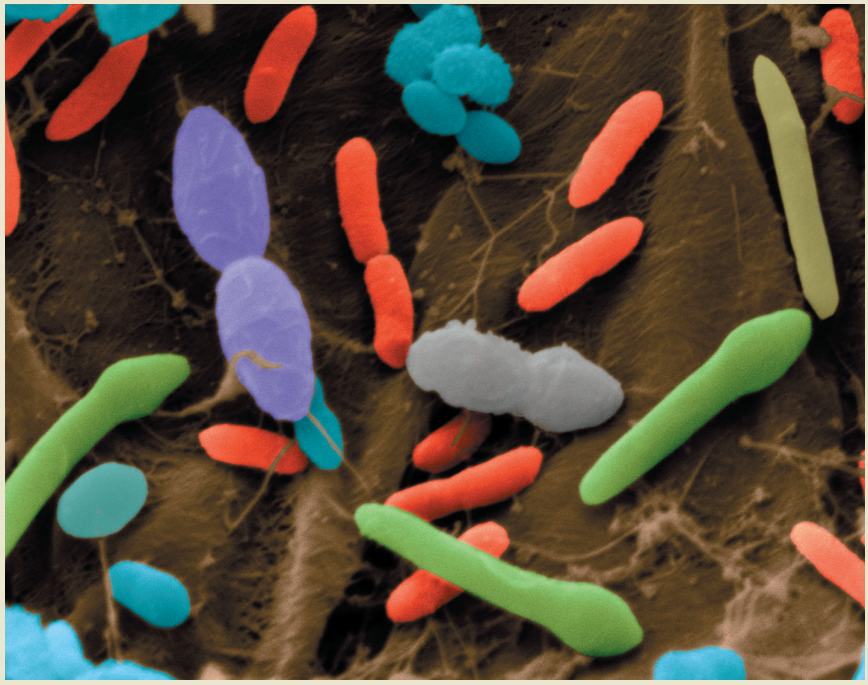
Gut microbiome profiling tests propelled by customer demand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Mixed bacteria from human faeces.

The San Francisco–based uBiome in November launched SmartGut, a clinical microbiome screening test that measures bacterial diversity in a person's gut using DNA sequencing. SmartGut classifies a person's gut microbiome by sequencing a single gene, the 16s ribosomal gene present in all bacterial DNA, to provide information with clinical utility. The test, which includes a kit to take a fecal swab, compares the results against a catalog of 100,000 microbial gut samples collected by uBiome through its crowdfunded platform launched in 2012 (*Nat. Biotechnol.* **31**, 90, 2013). Jessica Richman, CEO and cofounder of uBiome, says the test, which can be ordered only by health practitioners, identifies up to 26 microbial species to correlate the presence of different microbial groups with health risk factors, such as irritable bowel syndrome (IBS), chronic fatigue, diarrhea, depression, weight gain, skin conditions and rheumatoid arthritis. SmartGut is covered by US insurance payors and is the first such test to receive accreditation from the College of American Pathologists. The pricing for uBiome's SmartGut depends on the insurer, whereas its Gut Explorer kit, which is available to the public online, costs $89. The company has not yet published results in a peer-reviewed journal.

In the UK, Map My Gut, based in London, launched a microbiome-screening service in November that sequences DNA from gut bacterial populations and offers a comprehensive analysis and interpretation by comparing the sample profile against a highly curated, if smaller, data collection (*Genome Biol.* **17**, 189, 2016). Map My Gut charges £300 ($381) to profile a fecal sample using two methods: 16s ribosomal gene sequencing, which helps identify most of the common gut bacteria, and metagenomics, which sequences all genes in every living organism in the gut to identify bacteria up to the strain level. The gut microbiome analysis and interpretation is aimed at healthy people and those with conditions such as IBS. Clinicians can offer it within the UK's state-run National Health Service from company-trained and approved health professionals only.

Tim Spector, CEO of Map My Gut, says the firm adopted this model from their experience in the British Gut Project, a crowdfunded academic project launched in 2014. "People were dissatisfied with [those test] reports, because they were not giving them any sort of real evaluation or any real clinical utility. Because of that demand, we decided to provide a report that would be used in conjunction with a health professional that could actually give them good health advice," says Spector.

Similarly, the Israeli company DayTwo, based in Rehovot, links an individual's gut microbiota with their blood glucose levels after a meal to provide personalized dietary advice via an app. Individuals receive a nutrition plan over the app that uses an algorithm developed at the Weizmann Institute of Science in Rehovot. The app prepares food recommendations aimed at minimizing a person's postprandial glycemic response to prevent type-2 diabetes and metabolic syndrome, taking into account the gut microbial profile (*Cell* **163**, 1079–1094, 2015). The North Carolina–based Genova Diagnostics also offers targeted microbiota-profiling services, but bases them on PCR analysis, and identify up to 24 species of commensal bacteria.

Gut microbiome profiling is "an interesting [market] space," says healthcare analyst David Cox, associate director at Panmure Gordon, London, but there are many unknowns, and the field is still in its infancy. Eamonn Quigley, a gastroenterologist in the Houston Methodist Hospital, Texas, is sceptical about how useful sequence-based gut microbiome tests will be in the clinic and says he is unlikely to order a test. "We are still some way away from having a diagnostic algorithm based on the microbiome—there has been progress made in this area but there is still a long way to go," says Quigley. Others, such as the Saint Herblain, France–based contract research organization BioFortis (of Mérieux NutriSciences) provides microbiome analysis to their client companies for clinical trials, and the Paris-based Enterome, another French R&D firm is in discussions with another firm to identify a microbiome-based biomarker to non-invasively manage Crohn's disease using IBD110, their noninvasive gut microbiome biomarker surrogate marker of mucosal healing.

Vijay Shankar *Jena, Germany*

Corrected after print 30 January 2017

Erratum: Gut microbiome profiling tests propelled by customer demand

Ravi Shankar

Nat. Biotechnol. **35, 9 (2017); published online 10 January 2017; corrected after print 30 January 2017**

In the version of this article initially published, the first paragraph incorrectly stated that uBiome's SmartGut test costs $89. Instead, that should have said that the price depends on the insurer, as this is a doctor-ordered, insurance-reimbursable clinical lab test, and that the uBiome Gut Explorer kit, which is available to the public online, costs $89.