



Spotlight Interview: Pathnostics' CEO Dave Pauluzzi

Pathnostics, with a main lab in Irvine, California, and a satellite lab in Royal Oak, Michigan, specializes in advanced molecular testing for infectious disease (70% of volume), cancer diagnostics (20%) and Covid-19 PCR testing (10%). A second satellite lab in Orlando is set to open later this year. Pathnostics has a total of 300 employees, including three employed pathologists and six contracted pathologists. *Laboratory Economics* recently spoke with Chief Executive and Co-Founder Dave Pauluzzi.



Dave Pauluzzi

When and why did you start Pathnostics?

I co-founded Pathnostics, along with David Baunoch, PhD, in 2011. The goal was to create a research-driven laboratory that would bring new precision diagnostics to the clinical market.

For example, we currently have 25 employees devoted to R&D and clinical studies. Over the past 5 years we've invested more than \$10 million on clinical research related to our proprietary Guidance UTI test. This research has so far resulted in four completed studies and articles published in six peer-reviewed journals.

Can you describe the development of your Guidance UTI test?

Soon after starting Pathnostics, we identified current testing methods for urinary tract infections (UTIs) as needing improvement. Standard urine culture testing takes multiple days to process and yields a substantial number of false-negative results (30-50%) because of colonization and lack of sensitivity.

Furthermore, while traditional PCR testing for UTIs may be more sensitive than urine culture, it doesn't provide phenotypic susceptibility and thus lacks clinically actionable results.

Our proprietary Guidance UTI represents the next generation in UTI testing. It includes PCR testing for 27 individual organisms, and 3 bacterial groups, combined with genotyping for 32 antibiotic resistance genes and our patented Pooled Antibiotic Susceptibility Testing (P-AST) for phenotypic sensitivity. P-AST is important since bacterial interactions can impact antibiotic susceptibility allowing more informed treatment decisions

There are a total of 38 million UTI patient cases each year in the United States. The target market for Guidance UTI is the subset of 13 million complicated or recurrent cases. These patients are difficult to treat and often cycle through different antibiotic treatments.

How are Guidance UTI test results used?

Guidance UTI helps doctors select the best treatment, out of 19 commonly prescribed antibiotics, for each individual patient. Getting the right prescription, the first time helps reduce UTI-related emergency room visits and hospitalizations.

There are more than 40 antibiotic drugs FDA approved for use in UTIs, including some older antibiotics for which resistance is now significant. We continually monitor guidelines and current practice for the most relevant antibiotics in use, and periodically update the antibiotics used in Guidance UTI. Priority is given to oral and intramuscular antibiotics which are readily available and easily administered in an outpatient setting.

What are your volumes for Guidance UTI?

Since launching Guidance UTI in 2016, Pathnostics has performed 200,000 patient tests on behalf of more than 1,000 Urologists.

What is the list price or range of pricing for Guidance UTI?

We keep our pricing information confidential for competitive reasons.

Has Pathnostics raised money from outside investors?

The company was initially funded entirely by myself and Dr. Baunoch. In early 2019, Water Street Healthcare Partners acquired a 70% stake. I had previously collaborated with Water Street when I was President and CEO of PLUS Diagnostics, which was sold to Miraca Life Sciences in 2013.

How did Pathnostics fare through the worst peaks of the Pandemic?

We had the PCR testing capacity in place, so we were able to ramp up Covid-19 testing early in the Pandemic. At our peak in late 2020, we were performing 100,000 Covid-19 tests per month, including overflow for some of the nation's largest commercial labs.

Pathnostics is currently performing 10,000 to 30,000 Covid-19 tests per month. Our Covid customer base overlaps with our Guidance UTI customer base as we have focused on skilled nursing and long-term care facilities, urgent cares and at-home healthcare organizations.

Have Pathnostics' non-Covid testing volumes bounced back to pre-pandemic levels?

Our volume in infectious disease and cancer diagnostics testing has grown past its pre-Pandemic levels.