

# Smooth operations: We manufacture the cartridges for the SARS-CoV-2 PCR rapid test for Spindiag GmbH.

## Rapid MRSA detection to laboratory-based corona point-of-care testing

“The last few months have demanded a lot from all of us, but with our combined efforts we did it!” says Dr. Markus Rombach. He is in charge of the development project at Hahn-Schickard and, together with production manager Dr. Rouven Streller, has established the disposable test cartridges in production in accordance with the specifications of the distributor Spindiag.

Hahn-Schickard produces the cartridges for the handy “Rhonda player” analyzer for the market launch on

behalf of Spindiag on its own production line in multi-shift operation. “With the certification of our quality management system according to the medical device standard EN ISO 13485, we have reached an important milestone. It enables us to develop and manufacture in vitro diagnostics for clinical and point-of-care applications with the highest quality requirements,” explains Professor Roland Zengerle, Hahn-Schickard Institute Director in Freiburg and Head of Laboratory for MEMS Applications at the Department of Microsystems Engineering at the University of Freiburg.



In 2016, six Hahn-Schickard employees founded Spindiag GmbH: Dr. Gregor Groß-Czilwik, Dr. Mark Keller, Dr. Frank Schwemmer, Dominique Kosse, Dr. Oliver Strohmeier und Dr. Daniel Mark. Source: Spindiag GmbH



Spindiag receives EU market approval for Rhonda Corona rapid PCR test. Source: Spindiag GmbH



Highest quality and hygiene standards must be maintained on the production line.



The fully automated Rhonda rapid PCR test system consists of an analyzer with a test cartridge. Source: Christian Eichenauer, scinelion



**Dr. Rouven Streller**  
Leiter Lab-on-a-Chip-Fertigung | Hahn-Schickard

Whether for a small or large batch, we guide the customer from the prototype to the finished medical product. We manufacture in our own clean room. But we can also make the manufacturing processes we have developed available to the customer and integrate them for the customer or another service provider.

### Molecular diagnostics for point-of-care use: mobile on-site testing, digital read-out of results

Spindiag's Rhonda system is based on joint research work for the detection of multi-resistant germs and will be able to detect up to 36 viral and bacterial parameters in well under an hour. The test procedure is based on the so-called “polymerase chain reaction” (PCR), the gold standard of infection diagnostics. Whether a person is infected with the SARS-CoV-2 pathogen or not can be determined quite precisely with Rhonda. The system is characterized by its simple, safe testing procedure. The standard swab for sampling is inserted directly into the “Rhonda disk.” No further work with the patient sample is necessary, minimizing the risk of contamination and infection for the staff.

### The State of Baden-Württemberg provided 6 million euros in fast-track funding for the development.

The Ministry of Economic Affairs, Labour and Housing Construction for Baden-Württemberg supported the development phase of the SARS-CoV-2 test with a funding amount of 6 million euros. For the first time in history, the economic committee of the State parliament convened for a special online session due to the urgency of granting this funding.

One of the first sites to use the innovative test was Klinikum Stuttgart. At the market launch of the Spindiag Rhonda test system on November 16, 2020, Minister of Economic Affairs Dr. Nicole Hoffmeister-Kraut convinced herself of its functionality and got tested herself on the spot.

For 17 years, scientists led by Professor Zengerle have been conducting research in the field of “Lab-on-a-Chip” under the umbrella of Hahn-Schickard and the University of Freiburg. The CE-IVDD-compliant corona PCR rapid test of Spindiag is another impressive example of his team's success. Time and again, basic research at the University has given rise to concrete product visions that lead seamlessly into industrial application via applied research and development at Hahn-Schickard.