



# IMPROVING HEALTH TOGETHER

Employee ownership has fostered a highly motivated  
“culture of service” at Hardy Diagnostics.

President, Jay Hardy, discusses disease  
diagnosis and prevention

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“ We are committed to producing and distributing the finest products for the detection of microorganisms, as we collaborate with our laboratory partners to diagnose and prevent disease.”

This is the uncompromising mission of Hardy Diagnostics, whose medical devices have been helping people to live healthier lives for more than 40 years.

With microbiology products used all over the world to diagnose and prevent disease, it is the dedication and skill of Hardy Diagnostics' 450 members of staff, which includes microbiologists, medical technologists, engineers, and biochemists, that has resulted in the fully employee-owned company's remarkable success.

“We are 100 percent owned by the employees that work here. This is called an Employee Stock

Ownership Plan (ESOP), whereby all employees are granted shares in the company each year at no cost,” opens Jay Hardy, President of Hardy Diagnostics.

Jay Hardy comes from a long line of entrepreneurs and business owners. His father, Pat, was an innovative pharmacist for 50 years and was one of the first to implement the drive-up window, mail order prescriptions, and computerized labels on prescription bottles in his drug store.

The company was founded in 1980, but it wasn't until 2012, when Jay Hardy sold the majority of his shares to the employees, that Hardy Diagnostics became an ESOP, a very important and definitive feature for a company that this year is celebrating a decade of being employee-owned.

Only one in every thousand companies in the US is in fact 100 percent owned by its employees. Not only does this unique model

mean that Hardy Diagnostics is exempt from income tax, but it also means that each employee has “a stake in the outcome” and thus tries their utmost to make their company successful.

“Our workers are highly motivated and truly care about the well-being of the company, since there is a direct link between each other's success,” Hardy continues, “I remind them that if they take good care of their company, it will take good care of them.”

In addition, all the Hardy employees, even the part-timers, participate in the company's quarterly profit sharing program, in which it is believed that the profits ultimately belong to the workers that created those profits.

Since all employees need to be kept abreast of the financial condition of the company they own, the accounting team posts all financial statements monthly as part of their Open Book Management program. ■



## **NORTH AMERICA OUTLOOK: WHAT LED YOU TO FOUNDING HARDY DIAGNOSTICS IN 1980?**

**JAY HARDY, PRESIDENT:** “I finished my biology degree not knowing exactly what I wanted to do with it.

“I then heard about Medical Technology (now called Clinical Laboratory Scientist) and moved to Santa Barbara, California for an

internship in the lab at the local hospital there.

“When I finished passing the state board exams and got licensed by the State of California, there were no jobs available locally. However, I wanted to stay in beautiful Santa Barbara, so I decided to go into business with one of my classmates.

“We started out very small with only a handful of customers, one employee, and some horrible equipment in a small, rented space that used to be a motel room. Having eventually acquired day jobs in the laboratory, we did not pay ourselves from our media business for three years in order to sustain our fledgling company until it could stand on its own.”

## **LEADING EXPERTS**

Licensed by the US Food and Drug Administration (FDA) and operating under an ISO 13485 certified quality management system for medical devices, Hardy Diagnostics manufactures over 2,700 products used for the culture and identification of bacteria and fungi, including prepared and dehydrated culture media, reagents, automated slide strainers, and rapid identification kits for microbiological testing in clinical, research, food, and pharmaceutical laboratories. The company also produces products that are used to detect drug resistance in microorganisms in order to assist clinicians in making the correct choices for the appropriate therapeutics to be used on their patients.

Hardy Diagnostics' culture media is the food that supports the growth of bacteria and fungi. Packaged in petri

