Health, recently reported on the design and performance of its SARS-CoV-2 DETECTR, a lateral flow assay that takes 30 minutes to perform — or about 45 minutes including an RNA extraction step. The test employs simultaneous reverse transcription of the viral RNA and loop-mediated amplification, a simplified nucleic acid amplification technique that uses PCR-style primers but that does not require repeated cycles of heating and cooling. The amplified nucleic acid is then incubated with a guide RNA (gRNA) molecule targeting sequences in the envelope (*E*) and *N* genes of SARS-CoV-2 and the lbCas12a enzyme, which, after gRNA-mediated target-site recognition, cleaves nearby single-stranded DNA (ssDNA) indiscriminately. This allows the addition of ssDNA-based reporter molecules that confirm the presence of viral RNA.

According to initial validation testing against RT-PCR using samples from 6 patients infected with SARS-CoV-2, from 12 patients infected with seasonal influenza or the three coronavirus strains that cause mild symptoms (OC43, HKU1 and NL63), and from 5 healthy volunteers, the test had a positive prediction value of 100% and a negative prediction value of 91.7%. "We're right in the middle of additional validation," says Mammoth cofounder and CEO Trevor Martin. The company aims to ship the test as quickly as possible. "In an ideal scenario, it's weeks, not months," he says. It was purposely designed with simplified reagents to allow easy manufacturing. "There's nothing too exotic in what you're using, apart from the CRISPR protein itself," he says. Lyophilizing the reagents and developing portable microfluidic cartridges in which to run the test would enable it to be deployed outside laboratory settings.

Sherlock Biosciences is also working on several SARS-CoV-2 initiatives. "It's one thing to have a rapidly deployed technology," says Sherlock CEO and cofounder Rahul Dhanda, but "to get an assay to market requires a lot more than getting the assay working." The company aims to tap into partners to gain access to their regulatory expertise and manufacturing and distribution muscle. It has formed an alliance with Cepheid to develop CRISPR-based tests for a range of infectious diseases, including COVID-19, which will run on the latter firm's GeneXpert automated molecular diagnostic systems. The relationship was already under discussion before the present crisis broke, but it was an obvious step to include SARS-CoV-2. Given the urgency of the present crisis, Sherlock is also investigating whether it can bring a simpler test to market in a shorter time frame. "We started to engage with kit manufacturers to determine whether or not we could assemble a kit," Dhanda says. "There is the acute response and the comprehensive response we all need to be thinking of."

Given the uncertainties attached to the trajectory of the present pandemic, it is unclear whether CRISPR technology will make a major contribution to global efforts to track the progress of SARS-CoV-2. But the need for such a technology appears pressing. "This has exposed a big gap in the molecular diagnostics market," says Martin. It is just one of the many gaps in most countries' levels of preparedness for a viral pandemic. ❐

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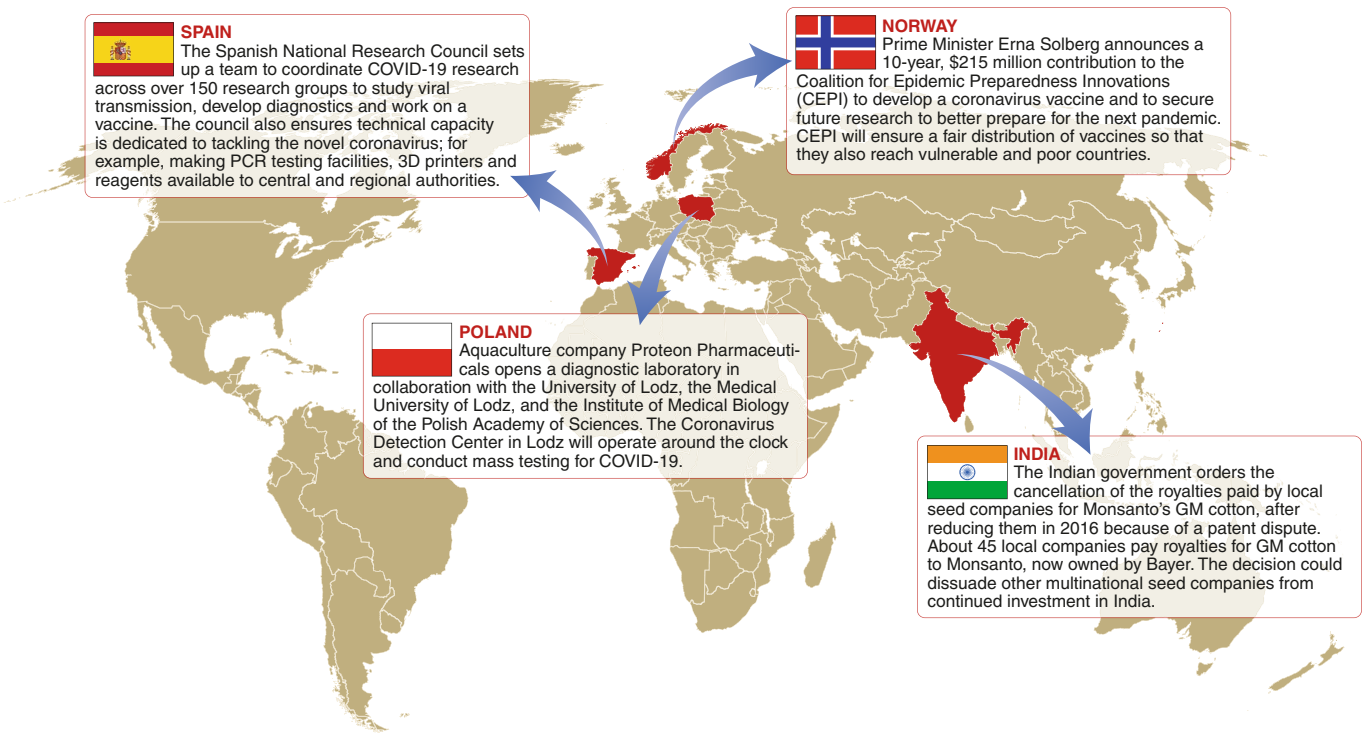
Around the world in a month



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