FUTURE DIAGNOSTICS

This is the future of diagnostics

Look ahead:

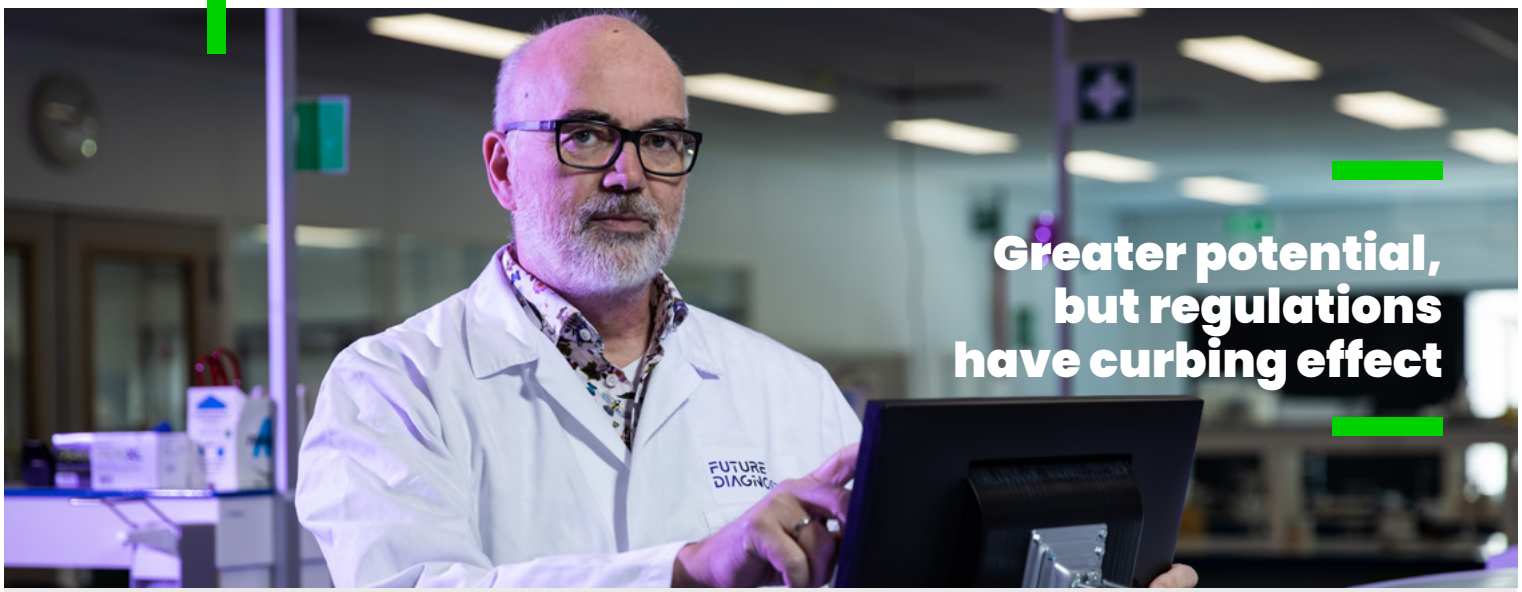
It's a hotly debated issue in the medical community: "the future of diagnostics". An uncertain subject with a changeable nature. But just because the road ahead is not yet fully mapped out doesn't mean we can't philosophize about it. And so our own Head of Research and Science Ernst Lindhout recently held a survey among colleagues and other peers to see where our field might be heading. And to be able to anticipate what awaits us.

Over 300 scientists, lab technicians, and laboratory managers shared their predictions in the past few weeks. Lindhout discusses them and shines his own light on the matter. With over 21 years of experience within our company, he offers an enlightening view.

The current state of affairs

To talk about the “future” of diagnostics, it is first of all important to be clear on the “past” and the “present”. For example, did you know that the first publications on the existence of antibodies came out in as early as 1890? That the first immunoassay was described by Solomon Berson and Rosalyn Yalow in 1959? And that their work resulted in a Nobel Prize in 1977? And what about the introduction of ELISAs in 1971, of monoclonal antibodies in 1974, and ACS180 - the first random access immunoanalyzer - in 1990? And that Future Diagnostics was founded in 1997? Now, in 2022, exactly 25 years ago?

