

Autism Diagnostics, LLC

Executive Summary

Goal: Develop and market a metabolomics-based diagnostic test for autism spectrum disorder (ASD)

Problem: Autism now affects 2% of children, and it is difficult to diagnose early and difficult to treat.

Solution: Blood/urine based diagnostic tests based on measurements of 30-50 key metabolites would allow early diagnosis, and provide personalized guide to treatment

Pilot Study: Our pilot study found 94% sensitivity and 100% specificity, which is sufficient to commercialize if validated in a larger cohort.

Market Size:

- 1.5 million people in the US with autism
- Approximately 80,000 new cases each year in US.
- Worldwide, the numbers are about 20x larger

Competition: No current approved test for autism (but several companies and research teams are working on it).

Return on Investment: Test would retail for \$800, and net profit of about \$500/test after all expenses.

- Year 1: conservatively estimate 5,000 sales: \$4 M gross, \$2.5 M profit
- Year 2: conservatively estimate 10,000 sales: \$8M gross, \$5 M profit
- Year 3: potential for much larger volume

Human Impact: As the first diagnostic test for autism, it could reduce age of diagnosis by several years, resulting in much earlier detection and intervention, and much reduced symptoms in children with autism.

As a personalized treatment guide, it will reveal each child's primary metabolic abnormalities, which in many cases are treatable.

Investment to date: \$100k Catalyst funding from ASU; over 15 years of studies of biochemistry of autism involving millions of dollars.

Future Investment: We need approximately \$100k to finalize our sample collection and test validation for CLIA approval. More funding would allow more rapid expansion of testing capabilities

Team:

Prof. James Adams – autism researcher

Prof. Haiwei Gu – metabolomics expert

Prof. Juergen Hahn – biostatistician

Prof. Rosa Krajmalnik-Brown: microbiome expert

Dr. Tapan Audhya – CLIA consultant (director of a CLIA-approved laboratory and has developed many CLIA-approved tests)

Unique Qualifications: We have invested many years of effort to reach this stage, and are near completion of our sample collection for final development and validation of our diagnostic test. We are prepared for CLIA submission after validation of our model.

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