CEO CFO

EXPRESS DIAGNOSTICS INT'L. INC.

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Manufacture and Distribution of DrugCheck® for Accurate Drug Detection

Healthcare
Diagnostics

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About Express Diagnostics Int'l
Express Diagnostics Int'l, Inc. (EDI), manufactures and distributes DrugCheck® onsite urine and saliva screening devices for the detection of drugs of abuse, as well as a growing line of rapid alcohol screening and health diagnostics products. With accuracy comparable to laboratory testing, Express Diagnostics onsite devices provide a variety of industries fast, cost-effective alternatives to higher-priced lab services.

All DrugCheck devices are 100% made in the U.S.A. Sold through a worldwide distributor network since 2002, DrugCheck continues to build on its consistent growth in IVD point-of-care testing. Learn more at drugcheck.com.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Mr. Johnson, what is the focus at Express Diagnostics International?
Mr. Johnson: We are an ISO-certified, cGMP-compliant medical device manufacturer. At this time the majority of what we manufacture are rapid drugs of abuse tests and we're bringing more infectious disease rapid diagnostic devices into the picture now. However, to this point, 98 percent of our business has been manufacturing rapid drugs of abuse tests.

CEOCFO: Was that by choice? Was it opportunistic? How did you decide on that area?
Mr. Johnson: It was opportunistic but really some by choice and some opportunistic. I was in the field myself, involved in a toxicology and clinical laboratory. We were distributing these onsite rapid devices back when they were just coming into popularity or becoming available. The quality nature of these onsite or rapid devices were helping them gain credibility, because they were very accurate. We became a large distributor of the DrugCheck brand of tests. They played well into our laboratory business. They drove much or our laboratory business, because they were a 'value add' to our laboratory. The manufacturer that we were buying from could not quite get the manufacturing and the company off the ground and to the next level. They were having some financial trouble. Therefore, opportunity knocked and we took over the manufacturing and the DrugCheck brand and built a business on rapid diagnostics from there. We subsequently sold the laboratory and just went straight into manufacturing of onsite devices.

CEOCFO: What are some of the more common tests and what might be something that people would still be surprised that you are able to test?
Mr. Johnson: The common tests when people thing about rapid drugs of abuse tests are typically the illegal substances; the THC, cocaine and methamphetamines. Those are typical. As for less typical, we are now able to test for a whole range of prescribed drugs: the oxycodones, benzodiazepine, whole opiate classes, whole amphetamine classes and so on. When most people think about drug abuse they are thinking of testing for pot being smoked or coke being snorted, when the majority of the business is now and heading towards controlled substances and the abuse that is happening with those. However, in our company part of our success has been being able to keep up on the drug trends and come out with tests for the latest ones.

Right now the latest thing is designer or synthetic drugs, like K2 or Spice, which just became illegal. It mirrors the effects of THC or marijuana, but it can be 20 to 100 times more potent and actually deadly, depending on the compounds included. We were able to be the first to come out with a test for K2 and that is big. The test for K2/spice has become one of our biggest sellers worldwide.

Clonazepam is another one that we have come out with. It is a benzodiazepine metabolite that cannot be picked up in a regular benzo test, but we have a specific test for it. We continue to invest in R&D so we can

keep up when new designer drugs come out.

CEOCFO: What goes into developing a new test?

Mr. Johnson: From my standpoint, what goes into developing a new test is making sure that we recognize and keep on top of the market and what is happening ahead of the market. Then it is the industry context and the relationships that I have and literally the staff of technical and scientific people that I have that make it happen. In our business it is antibodies and it is the scientific method and being surrounded by your own staff of development people, the contacts, connections and contracted facilities that we have across the world to put into it.

It is the people and it takes the flexibility of a small company to do it. That is what is driving our growth. My company has the flexibility. We have people in our marketing and communications department that are constantly watching drug trends from around the world and seeing what is the latest. Then we put it out to our technical staff and our group of industry experts that work with us and see what we can do and put resources behind it. There is a lot of due diligence and work to get behind it to make sure it is viable, because not every drug that comes up or new synthetic drug presents a widespread problem.

Another big one right now, that I forgot to mention earlier, is that we have developed the first patented test for GHB, the date rape drug. Most people consider GHB just that; the date rape drug. Even our industry competitors have not realized, but are starting to now, that GHB is being recreationally abused. We were a year and a half ahead of that trend. That just comes from having our "ear to the ground." Once we identified the GHB trend, that test was co-developed for us through UCLA.

