

AspirinWorks[®] Test Frequently Asked Questions

Q. What does the AspirinWorks[®] Test measure?

- A. When an individual's blood platelets become activated, they release a chemical called thromboxane A₂ (TxA₂) into the circulation that activates additional platelets and causes them to stick together, eventually forming a blood clot under the right conditions. The TxA₂ breaks down to the biomarker called 11-dehydro thromboxane B₂ (11dhTxB₂) and is excreted in the urine. The AspirinWorks[®] Test measures the level of 11dhTxB₂ in urine thus reflecting the amount of thromboxane production in the blood. Urine 11dhTxB₂ levels are lowered in individuals who respond to aspirin therapy.

Q. What does the CHARISMA trial mean for the AspirinWorks[®] Test?

- A. This clinically validated medical research could potentially change how millions of people worldwide are tested for aspirin effect and treated to prevent heart attacks and strokes. Findings from the CHARISMA trial, published in the October 21 issue of the peer-reviewed medical journal *Circulation*, directly link the level of the 11dhTxB₂ biomarker to an individual's risk of heart attack and stroke. The AspirinWorks[®] Test is the world's only non-blood-based test available to doctors who want to test for aspirin effect.

Q. Is the AspirinWorks[®] Test FDA cleared?

- A. Yes, the AspirinWorks[®] Test was FDA cleared in May 2007 and can be run routinely in a hospital or reference laboratory. It is covered by Medicare and most major health insurance providers. It is available nationwide through physicians offices and directly to consumers through HealthCheck USA.

Q. What makes the AspirinWorks[®] Test different?

- A. Unlike other tests for aspirin resistance, which require freshly drawn blood that must be evaluated within at least four hours, the Corgenix AspirinWorks[®] Test is non-invasive, easier to administer and not affected by sampling technique. Not only does the test result demonstrate the presence or absence of an aspirin effect but the level of the measured metabolite has been proven to reflect the risk of a future stroke, heart attack, or even death due to a cardiac event.

Q. Why is the AspirinWorks[®] Test important?

A. Medical studies indicate that not everyone benefits equally from low dose aspirin. In fact some people have been reported to be resistant to the effect of aspirin, but new studies indicate that it may be a question of aspirin therapy “failure.” Because aspirin is known to reduce the risk of heart attack and stroke by helping to prevent platelets from sticking together, the AspirinWorks[®] Test allows the doctor to determine if the patient is benefiting optimally from his or her aspirin regimen.

Q. What are the chances that a person’s platelets are not responding to aspirin?

A. According to reports in the medical literature, 10% to 40% of patients taking aspirin may not achieve the desired result. In fact, even if aspirin is working on platelets, there are other factors that may interfere with the benefits of aspirin. Traditional platelet function assays cannot detect these factors.

Q. What are the dangers if the patient is not benefiting from aspirin?

A. Numerous outcomes studies, including new findings from the prestigious CHARISMA trial, have demonstrated that patients with a poor response to aspirin therapy have a higher incidence of second heart attacks, strokes or even death than patients with a good response.

Q. Why shouldn’t a patient just take more aspirin?

A. Increasing aspirin dose may cause an increase in unwanted side effects, such as stomach discomfort or gastrointestinal bleeding. More important, the aspirin may be doing its job, but some other factor may outweigh the beneficial effects, which could require a change in therapy. Only a physician should decide if it is safe to change aspirin dosage.

Q. How long should a patient wait to be tested after beginning aspirin therapy?

A. According to the literature it takes up to five days for low-dose aspirin therapy to achieve maximum reduction in urinary 11dhTxB₂ levels.

Q. How often should a patient be tested?

A. The optimum frequency of testing has not been established. Clinical studies indicate that certain individuals lose the benefit of aspirin therapy over time due to atherosclerotic disease or increases in cholesterol.

Q. What should a physician do if a patient's result indicates a poor aspirin response?

A. Any change in treatment is at the discretion of the physician. However, the recently published CHARISMA trial results indicate that

1. Not all patients receive the same protective benefits from low-dose aspirin therapy

2. The thromboxane metabolite 11-dehydro-thromboxane B₂ (11dhTxB₂) is an independent, modifiable predictor of risk for stroke, heart attack and cardiac death

3. Higher levels of urinary 11dhTxB₂ are associated with as much as a four fold increased risk for adverse cardiovascular events or death

4. Statin treatment is associated with lower concentrations of 11dhTxB₂

Current recommendations for low-dose aspirin therapy include 81, 162 or 325 mg/day. It is important that the physician and the patient recognize that an increased level of 11dhTxB₂ may be an indication of increased risk of atherosclerotic disease or secondary cardiovascular events.