

## FDA Clears Silicon Chip Based Blood Test

by [Genalyte](#) | Jul 22, 2024 | [News](#)

**San Diego, CA — July 22, 2024 —** Genalyte announces that it has received the first U.S. Food and Drug Administration (FDA) clearance for a Thyroid Stimulating Hormone (TSH) Immunoassay performed on a silicon chip. The FDA clearance for this assay is a significant milestone for Genalyte, and the diagnostic industry, and further validates the company's ability to process labs in a way that is precise, fast, and shows promise for future availability at point-of-care locations, reducing the average turnaround time by 98%.

Hypothyroidism affects approximately [10%](#) of the American population, making TSH testing the most commonly ordered immunoassay lab test in the United States. The existing laboratory testing procedures often require patients to carve out additional time from their schedules for trips to off-site labs and subsequent follow-up consultations to discuss results, which can take anywhere from 2 to 5 days to process. The Genalyte tests can be done in approximately 30 minutes.

Just as mainframe computers were replaced by desktops computers, Genalyte has reduced large central lab machines to just 3% of their current size while maintaining central lab quality results. For example, the FDA comparator for the TSH assay is a machine measuring 6 feet x 6 feet x 3 feet, and weighing 1,400 lbs, whereas the Maverick is only 30 lbs and the size of a small microwave. By enabling dozens of tests to be conducted in minutes in a small benchtop machine, the Maverick's silicon chip technology is poised to revolutionize lab care in the same way silicon chips revolutionized computing.

*"This TSH assay is a powerful tool to rapidly diagnose patients and get them on a path to treatment quicker,"* said CEO of Genalyte Ashraf Hanna, Ph.D., M.D. *"This technology is groundbreaking for immunoassay development which hasn't changed conceptually since 1959. The Maverick has the potential to allow a broad menu of blood testing in a small, portable device at the point of care."*

The clearance of Genalyte's TSH assay marks the first quantitative immunoassay to be cleared on a silicon chip based device. Genalyte is currently pursuing several additional clearances within this year.

About Genalyte:

Genalyte's mission is to deliver healthcare providers and patients with blood diagnostic solutions that provide rapid, accurate, and convenient clinical laboratory results at the point of care to improve patient outcomes.

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Note to Editors: High-resolution images and further information are available upon request.