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The Most Powerful Name in Corporate News

Diagnostics Products from Sample Collection and Preservation to Isolation and Detection

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President and CEO

About Norgen Biotek

Norgen Biotek Corp. is an innovative Canadian biotechnology company focusing primarily on developing best-in-class kits for DNA, RNA, microRNA, and protein purification from all type of specimens, as well as molecular diagnostic and ancillary reagents. Norgen Biotek Corp is an ISO (9001:2008, 13485:2003, 15189:2007 / OLA) certified company and is fully equipped with all the necessary equipment to discover, develop, manufacture and market best-in-class sample preparation kits.

Among Norgen's leading products and capabilities are:

1- Kits to preserve DNA, RNA, microRNA and proteins found in various specimens including blood, saliva, urine, tissue, sputum and stool. These kits are used to collect and ship biological specimens at room temperature.

2- Kits to isolate DNA, RNA, microRNA and proteins from all types of specimens, including blood, saliva, urine, tissue, soil, plant, water etc. Currently, we sell our products to leading researchers in some of the most respected institutions and companies in the world including Harvard, Yale, Stanford, MD Anderson, Johns Hopkins, the Mayo Clinic, Merck, Pfizer, GSK Wyeth and many more. Norgen's products have been widely accepted by the research community, as evidenced by the hundreds of publications that cite Norgen's products.

3- Contract R&D and kit manufacturing services. We have a talented and highly qualified staff, and therefore we offer a number of services to the scientific community including contract R&D, kit development and manufacturing, and sterile liquid filling services in our ISO-certified clean room. Over the past 15 years we have developed hundreds of kits, from the initial R&D stage to the final manufactured product..

Interview conducted by: Lynn Fosse, Senior Editor, CEOCFO Magazine

CEOCFO: *Dr. Haj-Ahmad, what is the concept at Norgen Biotek?*
Dr. Haj-Ahmad: The concept at Norgen is in diagnostics all the way from sample collection and preservation to isolation and detection.

CEOCFO: *What happens day to day at Norgen?*
Dr. Haj-Ahmad: At Norgen, we develop best-in-class products for scientists at universities, biotechnology, pharma as well as diagnostic companies. Also, we manufacture our products. Our products fulfill the needs of scientists all the way from collection to isolation to detection. Diagnostics is moving toward nucleic acid based, be it DNA or RNA. DNA and RNA are not very stable, and therefore samples need to be stabilized/preserved. Traditional stabilization would be to freeze it on dry ice or in a minus 70 degree freezer, so we developed technology to preserve these nucleic acid materials at room temperature using chemistry. We preserve the DNA and RNA in various specimens from weeks to years. For example, we preserve DNA in saliva for over four years, and we have real time data demonstrating the preservation. For RNA, which is more unstable, we preserve it for weeks or months, depending on the specimen.

CEOCFO: *Would these be the new kits that you just launched?*
Dr. Haj-Ahmad: This is the general business at Norgen. We are always trying to preserve, and we always like to preserve specimens at room temperature for shipping since we are living in global village. You should be able to ship specimens from all parts of the world, to specialized laboratories in other parts of the world. Obviously, preserving DNA and RNA is extremely important and shipping on dry ice is problematic. Once a specimen is preserved, scientists want to isolate DNA, RNA or proteins in a very good quality. Therefore, we have all types of isolation kits. We have hundreds of isolation kits to isolate DNA, RNA and proteins from any specimen, preserved or non-preserved. The last part of Norgen's workflow is the

detection. Detection and diagnostic is the same as computers in terms of the idea of "garbage in, garbage out". For diagnostics, if you do not have good clean DNA and RNA, you are not going to have a good sensitive or specific diagnostic result. We have launched products in all three areas; for preservation, for isolation and for detection. That is the workflow of Norgen. The most recent kits we have launched were six novel kits for the isolation of high quality circulating nucleic acid from blood, plasma or serum, and urine. We isolate extremely high quality RNA or DNA from these bodily fluids from a small quantity of specimen. We have recently launched the best kit in the market in terms of diversity of the macromolecules you isolate from 200 microliters of plasma, and you elute in a small volume down to 10 microliters. Our kit is the only kit that can isolate nucleic acid from plasma and elute in such a small volume and retain diversity. That is where we differ from others. Other kits don't offer the same diversity as our kit.

CEOCFO: ***Do the potential users understand the difference in quality at Norgen?***
Dr. Haj-Ahmad: Some of them do. Many of them need to evaluate and compare before they could come to that conclusion. I will give you an example. A scientist that is searching for a lung cancer biomarker in plasma would typically take plasma and isolate microRNA and DNA, and then look for the biomarker. If the technology they are using to purify microRNA misses 50, 60 or 70 percent of the micro molecules for one reason or another, they would miss the biomarker they are searching for. They may not detect the biomarker all together. They may have spent millions of dollars and years to do the screening, and at the end of the day, they came up empty handed. With our new technology, screening these same specimens may lead to the discovery of that biomarker they missed in the first place. I think this is extremely important. It is a breakthrough in my opinion to accelerate discovery of biomarkers in blood.

CEOCFO: ***Do the people who should know about Norgen aware of your products. How do you reach new customers?***
Dr. Haj-Ahmad: Our channel to market and advertisement, at the present time, is limited to attending trade shows. We attend a dozen trade shows per year, and we use email marketing as well as our website. We do not have sales reps in various locations, and we don't spend money on advertisement. In other words, Norgen is in need of expanding its marketing and sales team in a big way.

