



savyonDIAGNOSTICS

member of the gamida diagnostics division

NEW

Haptoglobin Typing Test



CE IVD



A novel ELISA test for Haptoglobin type determination in diabetic patients, which is directly associated with the risk of developing cardiovascular complications

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In diabetic patients, Haptoglobin type is directly associated with the risk of developing cardiovascular disease and end-stage renal disease

The public health burden of cardiovascular and renal complications from Diabetes Mellitus (DM) is over \$100 billion per year in the USA alone and the problem is increasing. Medications to treat these complications are extremely expensive and require lifetime use. The purpose of this diagnostic test is to provide a once in a lifetime test that will indicate whether a particular DM individual is at high risk for these diabetic complications and may benefit from Vitamin E supplementation. **Savyon Diagnostics** is offering a novel ELISA kit intended for rapid and simple Haptoglobin (Hp) Typing. This test will give the patient and the physician information as to which of the three Hp types the patient has- Hp 1-1, Hp 2-1 or Hp 2-2.

Eleven longitudinal studies in diverse ethnic groups have demonstrated that DM individuals (both Type I & Type II) with the Hp 2-2 genotype (35% of all DM individuals), have a 2-3 fold increased risk of developing cardiovascular disease and end-stage renal disease as compared to Hp 2-1 and Hp 1-1 DM individuals. On the basis of this information the risk of diabetic complications is assessed, and decided whether the patient may benefit from vitamin E supplementation to assist in preventing these complications (see text-box below). Clinical accuracy of the test was determined and validated in over 8000 individuals with Diabetes from seven different clinical studies.

Should Vitamin E be Given to Individuals with Diabetes? It Depends on your Haptoglobin Type



Recent studies suggest that in Hp 2-2 DM individuals, vitamin E reduced myocardial infarction and cardiovascular death by 43% and 55%, respectively. In the ICARE study, approximately 1500 DM individuals with the Hp 2-2 genotype were randomized to vitamin E or placebo. One year after initiating the study, the primary composite outcome of cardiovascular death, stroke and myocardial infarction was reduced by over 50% in Hp 2-2 DM individuals receiving vitamin E compared to placebo. Therefore these data suggest a pharmacogenetic algorithm whereby all individuals with DM would be tested for the Hp genotype and vitamin E prescribed only to those with the Hp 2-2 genotype.

Clinical Performance of the Kit:

n = 8046	Hp 2-2 (%)	Hp 2-1 (%)	Hp 1-1 (%)
Sensitivity	99.0	97.4	92.8
Specificity	98.1	97.7	99.8
PPV	97.5	97.2	98.8
NPV	99.3	97.9	99.0

Taken from reference 17.

Features:

- Simple** – ELISA test, no need for electrophoretic analysis
- Rapid** – 1 ½ hours to process up to 92 samples
- Accurate** - High sensitivity, specificity, PPV & NPV (see clinical performance data)
- Clear** - Simple interpretation of results.
- Versatile** - Only 15 µL of serum or plasma are required
- Automated** – Compatible with ELISA automation

Ordering Information:

Test Name	Tests/kit	Catalog No.
Haptoglobin (Hp) ELISA	96	A-710-01M



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