About the present time at Future Diagnostics, Lindhout explains: “At our core, we have been doing the same thing for 25 years; we develop and validate IVD tests for medical diagnostics. Basically, the technology itself may have changed little, but the development of all the devices and the software used has continued over the years. This allows for more sensitive measurements, improved ease of operation, and more reliable results. And we have discovered new markers. Even though the blood you have sampled at the doctor’s office is now tested in basically the same way as it was 25 years ago, we measure and know much more today than we did then.”



Greater potential, but regulations have curbing effect

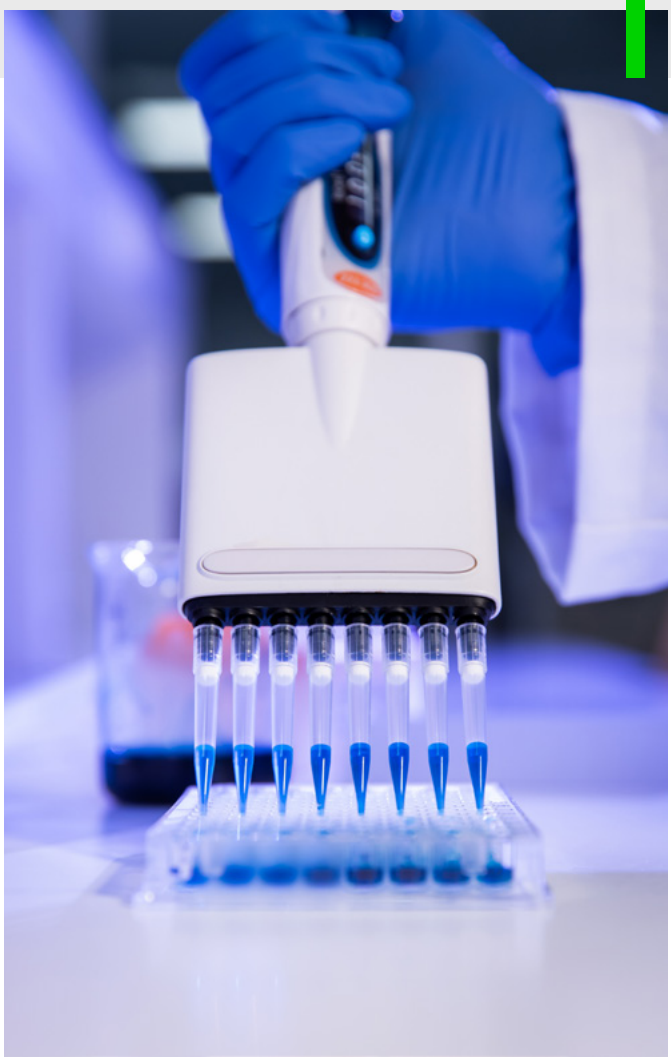
According to the Head of Research and Science, much more is possible, were it not for the fact that the regulatory landscape in this area is a conservative one. “With self-testing, for example, we would have been a lot further if the rules weren’t so conservative. The regulations are there for a reason, of course, and are very important for patient safety. But technically speaking much more is possible than we do now. It gets bogged down by the acceptance of clinicians and associated regulations. The whole COVID situation did change that slightly, but we’ve still

got a long road ahead of us. It's a complicated issue because what if something goes wrong..." Lindhout supports and evaluates ongoing projects on a daily basis. He also keeps up with the literature regarding his field and is on top of innovations. Asked what he thinks his workdays will look like in the future with today's knowledge, he doesn't expect anything too drastic. "The tools that go through my hands won't change much any time soon. It will be more about adjustments to the current rules. I hope."

Just immunoassays for now

Yet one of the questions he asked peers on LinkedIn was: Will immune tests still be developed 25 years from now? He himself has no doubts about it, he reveals. "But you never know. And if everyone agrees that a new way of testing is better, faster, cheaper, then we need to start using other techniques. It is important to anticipate this in time.

