



Frequently asked questions for the ScoliScore™ AIS prognostic test



Q: What is the ScoliScore™ test?

A: The ScoliScore™ is a clinically validated, multi-marker test that provides a qualitative and quantitative assessment of the likelihood of spinal curve progression for patients who have been diagnosed with AIS. The ScoliScore™ is leading the way to individualized scoliosis treatment by providing patient-specific information that is used to help health care providers optimize treatment plans.

Q: How does the ScoliScore™ test work?

A: The ScoliScore™ AIS Prognostic Test analyzes DNA extracted from a saliva sample and compares genetic markers that have been linked in clinical trials to the risk of spinal curve progression. The more genetic markers that there are, which indicate a high risk of curve progression, which are linked to curve progression, the higher the score will be. The results of the analysis are then put into a mathematical equation to convert those measures into the ScoliScore™ Curve Progression Score. The score is set in a range from 1-200. This range has then been further broken into categories: Low, Medium, High, that refer to the likely risk of curve progression among adolescents with mild scoliosis between the ages of between the ages of 9-13 years.

Q: When should the ScoliScore™ test be used?

A: The ScoliScore™ test is appropriate for adolescents between the ages of 9-13 years who have recently been diagnosed with Adolescent Idiopathic Scoliosis. The ScoliScore™ test is performed on a saliva sample obtained in a physician's office. Ideally the test is performed when scoliosis is first diagnosed. The ScoliScore™ test can help determine the most appropriate treatment for each individual patient.

It is important to know that currently the ScoliScore™ test is only for patients diagnosed with Adolescent Idiopathic Scoliosis (AIS). If you were diagnosed with Scoliosis several years ago, and do not know the type of Scoliosis you have been diagnosed with, check with your doctor and ask whether ScoliScore™ would be appropriate for you.

Q: What are the benefits of the ScoliScore™ test?

A: The ScoliScore™ test provides a Curve Progression Score™ result that assigns a numerical value of the likelihood of AIS curve progression that is specific to each patient. This result corresponds to the likelihood of mild, moderate, or severe curves—among adolescents between the ages of 9-13 years. The test report delivers information for both physicians and patients with AIS that may improve their confidence that treatment planning will be based on an understanding of each individual patient's disease characteristics.

Q: Is the Scoliscore™ right for me?

A: If your child has recently been diagnosed with Adolescent Idiopathic Scoliosis and have not yet begun a treatment regimen, the Scoliscore™ test may be appropriate for you. However, the decision to use the Scoliscore™ test is one that you and your doctor should discuss and make together.

Q: Can the Scoliscore™ test be used for other types of Scoliosis?

A: The Scoliscore™ test is intended only for patients who have been diagnosed with Adolescent Idiopathic Scoliosis. It is not intended for patients who have been diagnosed with Congenital, Infantile, Juvenile, Syndromic, or Adult Scoliosis.

Q: How do I get the Scoliscore™ test?

A: The Scoliscore™ test can only be ordered by an authorized healthcare professional, typically a spine specialist.

Q: How long will it take to get the results of the Scoliscore™ test?

A: It will typically take 2-3 weeks from the date the DNA sample is received by Axial Biotech Laboratories for the results to be available. The Scoliscore™ report form is sent directly to the physician who ordered the test. Your physician will explain the test results to you.

Q: What are the results of the Scoliscore™ test?

A: The Scoliscore™ test provides a Curve Progression Score™ result that assigns a numerical value to the likelihood of a scoliotic curve progression. This result corresponds to the likelihood of mild, moderate, or severe curves—among adolescents between the ages of 9-13 years. This test adds information beyond the traditional factors your physician considers when evaluating you.

It is important to note that a Low Curve Progression Score™ result does not mean that there is no chance that an Adolescent will have some curve progression. Instead, the Curve Progression Score™ provides information about the likelihood of curve progression—it cannot determine with 100% certainty that there will be no curve progression.

Q: Will the Scoliscore™ test results tell my doctor which treatment to use?

A: The results of Scoliscore™ can help your physician understand how likely it is that your curve will get worse. The test will not specifically identify which treatments to use. The results of the Scoliscore™ test should be used with other diagnostic information to help you and your physician determine which treatment option is best for you.

Q: What type of sample is needed to perform the ScoliScore™ test?

A: The ScoliScore™ process is performed using a very small sample of DNA collected from a saliva sample during a physicians' office visit. This means that you will NOT need to have blood drawn in order to have the ScoliScore™ test. The physician or nurse will ask you to spit into a plastic tube which is part of a special kit used to submit the saliva sample to the Axial Biotech Laboratory for analysis.

Q: Will I need to pay my physician for the ScoliScore™?

A: The ScoliScore™ test will be billed directly to your insurance company by Axial. There are no costs to the physician's office.

Q: Is the ScoliScore™ test covered by insurance?

A: Because this is a new technology, most insurers have not yet established coverage policies. The Axial Biotech Reimbursement Team will help you verify whether your insurance covers the test and help you through the entire reimbursement process.

Axial Biotech's Pre-Authorization Program is designed for U.S. Citizens and Legal Residents. This program can assist you by:

- ▾ Determining whether your insurance plan is likely to cover the laboratory testing
- ▾ Obtaining prior authorization, if required
- ▾ Submitting your claim
- ▾ Supporting you through the appeals process if your claim is denied by your insurance company
- ▾ Please note that you may be financially responsible for some or all of the cost associated with the test. If your insurance carrier does not cover some or all of the cost of the test, you can request Financial Assistance from Axial Biotech in setting up a payment plan.

Q: What if I don't have insurance or I am under-insured?

A: Axial Biotech believes that every patient for whom their physician believes this test is medically necessary should have access to the ScoliScore™ test. Axial Biotech is proud to offer the following programs to make this possible:

- ▾ Uninsured patient assistance / economic hardship
- ▾ Financial assistance for qualified under-insured patients
- ▾ Payment plans to meet your financial needs

For more information, please contact Axial Biotech's Reimbursement Team at 877-294-2598.

Q: How do I qualify for the financial assistance plan?

A: Axial Biotech understands that being financially responsible for some or all of the cost associated with the ScolioScore™ test may be a financial burden. The company offers financial assistance plans to help. The plans take into account your income and financial obligations such as house or rental payments, car payments, children's education, medical expenses, and other qualifying expenses. Financial assistance is NOT intended for only those with low incomes.

For more information, please contact Axial Biotech's Reimbursement Team at 877-294-2598.

Q: Where can I learn more about Scoliosis treatment?

A: To learn more about the ScolioScore™ test, talk to your healthcare professional and care team.

**For more information, please contact Axial Biotech at 877-294-2598,
or visit our website at www.axialbiotech.com**

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