NeuroQure ASD Insight Test Physician Discussion Guide

Introduction to NeuroQure

NeuroQure's ASD Insight test is an innovative early autism spectrum disorder (ASD) detection test used to identify ASD biomarkers in children as young as two days old. Scientific research has demonstrated that calcium signaling in cultured skin cells (fibroblasts) reflects the signaling patterns in brain neurons, and specific patterns of calcium signaling in fibroblasts have been reliably associated with a diagnosis of ASD[1].

This assay's benefit is enabling the detection of ASD risk from birth, years before traditional behavioral assessments are accessible at around two years of age, through a minimally invasive specimen collection technique. Early ASD detection improves the opportunity for early intervention, which can significantly improve outcomes for those with ASD[2].

Vocabulary to Know

Your physician may mention some of these terms. Here's what they mean.

Autism Spectrum Disorder (ASD)

A developmental disorder characterized by challenges with social skills, repetitive behaviors, speech, and nonverbal communication.

Calcium Signaling

A cellular communication process that plays a critical role in neural function and development.

Early Intervention

A system of specialized services that provides therapeutic support to those with autism spectrum disorder as early as possible.

Biomarker

A measurable indicator of a biological state or condition.

Autism Diagnostic Observation Schedule (ADOS)

A standardized assessment tool used for diagnosing autism.

Outcomes

The impact of a healthcare service or intervention.

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[1] Schmunk, G., Nguyen, R. L., Ferguson, D. L., Kumar, K., Parker, I., & Gargus, J. J. (2017). High-throughput screen detects calcium signaling dysfunction in typical sporadic autism spectrum disorder. Scientific reports, 7, 40740. https://doi.org/10.1038/srep40740

[2] Okoye, C., Obialo-Ibeawuchi, C. M., Obajeun, O. A., Sarwar, S., Tawfik, C., Waleed, M. S., Wasim, A. U., Mohamoud, I., Afolayan, A. Y., & Mbaezue, R. N. (2023). Early Diagnosis of Autism Spectrum Disorder: A Review and Analysis of the Risks and Benefits. Cureus, 15(8), e43226. https://doi.org/10.7759/cureus.43226

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Questions to Ask

These questions will help you start a conversation with your physician about NeuroQure’s ASD Insight early risk detection test.

About understanding ASD

- How does NeuroQure's ASD Insight test differ from traditional screening?
- What specific markers or patterns does the NeuroQure ASD Insight test look for?
- How accurate is NeuroQure’s ASD Insight test in predicting ASD risk compared to behavioral assessments?

About the test process

- What type of sample is required for the NeuroQure ASD Insight test?
- How is the skin sample collected?
- Where is the skin sample collected?
- Will my health insurance cover the cost of testing?
- Is the skin sample collection process painful?
- Where will the skin sample be analyzed?
- How long will it take to get results?

About the potential findings

- What are the possible results of the NeuroQure ASD Insight test?
- What does a positive result mean in terms of ASD likelihood?
- What does a negative result mean in terms of ASD likelihood?
- Is there a chance the results could be inconclusive? How often and why does this occur?

About what to expect once NeuroQure ASD Insight test results have been received

- How should the results be utilized alongside other developmental assessments?
- What are the recommended next steps if a positive result is received?
- What are the recommended next steps if a negative result is received?
- How often should follow-up assessments be conducted?

NeuroQure

About the Company

NeuroQure's early ASD Insight detection test was developed based on groundbreaking research at the University of California Irvine's Center for Autism Research and Translation (CART). NeuroQure acquired the exclusive patent from CART, a novel discovery, and developed a clinically validated test – the ASD Insight test – for use in healthcare settings.

CLIA & CAP Approval

The laboratory is accredited by the College of American Pathologists (CAP) and certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and accredited by the College of American Pathologists (CAP) as qualified to perform high complexity clinical laboratory testing.

About ASD Insight

This test was developed and NeuroQure, Inc determined its performance characteristics. The U.S. Food and Drug Administration has not cleared or approved it. The FDA does not require this test to go through a premarket FDA review. It should not be regarded as investigational or for research. This test should be interpreted in context with other clinical findings. This report does not represent medical advice. Any questions, suggestions, or concerns regarding the interpretation of results should be forwarded to a healthcare professional skilled in interpreting the relevant medical literature. This laboratory is certified under the Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high-complexity clinical laboratory testing.

The development of the ASD Insight test involved extensive clinical studies, demonstrating its ability to detect ASD-related biomarkers, identifying as early as birth 75% of individuals who test positive for ASD by research-grade ADOS testing. By utilizing advanced, novel techniques, NeuroQure has created a test that can revolutionize early ASD detection and the ability to provide long-lasting transformative early intervention strategies.

Request your ASD Insight test from NeuroQure today.

https://www.neuroqure.com/order