Indiana Spine Group

Fact Sheet
ScoliScore™ AIS Prognostic Test

About ScoliScore

- ScoliScore AIS Prognostic Test is the first and only genetic test to predict the likelihood of curve progression of Adolescent Idiopathic Scoliosis (AIS), the most common form of scoliosis in children.
- This test utilizes a saliva sample, obtained from the patient in the physician's office. This DNA sample is sent to the lab where it takes up to three weeks to process.
- The saliva sample is analyzed and compared to genetic markers that are linked to the risk of severe spinal curve progression in patients with AIS. The results are then converted into a risk of progression score that indicates low, intermediate or high-risk of curve progression.
- In combination with other diagnostic information, the ScoliScore Test results can reduce the frequency and/or extent of physical examinations and X-rays for patients considered low risk.
- In the design of this genetic test, scientists collected data from more than 10,000 patients in more than 100 clinical sites around the world and discovered that there are 53 genetic markers in human DNA that can be associated with severe curve progression (> 40º) in AIS patients. Researchers utilized this information to create the ScoliScore Test by developing an algorithm that assigns a risk of progression.
- Test scores range from 1 – 200 in patients already diagnosed with AIS indicating the risk of curvature progression. Patients with a score of 1 –50 are identified as low-risk, scores of 51 –180 are identified as intermediate risk and a score of 181 –200 identifies patients as high risk.
- ScoliScore is indicated for Caucasian boys and girls between the ages of 9 and 13, who have already been diagnosed with mild AIS. Patients receive a risk of progression score that provides the likelihood of whether the scoliosis curve will progress to a severe degree of > 40°.
- The SCOLISCORE Test was developed by Axial Biotech, Inc. and is marketed and distributed by DePuy Spine, Inc. and Smith & Nephew, Inc.

About Scoliosis

- Scoliosis is a condition that causes an abnormal curvature of the spine that may lead to chronic back pain or reduced respiratory function.
- Scoliosis affects 2–3% of the U.S. population, about seven million people. The most common form is Adolescent Idiopathic Scoliosis (AIS) which affects children mainly between the ages of 10 and 15.
- Girls are eight times more likely than boys to progress to a curvature requiring treatment, and the incidence increases by 20% if an immediate family member has scoliosis.
- It is recommended that females be screened twice, at age 10 and 12, and males once at age 13 or 14. Scoliosis is rarely painful, and a mild curve is usually unnoticeable by an untrained eye. Signs of abnormal curvature include uneven shoulders, ribs, hips or waist; back pain; one arm hanging lower than the other; a shoulder blade sticking out; or changes in the appearance or texture of the skin overlying the spine.
- The standard screening used in schools and pediatrician offices is the Adam's Forward Bend Test, in which the patient leans forward with their feet together and the spine is evaluated. Scoliosis is confirmed by a physician through physical exams, spine X-Rays, MRIs and scoliometer (device measures spine curvature) measurements. The curve is measured by the Cobb method, in which lines are drawn over the spine to determine the severity by number of degrees.
- Most scoliosis is mild or moderate and generally does not require surgical treatment. However, the condition can progress in one in four patients, requiring treatment such as physical therapy, back bracing and for some, spinal fusion surgery.

For more information, call (317)228-7000 or visit http://www.scoliscore.com/.