

A Break Through in Diabetes Testing and Monitoring: Exclusive Interview with Asad Zaidi CEO of Epinex Diagnostics, Inc.

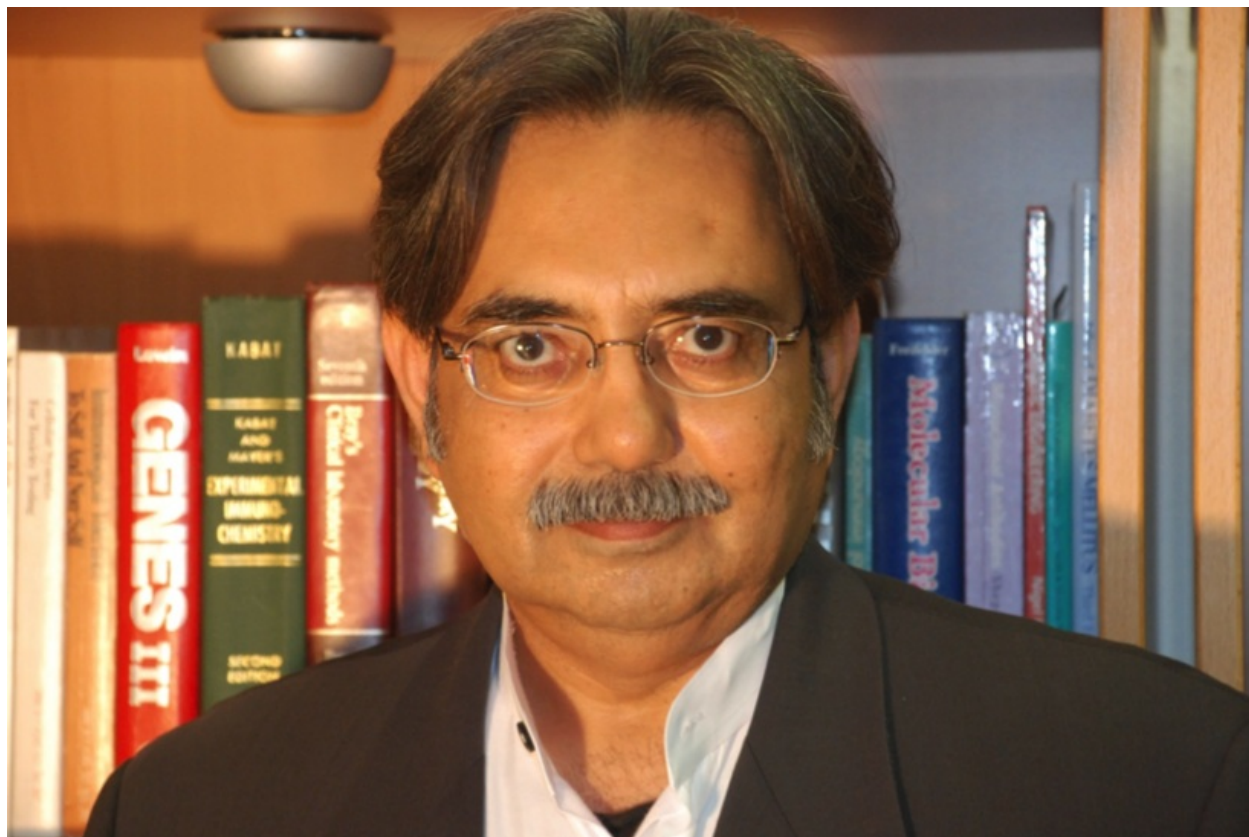
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Not a day goes by without any news on diabetes. It is one the world's most debilitating chronic disease. The number of people with diabetes is estimated to be over 500 Million, and it is increasing at an alarming rate of 9% every year. Diabetes is also rising more rapidly in the middle and low-income countries. It is one of the leading causes of death in the world. More than 100 million U.S. adults are now living with diabetes or pre diabetes, according to a report released in 2017 by the Centers for Disease Control and Prevention (CDC). The report finds that as of 2017, 30.3 million Americans – 9.4 percent of the U.S. population – have diabetes. Another 84.1 million have prediabetes, a condition that if not treated often leads to type 2 diabetes within five years.

Looking for new developments in Diabetes arena and the wake of these harrowing statistics, we found Epinex Diagnostics, Inc., a small company located in the Irvine/Tustin area in Southern California that has been working on a revolutionary idea of testing and monitoring diabetes on a monthly basis. Amazed at this idea, we contacted Asad Zaidi CEO of Epinex for an exclusive interview.