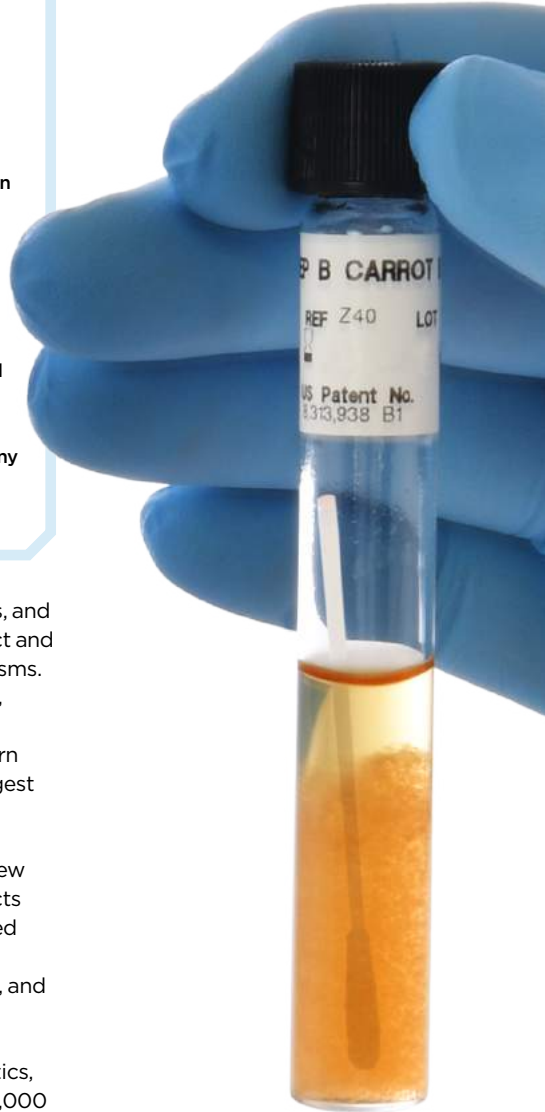


plates, glass tubes, flasks, bottles, and jars, it is used to selectively detect and identify pathogenic microorganisms. As a culture media manufacturer, Hardy Diagnostics is the only company of its kind in the Western United States and is the third largest in the whole country.

From variations of existing designs to the development of new proprietary formulations, products are customized and manufactured using raw materials to provide superior quality, short lead times, and a competitive price.

“We are a medical device manufacturer of *in vitro* diagnostics, and we service approximately 10,000 laboratory customers in the clinical, pharmaceutical, and food and beverage industries,” notes Hardy.

From laboratories that utilize these diagnostic products to employees that own shares in the company, Hardy Diagnostics is truly a group of people coming together to better the world, one test at a time. ■



Further to designing custom products, Hardy Diagnostics evaluates them through manufacturing process validation, failure mode analysis, and a variety of testing services using the latest lean industry tools and standards, to enable its highly trained, cross-functional quality assurance engineers and microbiologists to perform in-house validations.

In conjunction with its extensive library of over 1,000 microorganisms, real-time product stability testing can also be performed to match the intended use of custom products, whilst more sophisticated molecular testing and mass spectrometer methods have been recently launched through strategic alliances.

“We recently entered into an exclusive partnership with a company that has developed exciting new methods for rapid diagnostic testing through PCR technology that utilizes microscopic bar-coded beads,” Hardy reveals.

## **HARDY DIAGNOSTICS' CORE VALUES**

**CUSTOMERS** – Partner with customers to diagnose and prevent disease, and promote healthy living. Provide unmatched service for laboratory customers, supplying them with what they need, when they need it, at a fair price.

**PRODUCTS** – Create dependable products of superior quality, and continuously improve the performance of products and the efficiency of processes. Develop new and innovative products to meet customers' changing needs more thoroughly.

**WORKPLACE** – Nourish a culture of excellence in a beautiful, clean, comfortable and safe workplace, while providing opportunities for recreation, exercise, and social interaction. Support a variety of charitable causes to strengthen and support the community.

**CO-WORKERS** – Encourage personal, mental, and spiritual growth on and off the job, as well as honesty, integrity and a strong work ethic to promote the success of both the individual and the company.

**MANAGEMENT** – Respect and treat all co-workers with fairness and equal opportunities, while recognizing that skills and abilities vary.

**REWARDS** – Share in the financial rewards of business ownership. As part-owners of the company, employees have a “stake in the outcome”, which provides even more motivation to consistently please customers and fulfil Hardy Diagnostics' mission.



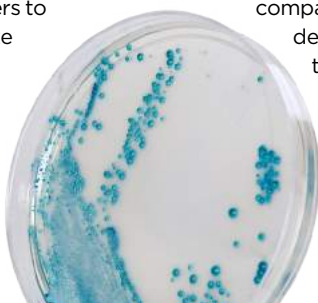


“This allows doctors to diagnose multiple disease states with only one specimen and test method. For instance, someone presenting with symptoms of pneumonia in the ER can be rapidly tested for 17 target bacterial, viral, and fungal microorganisms all at once.”

To help bring other microbiology products to market, Hardy Diagnostics’ technical and regulatory teams are highly specialized in the introduction of diagnostic equipment to the US market thanks to their extensive expertise in clinical trials and knowledge of FDA clearance processes.

Later this year, the company will be launching a new line of automated microscope slide stainers to simplify and standardize the preparation of specimens for microscopic examination.

As a distributor of



items from over 80 other lab supply manufacturers, Hardy Diagnostics is truly a “one-stop-shop” that offers a complete selection of over 13,000 microbiology and laboratory products.

### **STRATEGIC DISTRIBUTION**

Two manufacturing sites, located in the cities of Santa Maria, California, and Springboro, Ohio, are complemented by a network of nine Hardy Diagnostics warehouses across the US, servicing all 48 contiguous states in the country.

