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DIAGNOPTICS' AGE READER RECEIVES CE MARK

Powerful Tool for Cardiovascular Risk Assessment Now Available to European Clinicians and Researchers

Groningen, The Netherlands - May 5, 2006 – DiagnOptics B.V. has received the CE Mark approval in Europe to market its *AGE Reader*, a non-invasive tool to help physicians to assess cardiovascular risk. CE Mark approval is required for marketing within Europe and was granted by the Dutch Notified Body KEMA. This clears the way for immediate commercialization of the *AGE Reader*, which is designed to provide clinicians and pharmaceutical/medical researchers with comprehensive, easily and quickly obtainable data for making better clinical decisions.

The *AGE Reader* is a medical device to estimate cardiovascular risk. The *AGE Reader* non-invasively assesses the accumulation of advanced glycation endproducts (AGE's) in the patient using autofluorescence of the skin with ultraviolet light. AGE's have a pivotal role in the development of chronic complications of diabetes and other common conditions. The amount of AGE in tissue serves as an important risk predictor of such complications.
The non-invasive measurement immediately offers valuable additional information, comfortably and safely for your patient and you. The *AGE Reader* has been validated in several large-scale, clinical trials over the past 6 years involving 1000s of adults.

The *AGE Reader* advantages
The main function of the *AGE Reader* is to give the physician information on the amount of advanced glycation endproducts (AGE's) in the patient's tissue. AGE's are key players in glycemic and oxidative stress, and have been shown to be an important indicator of the cardiovascular risk. The information from the *AGE reader* can assist physicians in focussing treatment on patients with the highest risk on complications. This includes patients suffering from diabetes mellitus, renal failure, but also acute disorders like acute coronary syndromes and sepsis.
Ideally physicians need measurements that take little time, are easy to use and provide immediate results. The *AGE Reader* meets all of these demands.

- non invasive and thus easily tolerated, safe and comfortable for patients
- quick; measurement and its results within 30 seconds
- easy to use, not operator-dependent; in clinical studies it was operated by non-specialized nurses.
- clear evidence that the result adds prognostic information to that obtained from conventional risk factors and risk scores

The *AGE Reader* software enables the user to operate the device and save, analyse and export the measurements.

The *AGE Reader* has been evaluated in several large-scale, clinical trials over the last few years involving 1000s of adults, more than 1000 with diabetes. The clinical studies demonstrate that DiagnOptics' non-invasive *AGE Reader* effectively measures AGE's and have confirmed its value as a strong and independent risk predictor for mortality and cardiovascular events.

Cardiovascular risk
Cardiovascular disease is by far the most important cause of mortality and morbidity in the western world and responsible for the majority of health care costs. Prevention of cardiovascular disease is thus essential. To do so, we need to identify those at highest risk by early detection and treatment of risk factors. These include smoking, high blood pressure and cholesterol, diabetes mellitus and obesity. However, current risk assessments and treatment decisions based on them, are far from perfect: many without these risk factors will still die from heart attacks, and not all persons treated for risk factors may actually benefit.
The *AGE Reader* will contribute with a novel approach in risk stratification, and so help in focussing and tailoring treatment.

What is already known about AGE's and their important role in disease?
AGE's accumulate with age in normal man, but this process occurs more rapidly in patients with conditions like diabetes mellitus and renal failure. Accumulation of AGE's is considered to have a pivotal role in the development of chronic complications of these conditions; Skin AGE's, determined in skin tissue samples, not only correlate closely with early kidney, eye and nerve disease in patients with diabetes mellitus, but also predict these complications. And AGE's or not just passive bystanders: they bind to proteins and lipids and affect their structure and function: they make for example vessels stiffer and less elastic.

New drugs, aimed at prevention of formation of, or breaking AGE's are currently being developed. Other, common drugs like angiotensin receptor blockers also prevent AGE formation.

Measuring AGE's
Until now it has been complicated to measure tissue AGE's in patients because existing methods are expensive, time consuming, lack specificity, are poorly reproducible and/or are invasive. There is currently no gold standard for AGE measurements.
The *AGE Reader* is the answer to the need for measuring AGE's without the disadvantages of the existing methods.

About DiagnOptics
Founded in 2003, DiagnOptics is a privately held company that develops and provides products for the assessment of cardiovascular risk. The company's offerings, based on proprietary, field-tested technologies, have the potential to improve the care of patients with increased cardiovascular risk. On the internet: www.diagnoptics.com

For information on the AGE Reader and the availability in your country, please contact us by email b.vandenberg@DiagnOptics.com *or phone +31 505890612***.**