Asad and his team are not new to breakthrough medical technology and research. When he was only 20 years old undergrad student at UCI, his first breakthrough job was to change the entire paradigm of orthopedic industry. He worked on replacing heavy Plaster of Paris, used in the old days to fix bones, by making a light cast of a polymer cured with ultra violet light. Soon after he was involved in inspecting, testing and designing artificial heart valves that were used in first ever artificial heart, Jarvik Seven, implanted in 1982. His work included making one of the most successful artificial lung or oxygenator used in open heart surgeries. His focus changed from medical devices to medical diagnostics which included developing and conducting clinical trials on a rapid test for HIV in the late nineties. This is where he collaborated with Azra Zaidi, an immunology researcher who was involved in making monoclonal antibodies around the time when this technology won the Nobel Prize in 1984. His other cohort Dr. Henry Smith an immunologist, developed one the first CEA (Carcinoma Embryonic Antigen) test for detecting cancer.

All three of these principals of Epinex are now working to change the mindset for testing for chronic diseases like diabetes. Epinex has assembled a distinguished list of Scientific Advisory Board (SAB) members consisting of scientists, researchers, doctors and physicians including Dr. David Horwitz from Johnson and Johnson and Alan Carter of the Kansas Diabetes Action Council. Their research efforts and product development have been recognized by industry analysts like Frost &Sullivan with two awards, in 2009 and 2014. Their scientific papers have been cited copiously, and recently an article has been published in Inflammation Research an internationally renowned journal by Springer-Nature with the help of Dr. Vernon Roohk, another SAB member.



Epinex principals from left - Azra Zaidi (Director R&D), Asad Zaidi (President and CEO) and Dr. Henry Smith (CTO) receiving Frost & Sullivan award in 2014.

Q. So tell us what is Epinex all about?

Epinex is a biotechnology based medical diagnostic company developing simple and rapid POC (Point of Care) tests for doctors' office and for OTC (Over the Counter) where people can use them at home. Initially, we are targeting diabetes and CKD chronic kidney disease. There is a great need to have tests that can diagnose these diseases as early as possible so preventive steps can be taken and to monitor disease progression.

Q. How your test will be different from the glucose meters that diabetics use?

Well to start with most diabetics do not use the glucose meter. There are two types of diabetes Type 1 diabetics who need insulin to control their blood glucose level and therefore need to check their glucose level several times a day using the glucose meter in order to inject the right insulin dose; and then there are Type 2 diabetics who do not need to check their blood glucose levels so frequently because they do not require insulin but instead use other drugs to control their glucose level. It is important to note that Type 2 diabetics make up 90-95% of all diabetes. They still need a test to monitor the disease, but the glucose test is just not the right one for them to use. Lately, there has been a lot of scientific literature out that has started to question the use of blood glucose strips for type 2 diabetics.

EpineX is developing the right test that all diabetics can use. It is based on Glycation or damage caused by sugar to the largest circulating protein in our body called albumin. Our proprietary test is called G1ATM or Glycated Albumin Monitoring Index Test. It is a test that can be taken on a monthly basis because human albumin replaces itself every month. I think this test will have a major impact on the treatment of diabetes.

Q: Why do you think it will be a major impact?

Diabetes is caused by an excess of sugar in the blood. The excess sugar sticks to the proteins in the blood and essentially gum up the works or “glycation.” The more sugar there is, the more the proteins are affected, and this leads to the complications of diabetes. The most abundant protein in blood is albumin and therefore by measuring the amount of albumin that is glycated this gives you a direct measurement of the amount of damage that is occurring. So if you have a lot of glycated (i.e., damaged) albumin and this goes on long enough, then you will eventually get the clinical signs of diabetes... and this is something you don't want. That's why we believe our test is needed. It provides an early warning to encourage people to make the lifestyle changes and not get diabetes.

The test is also needed to monitor disease progression in people who are already diabetic. It will tell you if the treatments such as drugs and a change in lifestyle are working or not. This means that the treatments can be adjusted before the clinical condition worsens. These are the reasons why we believe our test will make a major difference in the prevention and treatment of diabetes.

Q: How the test will be used?

The test will have a disposable cassette, and a hand-held reader device similar to a blood glucose meter, and it will require a simple prick to get a blood sample. The test device will also interact with a mobile app on your cell phone where the results can be tracked on a monthly basis.

Q: What is the status of this test?

We are anticipating that our test should be in the clinical trials within a year permitting financial resources.

Q: How are you funded?

We have funded ourselves through private investors and now seek institutional investors.

Q: Do you have patents?

Yes, we have several patents granted in the USA as well as in other countries like Japan, Europe, and China.

Q: What other products are you planning to introduce.

We have recently been granted a USA patent for the first ever handheld test for CKD (chronic kidney disease) we are planning to launch this product next year. This will be a simple test for ACR or (Albumin Creatinine Ratio) which is used to detect CKD.

Q: What is your vision for Epinex?

Our vision is to empower people by providing them with simple diagnostic tools and applications to improve their wellbeing. We hope to make G1A a monthly test for diabetes diagnosis, screening and monitoring a standard of care in medical practice and same for our ACR test for CKD.