

**Lab Developed Testing** Solutions

Success Story

# LABOR BERLIN INTEGRATES THE RIGHT TECHNOLOGY TO CONTINUE TO BUILD THEIR MOLECULAR DIAGNOSTICS PORTFOLIO



Founded in 2011, Labor Berlin - Charité Vivantes GmbH is the joint venture of two of the most prominent public health service providers in Berlin: Charité and Vivantes. Today, Labor Berlin is Europe's largest clinical laboratory, running 12 facilities with around 500 employees.

#### Key challenge

The union of these big players meant a need to provide diagnostics for an accommodation capacity of nearly 17,000 in-patients as well as a large number of out-patients, accounting for more than 39 million routine tests in total per year. Anything but a small feat.

In fact, having to keep up with such a steep increase in throughput, while still maintaining the flexibility and efficiency they were known for, proved to be their greatest challenge.

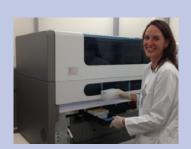
We spoke to Dr. Anke Edelmann, coordinator of the molecular diagnostic platform, to find out how the right instrumentation and solutions enabled them to overcome this challenge and expand their testing portfolio exponentially. Within the field of molecular biology, Labor Berlin combines testing for virology, microbiology, hemato/oncology and laboratory medicine on the molecular diagnostic platform.

#### What does a typical day in your lab look like?

Our lab routinely operates from 7am – 6pm and processes around 500 samples per day. These consist of both routine commercialized tests as well as Lab Developed Testing Solutions (LDT). After a day of testing, all the results are fed into the LIS (lab information system), which ensures that all our data is consolidated and securely stored. After that is done, validation of data is completed.

### How big of a role does the instrumentation you use play in the success of your lab's processes?

The molecular biology technology we use is key to our success. A lab's need for technology depends on the size of the lab and the throughput they're dealing with. The more the lab's throughput increases, the bigger the need for technology that enables you to standardize and automate processes. Our lab experienced this first-hand.



#### Company Quick Facts

#### **Labor Berlin**

#### - Charité Vivantes GmbH

12 facilities, 500 employees
Provides diagnostics totaling
nearly 39 million routine tests
per year for in-patients of an
accommodation capacity
of nearly 17,000, as well as
out-patients

#### Key Challenge

Dramatic growth while maintaining flexibility

#### The Solution

Adding Roche solutions to their existing testing environment for a standardized and automated workflow

#### The Solution

#### It sounds like your lab has grown quickly in the past few years. How did the right molecular biology technology enable you to expand your capacity?

In 2007, before the unification of Charité and Vivantes, the virological lab was using Roche's LightCycler<sup>®</sup> 2.0 for LDT solutions and the COBAS<sup>®</sup> AmpliPrep/COBAS<sup>®</sup> TaqMan<sup>®</sup> system for HIV and HCV testing. We found the instrumentation to be adequate for what we needed. But with the establishment of Labor Berlin, we naturally saw a dramatic increase in throughput requirements on the molecular diagnostic platform. This also meant that the need to automate and standardize became just as important. That's why we decided to add the MagNA Pure 96 for automated extraction in 2012.

In 2013, our need for increased throughput continued to grow. The LightCycler<sup>®</sup> 2.0 was incredibly flexible and could process 32 samples fast and accurately. But we still needed to add capacity on the testing side. That's why we chose to bring the Roche qPCR instrument for higher throughput on board to further increase the capacity of our LDT solutions. Not only is it designed to handle high-throughput testing, but it also enabled us to establish a more automated workflow.

### What are the top five to six lab developed tests which you run in your molecular diagnostics lab?

The top lab developed tests we run in our lab, include real-time PCR assays for the detecting of CMV, BKV, EBV, HBV and HSV1/2. Our current lab developed testing workflow, which include the LightCycler<sup>®</sup> 2.0 and the Roche qPCR instrument for high throughput, enables us to be more flexible – especially concerning rapid testing of a smaller number of samples including standby service.

#### Did the increase in throughput mean that you had to replace your existing instrumentation?

No, not at all. That's what makes Roche solutions so great to work with. They have been designed to work together and build on your existing workflow. As a result, labs with individual needs are able to create an optimized workflow that is unique to their requirements. In our case, Roche helped us to connect several different instruments the MagNA STARlet, two MagNA Pure 96 devices and three Roche qPCR instruments for high throughput. These instruments, working together, assist in quickly automating primary sample handling. In addition, it helped reduce the possibility of mixing up of samples and ensure true positive and true negative results.

### How would you say your lab environment has changed since implementing the above-mentioned workflow?

We have found that qPCR's sensitivity has increased and the closed systems help in increasing consistency but reducing the possibility of contamination. The direct volume transfer from nucleic acid preparation to PCR is quick and specific. In addition, our workflow has been streamlined by the fact that working lists generated from the MagNA STARlet can be used in the MagNA Pure 96 and the Roche qPCR instrument for high throughput – that way we can be sure that the sample and the test results match.

## How does this help you to expand your testing portfolio and equip your lab for the future?

When we run standard IVD tests we can rely on consistency and accuracy that goes together with extensive validation that has already been done. This works especially well with high-throughput testing. However, in order to stay flexible and agile enough to react to new emerging pathogens, thus differentiating our testing portfolio, we need to expand our lab developed testing environment too.

LDT solutions require optimization, testing of new assays with samples and lots of documentation; not to mention rigorous validation. To ensure that this process runs as efficiently as possible, we need to use instrumentation that streamlines, standardizes and automates the testing process.

And that is exactly where Roche solutions have become invaluable to us.

### Discover Roche LDT Solutions for yourself

Want to learn more about implementing more standardized LDT workflows into your own diagnostics environment?

Visit <u>ldtsolutions.roche.com</u> to learn more.