Each distribution center is strategically positioned to cover specific states across the country. Altogether, it means that the

company is capable of delivering products and tests to laboratories quickly and cost-effectively, with inexpensive next-day ground service

offered to more than 75 percent of the United States.

“One thing that makes us unique is that we maintain two manufacturing facilities, one in the west and one in the east, to better serve our customers with low shipping costs and reliable sourcing,” says Hardy.

“This also provides our customers with more security in terms of order fulfilment. Our company is large enough to provide the services typical of bigger companies, but small enough to foster personal relationships with our customers and vendors.” ■

Hardy Diagnostics' commitment to having an extensive nationwide distribution network reflects the fact that its products are used every day to diagnose and prevent disease, and that they need to be received quickly in order to effectively treat patients who are ill.

To meet the increasing demand for its products in California and Ohio, Hardy Diagnostics plans to expand its manufacturing capabilities in both states. The company constantly looks for ways to automate its manufacturing operations, with high-speed robotics and automated packaging machines utilized whenever possible.

In early 2016, Hardy Diagnostics purchased QuickSlide™, which manufactures automated slide staining equipment for microbiological and hematological studies. Later, the Wizard™ CompactDry™ Reader was also introduced, designed to read and document CompactDry™ culture media plates for colony counts with an automated color interpretation.

"We are committed to utilizing



lean techniques across the entire company in order to cut waste and increase efficiency. All employees will be trained and certified as either white, yellow, green, or black belts in Six Sigma Lean Techniques, and currently, we are in the process of switching our ERP software to a more sophisticated and efficient platform called EpiCor," Hardy outlines.

### RESEARCH AND DEVELOPMENT EFFORTS

"In the future, we look forward to our R&D department bringing us new and exciting products that we can provide to our laboratory customers, so we can make a continued contribution towards better patient health."

Hardy Diagnostics maintains a 2,300 square foot laboratory dedicated exclusively to R&D, featuring environmentally controlled rooms for carrying out molecular biology studies as well as traditional microbiology. The R&D laboratory is tasked with developing unique products and improving existing ones, as well as researching ways to speed up the reporting of antimicrobial susceptibility studies in

patient specimens.

A number of new products have been launched by the R&D department over the years, including HardyCHROM™ ESBL and CRE, which are used to detect highly drug resistant "super bugs" by colony color. Recently, a new unique chromogenic media was developed to detect an extremely pathogenic and drug resistant yeast called *Candida auris*, which kills about half of its victims.

In 2012, the department also released HardyCHROM™ SS for the detection of both *salmonella* and *shigella* from stool cultures, by utilizing chromogenic substances in the culture media. This patented medium is the first and only one that identifies both of these pathogens and differentiates them from non-pathogens, such as *Proteus*. In the past, time and money was wasted by having to identify non-pathogens that mimic true pathogens.

The company is also very proud of another patented product it invented called Carrot Broth, which detects *Streptococcus agalactiae* (Group B Strep) in pregnant women, so they can be treated during childbirth before they pass the infection on to their newborn babies. Around 25 percent of all women harbor this potentially dangerous organism that can be fatal to a newborn.

"We have a very robust R&D department that is continually involved in seeking new ways to diagnose and prevent disease through innovative technology. In addition, we seek out partners to share in new technologies that we can introduce to the laboratory," says Hardy.

### POSITIVE INFLUENCE

Hardy Diagnostics believes in giving back to the community, and is actively involved in promoting and supporting a variety of local community-based charities and non-profit organizations by donating one percent of its earnings annually.





“OUR WORKERS ARE HIGHLY MOTIVATED AND TRULY CARE ABOUT THE WELL-BEING OF THE COMPANY”

- JAY HARDY, PRESIDENT, HARDY DIAGNOSTICS

During the COVID-19 pandemic, the company also mobilized its efforts in providing the medical community with much-needed swabs, specimen transport media, sanitizers, masks, face shields, and COVID-19 test kits.

Sales came close to tripling in 2020 as a result, and just as impressively, Hardy Diagnostics has turned a profit every year since inception. The company was even a member of the INC 5,000 fastest growing private companies in the US in six separate years.

Consistent growth has been complemented by Hardy Diagnostics' green efforts, the central goal of which is to reduce energy at its facilities and to conserve the planet's natural resources.

An array of green projects have been completed by the company, including the installation of almost 1,000 solar panels across three of its buildings in Santa Maria. It is the city's largest solar project, and provides the majority of power needed for four of its buildings.

“Hardy Diagnostics has been certified as a ‘Green Business’ in recognition of the great efforts we have made to cut waste, conserve water, reduce energy consumption, and promote recycling,” Hardy states proudly.

Medical equipment manufacturing is in capable, sustainable hands with Hardy Diagnostics, whose people have come together to help people live healthy lives and thus better the world. 🌱



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