CEOCFO: What is the geographic range of you customer base?

Mr. Johnson: Right now, our business is 50 percent U.S. and 50 percent international. Seven years ago we were 99 percent U.S. and one percent international. Even just four years ago we were 70/30, now we are 50/50. We have an extensive distributor and wholesale network worldwide for our products. From there they go into the corrections market. They go into employment markets. They go into hospitals and clinics. Our devices are in Fortune 500 and Fortune 100 companies on the employment side. We are in staffing agencies. Our products are in five of the top 10 staffing agencies in the world. They are using our product for their daily testing. We have the military. One big contract that we have internationally is the Government of Israel for their military. We provide all of their rapid drugs of abuse tests. We have the Italian military and all of the military hospitals. We have tests in the Veterans Administration in the U.S., in the Federal Department of Corrections and Federal Drug Courts. Again, major corporations and governmental agencies across the world buy and utilize our tests on a daily basis.

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- Paul Johnson

CEOCFO: Why Express Diagnostics tests?

Mr. Johnson: A big thing that we have done is put an extreme amount of emphasis on quality. It is understood that everyone else in our industry is going to tell you that. However, I say it with a ton of confidence and no fingers crossed behind my back. Our success has been driven by the quality of our products and the relationships that we have built with our customers and them coming to rely on the product.

The more common drug tests and that kind of stuff are really pretty much a commodity item. I am competing doubly with China. Most of the competition comes in from China and, as we know here, it's hard to compete with Chinese product on price. Every last stitch of my product; every material that goes into it is 100 percent U.S. made or procured. That is a big part of it. Our quality standards are such that we've been able to compete with Chinese manufacturers, with a better value proposition than what they can come in at. We do not sell as cheaply as the Chinese, however, we have been able to differentiate ourselves. It comes down to the quality and reliability of the product for customers to know that on a DrugCheck screening test that they can take "that result to the bank" and feel comfortable with the results. Our quality standards coupled with our leadership in developing tests for new drugs have helped us become a leader in this industry worldwide.

CEOCFO: How do you reach your customers in the US? Is it distributors as it is overseas?

Mr. Johnson: We reach them the same way; wholesale. We do very little to no direct business, such as with end users. We don't necessarily go directly to a clinic or a staffing agency. In the medical market, we have got contracts and our product is distributed through one of the largest medical distributors/ wholesalers in the world; as well as McKesson, Moore Medical, Henry Schein, and Cardinal Health. Our products go through them. We have contracts with those wholesalers. We have independent distributors and wholesalers. We also have staff to support those wholesalers and distributors in training on the product for their sales personnel. We drive our business through the wholesale and distributor market on all levels, which allows us to concentrate on volume, manufacturing and shipping a high volume of product. Therefore, we support our wholesalers. They are anywhere from independent, single guys in New Hampshire to the McKessons and Moore Medicals and Cardinal Healths of the world.

CEOCFO: Are there regulatory issues that you need to deal with when you come up with a new test?

Mr. Johnson: Absolutely! Regulatory and FDA clearances are some of our biggest hurdles. We have a stout quality system. I probably spend more money on my quality systems and regulatory department than anything else; more so than even R&D. Based on the regulatory climate in the U.S., even though our device is a Class II medical device and a screening-only device, we are still regulated very heavily. In many cases, we are regulated and audited on the level of a Class III device. Therefore, it is not just a matter of coming up with the test and saying, "We have the science; it kind of works." There is a lot behind that and the regulatory and quality systems, validation, and authorization that go into it before we can even put that test out to the market. It is driven through the FDA and ISO 13485, but more so the FDA. That's because that is the body that says whether or not we can sell the product.

CEOCFO: Would you tell us a little bit about your facility? How are you manufacturing so successfully in the U.S.?

