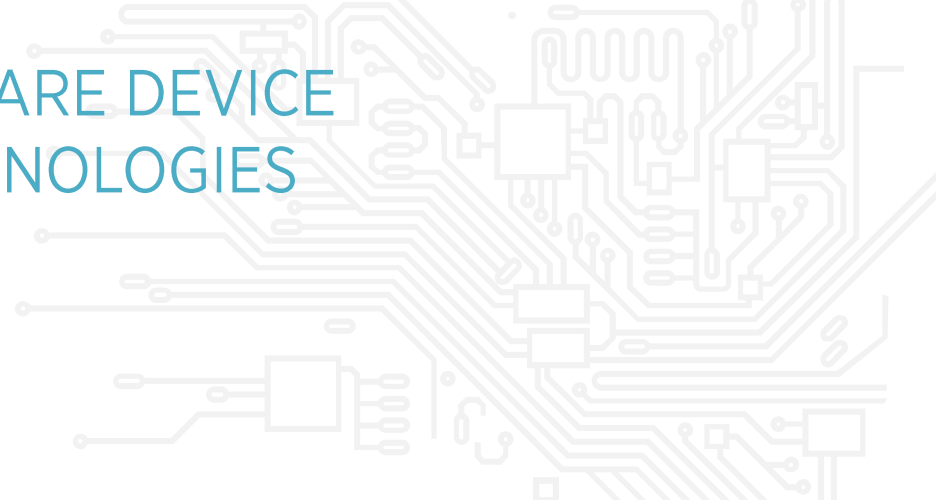




## DEVELOPMENT OF A POINT-OF-CARE DEVICE WITH 2 NOVEL DIAGNOSTIC TECHNOLOGIES

CASE STUDY



# INTEGRATION OF 2 NOVEL TECHNOLOGIES TO DEVELOP A POC IN-VITRO DIAGNOSTIC PLATFORM

## Customer Challenges

Our client developed two novel clinically validated technologies for malaria and sickle cell disease diagnosis.

The customer was seeking a product engineering partner with proven R&D success in global markets, an established in-house infrastructure, supplier ecosystem, and extensive experience in market research, design, implementation, and manufacturing support to realize commercialization goals.

## Scope

- Extensive market research to understand emerging markets
- Product requirements and specification identification
- Product design and engineering
- Packaging, branding, and visual content development
- Product software development
- Qt-based implementation for design, development, and validation
- Compliance testing and documentation as per the new EU-IVDR 2017/746 requirements



# INTEGRATION OF 2 NOVEL TECHNOLOGIES TO DEVELOP A POC IN-VITRO DIAGNOSTIC PLATFORM

## Approach

Tata Elxsi carried out pan-India market research that included market sizing and user research to understand the product’s viability in the developing markets.

Tata Elxsi established a global engineering network with R&D and engineering centers in India and the US and a network of suppliers and vendors. Tata Elxsi team developed a proof-of-concept for battery-operated, easy-to-use, connected, and integrated malaria and sickle cell disease diagnostic platform and enhanced the technologies for real-world scenarios.

Tata Elxsi also undertook product commercialization complying with the regional regulatory requirements and set up a manufacturing vendor ecosystem in India.



## Impact

- The customer launched the product in June 2020, and it is currently being sold in 12 countries
- The product offers 20X improvement in test time and sensitivity for malaria and sickle cell detection compared to conventional technologies
- The battery operated and portable device is designed to be used in rural settings, extending healthcare access in the remote areas
- The connected platform collects patient records, test results, and the GPS location of the tests providing insights for the interventions needed in the disease clusters

