

# Diagnostic Sample Preparation System

## Capturing early market share by bridging product lines.

In order to capture early share in the HPV diagnostic market, Plexus was engaged to design and develop a non-assay system that performed decapping, recapping and sample prep functions to secure floor space and alleviate the need for tedious tasks that would otherwise need to be performed by lab operators.

### SOLUTION SPOTLIGHT



#### CUSTOMER:

MAJOR HEALTHCARE AND LIFE SCIENCES OEM



#### PRODUCT:

DECAPPER/RECAPPER SAMPLE PREP SYSTEM FOR HPV DIAGNOSTICS



#### SOLUTIONS:

- Design and Development
- Supply Chain Solutions
- New Product Introduction
- Manufacturing

## Cervical cancer affects more than 8 out of 100,000 women per year in the U.S.

Cervical cancer screening includes two types of screening tests known as the Pap smear and human papillomavirus (HPV) testing. Pap smear testing is used to detect abnormal cells that develop into cancer if left untreated. Since HPV is found in about 99% of cervical cancers and certain types of HPV are known to cause cell abnormalities and cancer in women, HPV testing can predict the type of infection that may ultimately lead to cancer before cell abnormalities can be seen.

With competing HPV diagnostic solutions entering the market, our customer identified the imperative to develop an automated sample preparation system to mate up to their assay system and introduce it into the market in as little as two to three years. Cost effectiveness and process improvements were also imperatives as lab technicians had been known to have had carpal tunnel issues due to the number of caps they had to remove and replace. Plexus was able to meet all system requirements and introduce the system and associated testing equipment into production in less than three years.

System design and development was facilitated by leveraging the design and learnings from a previous project which was being executed at the same time. Plexus was able to provide enough engineering support to successfully complete both projects.



## Defining the concept.

Plexus had a complete design team working with the customer's small-scale internal team. Our industrial design team worked directly with the customer's marketing team. Mechanical, electrical and software teams worked with technical engineers from the customer's design site. Weekly meetings were held with several visits to the customer's site as well as visits to the end customer's site to understand the task workflow that operators needed to carry out prior to the introduction of automation. Together, the teams were able to examine the system concept from the very beginning and bring all of the customer's various ideas on leveraging existing design aspects into the system to optimize time-to-market.

## Building the solution.

Plexus applied our full value stream of product realization services to design and develop the product. The time-to-market strategy placed constraints around components to be used in the system. While there is certainly merit from a timing standpoint to the use of proven components in system design, integration of these components together in a system can prove to be complex. The system contained 29 axes of motion, internal bar code readers, shakers, decappers, pipettors, heaters, and reagents and buffer solution handlers. Software control of the system relied on a Programmable Logic Controller that was able to interface with the Graphical User Interface designed by Plexus using C# coding with XAML files and a SQL Server database. Common functional test systems were devised to test ten different subassemblies to allow them to be treated as Field Replaceable Units (FRUs) and duplicate test systems were built to allow for parallel manufacturing tests.



The product's complexity required advanced supply chain problem solving. In some cases, the Plexus team had to introduce multiple vendors so they could source their own materials and pre-assemble the required components. Some of the key components were prescribed by the customer, and when the system as a whole did not meet the technical requirements, Plexus worked with the customer and their vendor to update component specs to allow for system functionality. The requirements evolved during the development process that led to the stabilization of the design after discoveries we made in confidence testing to allow the product to be redefined to meet expectations.

Keeping a sharp eye on the deadlines, our team of Design and Development, Manufacturing, and Supply Chain Solutions experts worked closely with the customer to create efficiencies. Regularly scheduled management meetings and close contact with the customer's team kept communication very open. Direct involvement with prototype trials and testing allowed us to iterate the design as we discovered areas to improve or as requirements evolved. Direct feedback on prototypes helped further refine the user experience.

The system delivered a repeatable, cost-effective, and timely solution to allow for the introduction of a diagnostic assay for HPV detection into the marketplace so that women all over the world can stand up to cervical cancer.

## Bringing a better diagnostic solution to patients worldwide.

In the end, thanks to Plexus' tightly integrated processes and team passion, the customer hit their timing to allow their assay to enter commercialized equipment, thereby enabling their ability to capture HPV testing market share. The system complied with all regulatory requirements, including but not limited to, EMC, electrical safety, and IEC62304 medical device software with a class B software safety classification. In addition, it fulfilled the desire of the end customer to have many of the functions be automated to prevent workplace injuries and allow for more reliable sample handling at a faster speed.

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