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Indications for Use

(This form is available in an editable format at www.axialbiotech.com/forms)

DESCRIPTION OF TEST:

The SCOLISCORE™ AIS Prognostic Test is intended for *in vitro* use only. This test utilizes DNA extracted from a saliva specimen in a polymerase chain reaction to detect the genotypes for genetic markers found in clinical trials to be associated with curve progression in patients diagnosed with Adolescent Idiopathic Scoliosis (AIS). An algorithm derived through logistic regression, which utilizes the genetic markers as well as the patient's initial Cobb Angle, assigns a Curve Progression Score ranging between 1-200. This score will indicate the potential risk of curve progression in AIS patients.

INTENDED USE:

The SCOLISCORE AIS Prognostic Test has been shown to be effective in detecting the genotypes for 53 genetic markers found in clinical trials to be associated with curve progression in self-reported Caucasian (North American, South American, European, Eastern European, Middle Eastern Descent) male/female patients from 9 through 13 years of age, who have been diagnosed with Mild AIS (10-25 degree Cobb Angle).

Results from the SCOLISCORE are intended for use as an adjunct to existing clinical and radiologic information to determine the risk of curve progression.

The SCOLISCORE AIS Curve Progression Score is NOT intended as the sole basis for treatment or disease monitoring decisions. All other available clinical information should be taken into consideration when counseling the AIS patient regarding the risk of curve progression.

This test is NOT intended to screen or diagnose AIS. The Curve Progression Score correlates with the potential risk for curve progression in patients already diagnosed with AIS.

Studies have NOT established the effectiveness of the SCOLISCORE test in the following situations:

- Congenital, Infantile, Early Onset, Juvenile, Syndromic, Neuromuscular or Adult Progressive Scoliosis.
- For diagnosis of at risk family members or relatives of diagnosed AIS patients who do not themselves meet the indication for use criteria.
- For any other race or ethnicity other than Caucasian patients.

Caution:

Under Federal law, this test may only be performed on the order of a physician and its results may only be reported to the ordering physician. The potential risks associated with misuse of the assay, or misinterpretation of the test results to recommend specific surgical decisions, could potentially expose the patient to serious side effects, complications and, in rare cases, death.

This Laboratory Developed Test was developed and its performance characteristics determined by Axial Biotech, Inc. The laboratory is regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high-complexity clinical testing and has established and verified the test's accuracy. This test has not been cleared or approved by the US. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. These results are adjunctive to an ordering physician's diagnosis and must be interpreted in consideration of all other clinical variables.

CLIA Number: 46D1077919

Questions? Call Axial Biotech, Inc. at (877) 294-2598.

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