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Quidel's Solana Group A Strep Test Fares Well in Prospective Evaluation

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NEW YORK (GenomeWeb) – A Group A Strep test to rapidly detect pathogen DNA causing "strep throat" performs well compared to gold-standard testing, according to a recently published study.

Laboratorians at the Marshfield Labs, the Medical College of Wisconsin, the Laboratory Alliance of Central New York, and the University of Utah and Primary Children's Medical Center in Salt Lake City compared the Solana Group A Strep test from Quidel to bacterial culture.

The Solana test, which was cleared by the US Food and Drug Administration in June of last year, is an isothermal nucleic acid amplification assay to detect Group A Strep from throat swabs of patients with symptoms of pharyngitis. It runs in 35 minutes on the Solana platform, which can handle up to 12 tests at a time.

According to the study, which was funded by Quidel as part of clinical trails for FDA submission and published online in the Journal of Clinical Microbiology, the four trial sites prospectively collected 1,082 samples, testing each with the Solana assay and bacterial culture.

Tim Uphoff, corresponding author on the study and molecular pathology section head at Marshfield, noted that the labs also sent the samples to Quidel for duplicate culturing.

That was a little unusual in this protocol, in that it enriched for culture positives because a sample was called positive whether it was positive at the trial site or at the Quidel labs, Uphoff said.

"This actually provided the best sensitivity you can get for culture," he said, making it an extra-stringent standard.

The Solana Group A Strep assay showed 98 percent sensitivity and 97 percent specificity. Uphoff noted those measures are using culture as the gold standard, but that the positivity was actually higher for Solana than it was for culture.

Uphoff's molecular pathology lab at the Marshfield clinic serves a 500-bed hospital in Marshfield, Wisconsin, and also does testing for Central and Northern Wisconsin. The lab runs primarily infectious disease assays, but also does some genetics and oncology testing, he said. In the trial, the lab was responsible for about 250 of the strep assessments.

Last year, Quidel noted in an investor presentation that it was planning to encourage adoption of the Solana Group A Strep test as a faster alternative to culture, since guidelines

do not yet clearly recommend stand-alone molecular testing. At the time, GenomeWeb reported that the Infectious Disease Society of America was gearing up to revise its guidance, but the agency has not yet done so.

Guidelines are not the only struggle for Group A Strep molecular testing, however. Uphoff noted that there are nuances with reimbursement for the test that also need to be addressed by regulatory bodies in the future.

Specifically, clinicians typically run rapid antigen tests on patients with pharyngitis. These are not extremely sensitive, however, so negative results must be confirmed using another technique.

So-called reflex testing with culture is the gold standard, but is time consuming. Molecular testing is faster, and can also be very sensitive.

Following up negative rapid antigen testing with culture is fully reimbursable for both tests at this time, Uphoff said. Yet, currently the Center for Medicaid and Medicare Services will not reimburse for both the rapid antigen and the molecular test to be run on the same patient. "We would have to bill for one or the other, we couldn't bill for both," explained Uphoff.

This means that if a physician chooses to use the rapid antigen test with a molecular test for confirmation, he or she will usually submit the molecular for reimbursement and not be reimbursed for the immunoassay.

"That's really a lag in their guidelines, because it really makes no sense to have that exclusion," he said.

For the healthcare consumer, it would be better to do a rapid antigen test first, and if that is positive, stop right there, since these tests are specific and inexpensive, Uphoff said. But following up negative results with molecular testing would be much faster than culture.

Using molecular alone might ultimately be ideal, as it does not require any culture follow up, and would then allow for full reimbursement. However, that might require a workflow change that is not yet supported by any guidelines.

Both IDSA and CMS guidelines and policies need to change, Uphoff said. In the end, doctors may be doing patients a disservice by performing culture, he said, because it leads to over-prescription of antibiotics if doctors prescribe before waiting for the culture results or under-prescription if the patient is actually infected with Strep A but the rapid antigen test was not sensitive enough to detect it.

"The patients deserve [a rapid] answer, if it is available, and really what is holding back widespread adoption are guidelines and reimbursement at this point," Uphoff said.

Menu expansion may also be an important component for Solana adoption. At a symposium last year, Quidel representatives noted that the firm's AmpliVue line of tests — which includes FDA-cleared assays for Clostridium difficile, Group A Strep, Group B Strep, HSV 1+2, Bordetella pertussis, and Trichomonas vaginalis — is potentially being ported to Solana. The Solana platform is "random batch," so that different tests can be run at the

same time, the representative said. The firm has reportedly been working on a combined herpes simplex virus 1+2/varicella-zoster, influenza A/B, and trichomonas tests for Solana.

The Marshfield lab will eventually be adopting the Solana system, but Uphoff said the lab likes to see a broader menu before bringing on new platforms. "We actually use their AmpliVue products, and I anticipate we will adopt [Solana] within a year," he said.

Uphoff also noted that other rapid molecular tests for Group A Strep tend to be lower throughput, with the exception of the Meridian illumigene test, which was cleared in 2012.