

RHEOSCAN

Diabetic Complication Screening Assay

Hemorheology Test

Assessment of Deformability, Aggregation, and Critical Shear Stress of RBCs Innovative technology of diabetic complication screening assay



Innovation In Healthcare Diagnostic Screening device Point of Care Technology RheoScan Early detection of diabetic complications

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POCT





Global impact of Diabetic Complications

Diabetes is a condition in which blood sugar is too high, which interferes with the flow of blood, causing several complications. Fatal diabetic complications, such as blindness, foot necrosis, and kidney failure, can also lead to death if not properly treated.

Diabetic Complications



Diabetic Kidney Disease (DKD)

The kidneys are blood vessels in which capillaries are intertwined. 20 ~ 40% of diabetic patients suffer from kidneys disease. Once kidney fail, dialysis or kidney transplantation is necessary.

Current diagnostic methods

Estimated Glomerular filtration rate (eGFR) Urine Albumin to Creatinine Ratio (UACR) First morning urinary albumin concentration Timed urine collections for albumin excretion rates



Diabetic Retinopathy (DR)

Diabetes has a huge impact on eye health. Severe diabetes can lead to vision loss or blindness. According to one study, people with diabetes have a 20-fold increased risk of blindness compared to healthy people. Diabetic retinopathy develops in 50% of patients who have been diabetic for 10 years.

Current diagnostic methods

Fundus examination Mydriatic ophthalmoscopy



I Metabolic Syndrome (MetS)

Metabolic syndrome is a set of abnormal conditions, such as increased body fat, increased blood pressure, increased blood sugar, and abnormalities in blood lipids, which increase the risk of cerebral cardiovascular disease and diabetes. People with metabolic syndrome have more than double the risk of cardiovascular disease and have a 10-fold increase in diabetes.

I Current diagnostic methods

Abdominal Obesity / Hyperneutral Lipidemia / Low HDL / High Blood Pressure / Blood Sugar Disorder



It is highly important to screen before symptoms occur. Early detection, timely treatment, appropriate follow-up care can reduce the risk of severe symptoms .



Who is at Risk?

• Anyone with diabetes mellitus

| Diabetic Complication

- No early symptoms
- · Losing chance to recover
- No screening test available

The Best Treatment starts with Early Detection

RheoSCAN supports early screening. Make RheoSCAN system your new health check up.



 RBC deformability RBC aggregation







I Alteration of hemorheological properties comes first prior to diabetic complications

RheoSCAN as a Point of Care Technology

The best treatment starts with early detection

RheoSCAN system

RheoScan Measures

(1) RBC deformability(2) RBC aggregation

Associated Pathologies

- Diabetic Kidney Disease
- Diabetic Retinopathy
- Metabolic Syndrome





Impaired RBC Deformability leads to hypoxia

RBC **deformability** plays a critical role in blood circulation. Healthy RBCs have to pass through capillaries whose diameter is smaller than their size.

Decreased red blood cell deformability results in **hypoxia** due to decreased oxygen delivery capacity in blood vessels.



Hyper-aggregated RBCs result in vascular diseases

RBC **aggregation** is one of the key factors in determining blood flow resistance in microcirculation. Healthy red blood cells are easy to disaggregate and enter small vessels in an efficient manner, whereas hyper-aggregated red blood cells do not dis-aggregate and causes **local hypertension**, **vascular sclerosis, and hypoxia.**

Patients with DM have hyperglycemia and elevated fibrinogen, which leads to alterated **RBC deformability** and **aggregation**.

| Diabetic Complication Screening Device : RheoScan

Easy Operation	Fast results	High Precision & Reliability	Small sample needed	
One step pipetting	Rapid test, Instant results	Excellent screening	Small sample of whole blood	
One-touch operation	1 Deform. : 30 sec	Clinically approved	(1) Deform. : 6 μl	
Fully-automated	2) Agg. – I (CSS) : 20 sec	High repeatability	② Agg. – Ⅰ (CSS): 0.5 mℓ	
	③ Agg. – II : 120 sec		3 Agg. – Π: 8 μl	

Standard comparison



Deformability comparison between healthy control and diabetes group.

