

# Diagnostic Case Studies

40 years of experience has enabled ATS Automation to be a key partner for many global medical device and life science companies, including those that produce diagnostic products. Our assembly systems that have produced test strips, biochips, single-use diagnostic test cartridges, lab-on-a-chip and DNA microarrays. These systems have included precision steps such as the micro-dispensing, laminating, coating, ultrasonic welding, part assembly, in-process and final test—all in systems with cycle times down to less than one second. Our automation systems are designed to help our global diagnostic customers maximize their reliability, maintainability and sustainability.

## Manufacturing High-volume Point of Care Diagnostic Devices

*A major medical diagnostics manufacturer wanted to automate the assembly and die insertion process for their industry-leading point of care product*



### Challenge:

Our client was looking for a high-volume solution to manufacture a point-of-care diagnostic device; the assembly of this device required expertise in placement of a very delicate wafer die into molded plastic parts at high speed.



### Approach:

The die insertion process required knowledge of high-precision handling and vision inspection of delicate electronic components. Insertion trials showed high reject rates, indicating the need for Pre Automation Solutions. We completed a Proof-of-Principle test to develop a reliable process to insert the die at high speed. The test demonstrated picking die of various sizes from waffle packs and placing to plastic housings without damage.

The insertion process was then refined to fit into a high volume system to fit production requirements. The success of the solution has led to the delivery of several additional systems for the assembly of multiple product variants. Some key processes included in these systems:

- Die placement to +/- 25 um
- 1-second cycle
- Online vision inspections (presence, position and defects)
- Corona treatment
- Vision guided parts feeding
- Gasket apply
- Cold staking

We have also reduced the number of process equipment required to assemble this product; this additional improvement was the result of closer collaboration and a strong relationship.



### Results:

Our client realized a successful launch of high-volume production with improved manufacturing performance features, including:

- Reduced cycle time by 40%
- Reduced reject rate significantly from early projections
- Reduced floorspace by integration of processes into single machine

In addition, a closer relationship means that new product developments benefit from Design for Manufacturing (DFM) and Design for Assembly (DFA) input and improved design processes are implemented in new and existing equipment.

## Meeting Market Demand: Diagnostic Slide Kit Assembly and Production

*A world leader in Clinical Chemistry Diagnostics approached ATS Automation to develop a high speed, batch driven automation solution to match a quickly rising market demand*



### Challenge:

A leader in chemical diagnostic slide kits wanted to implement a high speed, high precision assembly and packaging automation solution for diagnostic slides to meet an escalating market demand. The client required a turnkey automation solution from MES management to final packaging and shipping. The system required 21 CFR 11 compliance and flawless product traceability verified through full regulatory compliant validation documentation. The clients user environment required common easy-to-use controls and maintenance interfaces.



### Approach:

We worked collaboratively with our customers staff to fully understand the required processes and historical lessons learned. With that knowledge in hand we then custom designed a turnkey solution to fulfill the defined requirements. The solution included:

- Precision high speed product processing and assembly automation
- Multi vendor management
- Third party equipment packaging equipment was integrated
- Controls written by ATS for common functionality as well as look and feel
- Fully expandable controls strategy to allow for future capacity expansion
- Custom MES and recipe management application
- Full product traceability
- Custom database and reporting software for paperless batch and production records
- Full testing and validation documentation and execution
- Embedded on site resources
- Ramp up support



### Results:

The final result was the on-time launch of an automation platform that achieved all of the design goals and requirements. The customer has since further expanded production capacity by commissioning a second system into service.