

## Faster to Market While Delivering Cost Savings

### The Starting Point

A point-of-care (POC) test is defined as a test performed at or near patient site with a rapid turnaround time (less than 15 minutes) that provides valuable and accurate diagnostic information. While classic examples of POC tests such as blood glucose monitoring and pregnancy tests exist, many other tests still must be done at a centralized laboratory because of accuracy and reliability required. There is a significant drive within the market to decentralize testing away from the centralized lab due to the time it takes for results and subsequently the timeliness of diagnosis and treatment that is beneficial to the patient. For that, POC solutions are needed to serve the hospital, physician’s office labs, urgent care and retail clinics, and eventually home care and self- testing markets. This is true across a spectrum of disorders and disease states ranging from cardiac and hormone testing, to a variety of infectious diseases- including the latest examples such as COVID-19, both in developed and developing countries. One of the companies attempting to enable this growth is Qorvo® Biotechnologies (Qorvo). BIT partnered with Qorvo in 2017 to help finalize the development and commercialization of a rapid diagnostic biosensor platform for immunoassay testing based on their innovative Bulk Acoustic Wave (BAW) detection core. Qorvo’s goal is to utilize their advanced technology to deliver centralized lab results level diagnosis at the POC test site to help make informed decisions that will impact the patient workflow and fasten treatment. While currently finishing up the development of the IVD instrument, Qorvo is finalizing their veterinarian market version of the platform and is projected to [hit the market in 2020](#).

### The Qorvo Challenges Faced

- Missing In-House Regulatory Processes to Execute Market Launch**  
 As a young company in the IVD market, Qorvo recognized the added value of gaining input from a more knowledgeable partner for technical support and additional regulatory and quality input to support the commercialization of their POC platforms. By leveraging a knowledgeable IVD partner’s input, they could uncover additional opportunities they may have missed during their initial development phases.
- Limited Resources to Transition Technology into Automated Device**  
 Qorvo did not have adequate in-house capabilities to move from early prototype stage to a fully functioning prototype and ultimately into serial production. Qorvo needed engineering support in making the design robust for manufacturing and automating the technology. The lack of resources to finish the development and the need for specialization required Qorvo to either outsource the project or hire internally and delay launch.
- Delivering High Instrument Volume and Decreasing Manufacturing Costs**  
 Qorvo does not presently manufacture products therefore did not have the capabilities to manufacture the instrument at scale and cost in-house. The best option for a rapid ramp-up to manufacturing was to outsource to a reliable and experienced partner that had consistent operations over time and could leverage knowledge to drive more efficient costs.

### The Results



## BIT's Solutions

- Proven Commercialization Expertise and Market Knowledge**

Initially, BIT helped Qorvo solve many of their technical challenges in the design transfer to prototype. This was done under budget and within tight timeline. BIT did not stop there and assisted in ramp-up, commercialization process and technical product support in field. In addition, BIT provided regulatory guidance which assists Qorvo in achieving quality but also will support any future shift of the product into the IVD market. This helped save Qorvo money and time by not having to manage multiple vendors and agencies but working with a partner that has all this expertise in house and aligned through the development and transition processes.

- 44 Years of Know-How in Automation**

Qorvo's commercial success, and that of their private label partners, is dependent on introducing well-functioning and durable technology to the market. Thus, the main goal of BIT was to make the design more robust which ultimately enhances the reliability and supports the consistent performance of the instrument. An example of this includes the proposal by BIT to exchange the existing heater PCB to a new generation PCB with a flex cable. While the new PCB itself is more expensive than the old PCB, it will cut labor costs in manufacturing through more efficient assembly processes and support the reliability of the device during operation (Design for Assembly and Design for Service).

- Experience as Long-Term Manufacturing Support Partner**

Based on Qorvo needs for a consistent manufacturing environment and market experienced partner, BIT was the choice partner. By working with BIT, Qorvo was able to leverage BIT's experience and decrease manufacturing costs by 10% between development and launch. In addition, with its global footprint and more than 130,000<sup>2</sup> of floor space, BIT can grow with Qorvo both in size and geography. Finally, BIT has a history of long-lasting client relationships (average business relationship of more than 10 years) providing Qorvo with a reliable partner for now and the future.



## Why BIT?

- 150 Engineers and Scientists Holding over 30 Internal Patents** - Systems, Software, Electronics and Mechanic Engineers with a vast knowledge in a broad variety of technologies receive continuous updated training in spaces like market regulatory requirements, risk management and design processes to ensure they are leaders in their space. Our patents can be utilized by clients to accelerate time to market and to add additional beneficial features to their products.
- 43 Years of Excellence with More Than 190,000 Instruments on the Market** - Our competency is evident in our long-term manufacturing relationships with industry leaders like Siemens, Abbott, Beckman Coulter.
- We Speak Regulatory** - With an in-house regulatory team and all BIT manufacturing facilities operating under ISO 13485 and FDA certifications we ensure our customers are planning and achieving all relevant regulatory requirements.
- Long-lasting Team Collaboration** - We have over 95% full-time employee's with low turnover rates and long work relationships in our engineering and manufacturing department. This allows working together with a stable and consistent project team throughout development and manufacturing.