The early detection of diabetic complications

Diabetic Complications



Alteration of deformability and aggregation of RBCs can be **detected with RheoScan** system at earlier stages of diabetic complications



Critical Shear Stress (Aggregation – ${\rm I}$) comparison between healthy control and diabetic / Hyper aggregation group.

RheoSCAN system

Clinical Test Results

| Clinical analysis



Diabetic complications have been reported to significantly decrease in RBC deformability compared to the healthy group.



RBC deformability yields a strong correlation with glycated hemoglobin.





DM complication shows significantly elevated RBC aggregation compared to healthy controls and Pre-DM groups.



RBC aggregation also yields strong correlation with estimated GFR.







Critical shear stress(CSS), representing RBC aggregation can identify the diabetic kidney diseases classified with urine ACR.



		Systolic BP	Waist circum	HDL-C	Triglyceride	Fast glucose
CSS	r	.383	.419	459	.591	.200
	Р	.000	.000	.000	.000	.049





Leading-edge Technologies

| Microfluidics and laser optics meet Hemorheolgy

The Rheoscan System is an innovative technology to measure RBC deformability and aggregation with adopting leadingedge microfluidics and laser optics.

DEFORMABILITY AGGREGATION - I (CSS) AGGREGATION - II Microfluidics / Laser-diffractions / Image-processing Microfluidic Shearing / Light Backscattering / Data-processing Microfluidic Stirring / Light Transmission / Data-processing

Operating Principles





0 T_{half} 10

Time (s)

120

DEFORMABILITY (EI)

- A blood sample is driven by a vacuum pressure, which is automatically decreasing with time.
- •While the sample flow through a microchannel, laser light irradiated to the blood sample forms a diffraction pattern, which is an average shape of RBCs.
- The shear stress of sample flow and diffraction pattern are simultaneously recorded and analyzed.

AGGREGATION - I (CSS)

- A blood sample is driven by a vacuum pressure, which is automatically decreasing with time.
- •While the sample flow through the microchannel, a laser irradiated to the blood sample and part of it is backscattered and collected on an optic detector.
- The flow shear stress and light intensity are simultaneously recorded and analyzed.

AGGREGATION - II (AI)

- A blood sample is sheared with a stirrer for 10 s and RBCs are completely disaggregated.
- •With sudden stoppage of the stirrer, RBCs tend to aggregated, immediately.
- •A transmitted light through the sample is recorded with respect to time and analyzed.

Specifications

Instrument



Rheoscan system must be connected to the computer to operate and the program / user manual will be provided.

Consumables



The test kit (RSD-K01, RSD-K02) and test chip (RSA-C01) are disposable kits consisting of a sample chamber, a micro-channel, a waste sample chamber, and a rubber cap. These test kits are made of transparent plastic, which are disposable after use. This disposability makes it possible for the Rheoscan System to be used in clinical environments. The test kits is intended for single use only.

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Magnet rotatin

Laser dio

RheoSCAN-AnD 300



Deformability	Aggregation-I (Critical Shear Stress)	Aggregation-II	
$6\mu\ell$ whole blood, $600\mu\ell$ PVP	$0.5 \text{m}\ell$ whole blood	$8\mu\ell$ whole blood	
30 s	20 s	120 s	
EI, SS½, EI _{MAX}	$ au_{\rm c}$ (Critical shear stress)	AI, M, t _{1/2} , Amp, t _{fast} , t _{slow}	
RSD-K02	RSD-K01	RSA-C01	
Microfluidics, Laser Diffraction	Micro-stirring, Light Backscattering	Micro-stirring, Light Transmission	

RheoMeditech Inc. -



RHEO Meditech

RheoMeditech Inc. is a leading manufacturer of wide range of in vitro diagnostic analyzers, test kits, and consumables. Our line of instruments and test kits are specially designed to elevate the best performance to hospitals and laboratories. RheoMeditech offers early screening and diagnostics that provide health care professionals to make better decisions. With greater trust, we can help people achieve better health through our early diagnosis systems with innovative technology. The best treatment starts with early detection.

Certificate



References



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