NEW YORK – A team at Stanford University has developed a new point-of-care genotyping technology, testing it in a recent study to genetically predict which patients are likely to respond to hypnosis for pain management.

Magic LifeScience, a spinout from the lab of Stanford engineering professor and senior study author Shan Wang, is working on commercializing the technology, initially for infectious disease testing.

The rationale for using SNPs to test for hypnotizability is surprisingly sound. Research has suggested that certain variants in the catechol-o-methyltransferase (COMT) gene, which produces an enzyme for dopamine metabolization, are correlated with high scores on the hypnotic induction profile, a validated questionnaire that can recommend patients for clinical hypnosis.

The study, published in the *Journal of Molecular Diagnostics* in January, helped expand the number of single-nucleotide variants associated with hypnotizability, showing that a four-SNP panel may clear up previous conflicting results in research using a one-SNP test.

To get their results, the researchers used a new version of an older technology: giant magnetoresistive biosensor arrays.

Their test has the potential to help recommend patients for pain management without the use of opioids, said Dana Cortade, the first author of the *JMD* study, who was a graduate student at Stanford at the time. "We'd really like to further these findings in a larger cohort of patients with a wider range of clinical pain types," she said, "because it could be a valuable tool to provide predictive patient profiles [for hypnotizability]."

"These non-pharmacological treatments are really having huge impacts on patients," she said, noting that not many people are trained to provide the hypnotic induction profile assessment. "When it does work, it really works. What we need are the tools to figure out who could use it."

Wang's lab has now automated the test for pain management research in Stanford's department of psychiatry, one of several ways that GMR could end up in the clinic.

He has tested the technology for other genotyping applications: A 2021 paper in *Clinical Chemistry*, for example, demonstrated the ability to perform EGFR genotyping and provide prognoses for cancer patients under treatment.
"This GMR sensor can do anything any other assay does," Cortade said, including determining methylation status, mutations, or gene expression. "At scale, these cost $5 a test [and] can be used for detection pretty much anywhere."

Magnetoresistance is a physical concept that has been known since the 19th century and was discovered by William Thomson, aka Lord Kelvin, one of the pioneers of thermodynamics. The basic concept is that certain materials have their electrical resistivity — how strongly they resist an electric current — changed in the presence of a magnetic field. The "giant" version of the effect was discovered in the late 1980s, led to a Nobel Prize in physics, and became the standard for how magnetic computer hard disks were read.

Wang's early work with GMR biosensors applied the concept to ELISAs, using an electrical readout instead of fluorescence. The method functionalizes a surface to capture biomolecules, and precision droplet loaders are able to put antibodies at each of the GMR nanosensors in an array. The detection antibodies in the sandwich assays are labeled with small molecules that attract magnetic nanoparticles, which causes changes in the resistance at the GMR sensor circuit.

Since then, the lab has turned to incorporating PCR for SNP analysis. To detect single-stranded DNA, a DNA probe is printed onto the chip instead of a capture antibody. DNA analytes are biotinylated and conjugated to a magnetic nanoparticle. "You can do both identification and quantification," Wang said. "Depending on where we capture the analyte, we know which sequences were detected."

The JMD paper performed PCR off of the GMR sensor, he said, "but we actually demonstrated we could do PCR on-chip as well." Wang has secured a patent for that method and has launched Magic LifeScience with Bryce Yao, a former graduate student, to commercialize the PCR-GMR sensor for DNA detection.

Founded in 2021, Magic LifeScience initially planned to address the cancer testing market, but decided to pivot to infectious disease because of the COVID-19 pandemic. "We can do coronavirus, but it was a bit too late for us to join the pursuit at that time," Wang said.

Now, the firm is planning to make sexually transmitted infection testing its beachhead into the clinic. "Most tests are only available in centralized or CLIA labs and so far are very limited in their multiplexing capabilities," Yao said, making them slower than what Magic LifeScience thinks it can achieve. Moreover, STI testing has an existing diagnostic and treatment process. "Part of why we chose this is a well-established product and reimbursement code," he said.

The Magic LifeScience test includes genotyping for gonorrhea, chlamydia, Mycoplasma genitalium, and Trichomonas vaginalis as well as antimicrobial resistance genotyping for gonorrhea and mycoplasma. It will be able to accept multiple sample types, including urine as well as vaginal or rectal swabs. "Within 18 minutes, we're able to do 40 cycles of PCR ... so patients can leave with a test result as well as a proper treatment plan," Yao said.

Launching a successful POC test platform is "a multifaceted challenge," said Rob Cohen, managing director of Chrysalis Biomedical Advisors, a strategy consulting firm for the genomics and diagnostics industries. "The technical piece is at the center, of course, but there are many layers to success," he said, such as having a proper test menu and ensuring actionability of results. "Exquisitely thought-out technical solutions to [POC] COVID testing failed because the test menu didn't anticipate anything beyond just COVID, such as flu plus respiratory syncytial virus."

"Assuming technologies work, and that they work like they're supposed to, it really becomes about
price, speed, test menu, and then a back-end piece, linking to interventions to deal with symptoms or cause of disease," Cohen said. "That's what makes a test successful."

STI testing "is a really good beachhead," he noted. The current standard of care won't necessarily be easy to topple, as centralized testing continues to get faster and cheaper and fluorescent-based PCR readout is about as "hardened" a technology as there is. But POC testing in the clinic offers the possibility to get an immediate result and, if appropriate, provide a therapy within the same visit. "That becomes hugely important, epidemiologically," Cohen said.

Moreover, POC testing could offer a greater degree of privacy to help reduce the stigma of getting an STI test, especially if the assay could be performed at home.

The test cartridges are based on modern semiconductor fabrication methods. "On a single wafer, we're able to make over 1,000 biochips. The sealed cartridges use minimal reagent volumes, resulting in a cost of $5 per test, or less," Yao said.

Cartridges run on the firm's MagChipR, a benchtop instrument enabling GMR-based detection. The firm is also looking at applications in the emergency department and urgent care clinics, such as sepsis or hospital-acquired infections, and respiratory infectious disease panels.

Based in Mountain View, California, the company has nine employees and seven additional part-time "contributors." Additional founders include Elaine Ng, Avril Jiao, and Tianhao Zhu, and the firm has hired Jessica Barrett, a veteran of BioFire's FilmArray product line, to lead commercialization.

Magic LifeScience has received angel and seed funding and is about to launch its Series A fundraising efforts, aiming for the "multimillion-dollar range," Yao said. Closing that round would allow the firm to finish its clinical studies, which he said they've already begun planning. The firm has identified three sites for a US-based study that it hopes to begin in the second half of the year. The study would test its assay against the standard of care, PCR-based centralized lab tests, with a main endpoint of time to treatment.

Yao said he's also exploring research-use-only tests in the meantime. "We receive a lot of interest to use this product in research, especially for antimicrobial resistance detection," he said, noting that he hopes to have a product ready to be cleared by the US Food and Drug Administration by 2025.

"I think the biggest challenge in developing these tests is to prove their efficacy and break an existing pattern for clinicians and healthcare providers," Yao said.

"It is not our goal to just raise money to make money," he said. "If we make the right product, people will recognize that, and we'll be compensated for our work."

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