2 or 3-step assays, with variable incubation time and number of wash steps

^{*} < 10 μ l requires pre-dilution step

Measurements from $Simoa^{\mathbb{M}}$ (blue) of PSA in radical prostatectomy patients are well below the LOD (green line) of leading PSA diagnostic assay. Red measurements represent healthy controls.



ELISA Kits

Quanterix offers a broad range of complete ELISA kits as well as a robust homebrew list.

Please visit www.quanterix.com for an updated list of all available assays and for detailed specifications.

Contact sales@quanterix.com for assays available in prototype format and custom assay development services.

Instrument Operation:

The Simoa HD-1 Analyzer allows users to run either pre-packaged reagent kits from Quanterix or to develop their own assays using a robust homebrew protocol. The instrument was designed to automate the entire process, including making dilutions; mixing, washing, incubation steps, and finally read-out/analysis of the results.

Five Simple Steps to Operate:	
1. Select Assay:	Using the intuitive integrated touch-screen monitor, users select assay to be run and follow instructions for loading instrument and starting test.
2. Load Reagents:	Following on-screen instructions, users load reagents into reagent bay.
3. Load Samples:	Using either conventional 96-well plates or sample tubes, samples are loaded into the instrument.
4. Load Consumables:	As needed, users load discs, pipette tips, and cuvettes into instrument.
5. Run Assay:	Users instruct instrument to run assay and can walk away until measurements are complete. First result is available in as little as 30 minutes with subsequent results every 45 seconds.

All system buffers, reagents, and waste are monitored on-board and users are alerted whenever action is required.

About Quanterix

Quanterix is a venture-capital backed company located in Lexington, MA. Founded in 2007 by Dr. David Walt, founder of Illumina, Quanterix has developed the world's most sensitive immunoassay platform and launched the fully automated Simoa HD-1 Analyzer for research use only in 2013. Quanterix has also partnered with the diagnostics leader bioMérieux to develop and commercialize assays for clinical use. For more information, please visit www.quanterix.com

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