Mr. Johnson: This is the most fun bit that I get to tell and promote. That is because I appreciate coastal cities and major metropolitan areas. However, the reality of it is that our decision came when we opened up and took this over to manufacture. We were looking at the business plan and at the challenge of competing with imported product. It could not be done in a major coastal city. We are in Blue Earth, Minnesota, which is two hours south of Minneapolis and where I could "throw a stone" into Iowa. We are not in Minneapolis or a coastal city. However, by doing that I am in a small community of 4,000 people with many small communities surrounding us. I cannot tell you the number of what my overhead is, but my bottom line is a third less than what it would be almost anywhere else in the world. Our model is successful because we are in a small community in a rural area and we are able to keep our overhead down. We have all of the amenities here that we need. We are near the intersection of Interstate 35 and Interstate 90, which runs through the entire U.S. Most of the largest trucking companies in the world are based within a 100-mile radius of us. Therefore, we are not so remote that we cannot get shipments and move a lot of product out of here in a timely manner. It is just less convenient for air travel in and out of our location. In some cases it is more about recruiting for me to get my high-level talent down here, for example on the scientific, regulatory or operations side of it. However, it is just a little more work. We've been able to recruit some very high-talent people with great experience. In the end, many come to appreciate the living standard in southern Minnesota. It is based on us being in a small rural community. With that said regarding recruiting high-level personnel, I have got the best production staff there is. We have very low turnover. We have very committed and very dedicated people right here in the Midwest. The business model was "Rural USA."

CEOCFO: What you have introduced recently?

Mr. Johnson: The GHB test is a pretty new introduction, which is on the drugs of abuse side. We have introduced some rapid alcohol screening products. We have probably had the greatest success with the introduction of our oral fluid based drug test. When our business started, all of our tests were urine based. We developed and launched an oral fluid based product in 2009. Our DrugCheck® SalivaScan™ has quickly become the leading oral fluid drug test in the world and has been our biggest launch to date.

As far as things that we are preparing to launch or have launched in some markets; we have an anemia, iron deficiency test. This is where we are starting to expand beyond our drugs of abuse market. The AnemiaCheck™ POC Quantitative Hematocrit Test is a new technology. We are taking two or three products in to the veterinarian market right now, one of which is based on that same iron deficiency test. The test was initially developed for human use, but it fits right into the market for veterinary lab tests.

We have another product that will launch later this year, based on a whole new technology. About six months ago we bought a small company out of Colorado. We acquired them for their technology and intellectual property. We are very excited about the products that we are getting ready to launch as result of that acquisition.

CEOCFO: How do you decide on the new areas? You mentioned iron deficiency. Is there a particular design in what you are adding in the new areas?

Mr. Johnson: There is. To be honest with you, the way the iron deficiency test came about was somewhat opportunistic, through my relationships and "nose to the grindstone," trying to see what is the newest technology out there or something that can help propel us. It was iron deficiency, but more than anything it is the technology behind the iron deficiency test, more than the test itself.

The iron deficiency test has great potential worldwide, especially in developing countries. We have established relationships with partners in India and Indonesia to introduce our AnemiaCheck test into their countries. The Surgeon General of Nigeria is also testing our product. Again, it came about because of the technology. The iron deficiency test was the easiest one to develop and get to market on this new technology. The sooner to market, the sooner we have revenue to help drive and develop more tests using the underlying technology. Therefore, that one is more about the technology than the actual test itself. It just so happened that it has a great potential for hundreds of millions of dollars in business that could drive Express Diagnostics to a whole new level. The technology is patented worldwide. We have patents in seven countries on that platform.

CEOCFO: We know that business is good, because you have been on the Inc list. What is next? Why should investors and people in the business

community pay attention? Why does Express Diagnostics stand out?

Mr. Johnson: Express Diagnostics stands out for its innovation, its flexibility within the market and its leadership in the development of new tests and new technology. We've got the flexibility to do that, where the large companies don't. When you get to be a billion dollar company; granted they have R&D departments that are probably 10 times my revenue, but they also lack any flexibility to develop and bring new products and technologies to market. The beauty of Express Diagnostics is the flexibility to do that; the looking for and actively searching for the new technologies, the new products, the new tests; either independently or with our internal and external resources, developing tests and getting them to market and being the first. The larger companies cannot do it. As a result, we've got a lot of "firsts" and we will continue to have a lot of "firsts." That is what is going to drive us. That is why people should pay attention.

In many cases, moving into this new technology is going to help reduce the cost of healthcare. That is because our new technology is going directly after many tests right now on the clinic and hospital level that have to be done on an analyzer. It costs much more money and much more time. Our new technology is going to allow many of those tests to be done in a rapid-test format. That is going to bring costs down. It is also going to significantly reduce the time to wait for the results. We are the first. We are going to be the first. Our path to continued success is our focus on quality, flexibility, and innovation.

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