"At Norgen, we develop best-in-class products for scientists at universities, biotechnology, pharma as well as diagnostic companies. Also, we manufacture our products. Our products fulfill the needs of scientists all the way from collection to isolation to detection."- Yousef Haj-Ahmad, M.Sc., Ph.D

CEOCFO: ***Do you have plans to do so?***
Dr. Haj-Ahmad: Yes, we do. It will take time, and the biggest advertisements come from publications. When scientists try our kit, and find that they could detect 50 percent more from the same specimen than using another kit, they want the kit and they go ahead and publish. Publications are the most powerful tools for publicizing our products. Some of the products are first in class. For example, right now we could take plasma, 200 microliters, and out of those 200 microliters of plasma we can isolate sequentially RNA and DNA. That is powerful. Most people want to isolate only DNA or RNA, but we can isolate both.

CEOFO: ***Why is this the time that you are looking to make a larger push into expansion?***
Dr. Haj-Ahmad: At the present time, I am definitely focused on establishing a marketing and sales team to cover North America. Starting with Canada because we are a Canadian company, we are looking to bring people onboard and actually have Sales Reps in various locations across North America. That is my major objective for moving forward right now.

CEOCFO: ***What surprised you as the company has grown and developed?***
Dr. Haj-Ahmad: The rate of adoption. People still use old technology and will not change easily even though the new technology would give them much more than what they are looking for. For example, if somebody is using an old telescope and looking at the sky, they will see fewer stars and fewer galaxies. Give them the new technology, such as the Hubble telescope, and they will see much deeper into space. That is the kind of analogy I am talking about. The rate of adoption of new technology is pretty slow in the scientific community. Generally, scientists at leading institutions seem to adopt the technology first, so it is no coincidence right now that most of our customers are at leading institutions in North America. We have customers at companies such as Merck, Pfizer, GE, Johnson & Johnson etc. We have customers at universities such as Harvard, Yale, Stanford, etc. We have customers at various institutions such as NIH, Johns Hopkins, Mayo Clinic, etc. These scientists are ahead of the wave. In time other scientists will follow. Thus the rate of adoption is time dependent. It takes time for somebody to use our kit and to produce the data, and finally to publish.

CEOCFO: ***Would you tell us a little bit about your facility?***
Dr. Haj-Ahmad: We do have a state of the art facility. We have a nice, clean building, and we built it specifically custom made for Norgen. We have all the necessary tools and equipment to conduct our work and research. We are located

halfway between Toronto and Buffalo in the Niagara Region. We are in the heart of Niagara, not far from Brock University. As a matter of fact, I see Brock University from my window. We are just 40 minutes from Buffalo and about an hour from Toronto. We have everything we need to do all of our R&D and manufacturing. Norgen is an ISO (9001:2008, 13485:2003, 15189:2007 / OLA) certified company. By the way ISO15189 is equivalent to CLIA labs in the USA.

CEOCFO: *Would you tell us about your student programs?*
Dr. Haj-Ahmad: I have been a molecular biology professor at Brock University for 25 years. I have graduate students and post-docs. In the summertime, we do hire undergraduate students. Currently we have six summer students working at Norgen. Some of them are second year students, and others are third and fourth year students. We select good students and we have many projects to keep them busy.

CEOCFO: *Why take notice of Norgen Biotek?*
Dr. Haj-Ahmad: I think we will be coming with a series of products to fill unmet needs in diagnostics. Diagnostics is extremely important, as you know. In the past, be it Spanish Flu, the plague or any type of pathogen, it wiped out millions of people in the world despite the fact that travel was not really as common as today. In the past, travel was not common, yet pathogens started in one location and spread around the world in a matter of months or years. They wiped out millions of people. Today, we are living in a global village, and people travel around the world constantly all the time on a daily basis. If a pathogen emerges in Shanghai, Hong Kong, or in any part of the world, it can spread very rapidly globally. What is preventing those pathogens from spreading so rapidly? What prevents these pathogens from killing millions of people? The answer is surveillance, detection and diagnostics. That is why rapid diagnostics is very important. With all of this pollution in the world, cancer rates did not increase significantly, why? The reason is because of diagnosis becoming more and more sophisticated, and Norgen is working on a project to do diagnostics for resource limited areas. Nearly three quarters of the world's population are living in resource limited areas; they do not have access to laboratories the same way we do in the US and Canada. So, if you want to do a diagnosis in resource limited areas, you cannot do it on site in a timely manner. Diagnosis for resource limited area should be as good and reliable as that in the most sophisticated laboratory. This is one area we are working on. The second focus is on point of care. Can you do detection on the spot in less than an hour? If we are successful in a resource limited area and point of care, the same technology can be applied for home use. Instead of going to the hospital and clinic to be tested for a given pathogen or cancer, you could do it at home. You could do it at home as often as needed. The most logical way to do these test is non-invasively, i.e. using urine or saliva. We are currently focusing on urine, so we are using urine as a specimen of choice to detect all kinds of pathogens, for application in resource limited areas, home use and for point of care. We are making very good progress on all three areas.

BIO: Dr. Yousef Haj-Ahmad, President and CEO. Dr. Haj-Ahmad has been a molecular biology professor at Brock University since 1989. He is the founder of Norgen Biotek and has been involved in every aspect of the company since its inception. Dr. Haj-Ahmad is the founder and co-founder of several biotechnology companies and brings many years of experience to Norgen. He has served on many prestigious committees such as the "Strategic Research Grants Selection Committee" for NSERC, as Vice-chair and a Board member of OAFT, and has been the recipient of many awards including the Bell Canada Entrepreneur of the Year Award in Technology and Innovation. Dr. Haj-Ahmad has over 25 years of experience in managing and overseeing various projects, including R&D projects, the design and building of Norgen's state-of-the-art facility, and various manufacturing projects including the development of Norgen's Class 5 liquid filling cleanroom and the automation of Norgen's column manufacturing processes.

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