But it turns out Lindhout isn't the only one who doesn't see the immunoassay disappearing for the time being. Because 87% of the respondents agree with him as far as the next 25 years are concerned. "There just are no good alternatives at the moment," he states. LC-MS was frequently mentioned by respondents as an alternative, should it come to that. "In the long run, LC-MS - which allows you to detect certain substances without antibodies, also in blood - could turn out to be useful. Because, unlike immunoassays, there is essentially no way to get a wrong result from that. LC-MS is already the gold standard for measuring steroid hormones and vitamin D. But for proteins, that method is still largely



in the research phase. So that is not available for now. Moreover, it is currently a relatively expensive, time-consuming method using rather large machines. And in most cases, you need specialized personnel to perform the assays and read the results. It's not suitable for a home test, for example."

Other binders besides the classics

Respondents do indicate that they expect other binders in addition to classical antibodies. “If you want to make antibodies, until recently you had to immunize a test animal, such as a mouse or a rat. There are other methods now, which are basically better. Monoclonal antibodies have been used since 1974 and are still the preferred method. But if, for example, the use of laboratory animals is banned internationally in the future, we will have to rely on alternatives. So we are closely monitoring developments in that field and they are already being tried out in pilot projects.

And ELISAs specifically are here to stay, the majority of respondents expect. “Because the technique is very simple, the equipment is not that expensive and you can do a lot by hand,” Lindhout adds. “I do expect it to move toward an automatic solution.”

Smart devices in the future of diagnostics

Another topical question about the future: Will diagnoses be made based on smart wearable sensors, smartphones, and smart devices? Most of Lindhout’s peers think so. Lindhout himself? He even knows for sure. “But therein lies the difficulty; technologically, a great deal is already possible, only it is not yet clear who owns all that privacy-sensitive information.” This is something that needs to be worked out further. The Head of Research adds a side note. “In the future, if a wearable detects that something is different than usual, you’ll still have to go to a clinic or do a self-test to determine exactly what’s wrong. So it’s not a cure in itself.”

In 2020, American users of the FitBit[1,2] were asked to participate in a study aimed at examining who among that group got COVID. It was investigated retrospectively whether that could be seen in the data. It showed that even days before the COVID infections manifested themselves, there were differences in the basic bodily functions, Lindhout explains. And there are more studies on detecting all kinds of conditions with such wearable data. “That means you can start testing for diseases earlier. Which is very interesting. But at the same time, there is also a very large group of people who does not want to get that kind of information .”

No more waiting in the waiting room

According to Lindhout, more and more research is being done on the complete prevention of diseases. “Data is used to determine whether someone will fall ill some time. That means the waiting room can be skipped because you can act before it even happens.” A good example according to him: is the smart mirror. This can tell from your face if you have a fever, high blood pressure, or liver problems, for example. Or clothing with sweat analysis; it’s all under development. While it is all technically possible, the focus now is on expanding those techniques and making them reliable.”

And so in the future, if there are anomalies in the data from such applications, a signal can be sent to your smart toilet. “Telling it that the next time you sit on the toilet you should be tested for certain values. This is already being worked on by Stanford University and a German-Dutch consortium, among others. But there’s a bit of a hold-up. Especially on the side of - there it is again - regulation.”

Many developments waiting for green light

The bottom line according to the Head of Research and Science: In the future, many changes will be possible, as long as they can be implemented not only technically but also in terms of regulations. But also: many things will remain the same in the coming years. “Take smartwatches like the FitBit for example: they offer an incredible amount of potential. But if you want to put such a device to good medical use, there are still a lot of hurdles to overcome. And in the end, there will always be things that need testing. Whether it’s in the form of a device at home, or at an out-patient clinic. So we remain relevant.”

“Our technology is future-proof for now,” he also concludes. “That’s what we think, and it turns out that’s what our peers think, too. In that respect, we have a wonderful position. We adapt to developments, but our product basically stays the same. And in the meantime, we follow what else is happening in the field. So bring it on, our next 25 years!”

References

1) https://blog.fitbit.com/early-findings-covid-19-study/
2) https://doi.org/10.1101/2020.08.14.20175265

Address
Nieuweweg 279
6603 BN Wijchen
The Netherlands

Give us a call
IVD Assay Development Services
phone: +31 (0)24 64 52 900
www.future-diagnostics.com

July 2022