

**Docket #:** S18-001

# **Biomarker for diagnosing autism spectrum disorder**

Researchers in Prof. Karen Parker's laboratory have discovered a biomarker that could enable an objective laboratory-based test for diagnosing autism spectrum disorders (ASD) and predicting the severity of a patient's symptoms. Currently ASD is diagnosed on the basis of subjective behavioral criteria because its underlying disease mechanisms remain poorly understood. To address this problem, the inventors determined that the “social” neuropeptide arginine vasopressin (AVP) and its receptor are potential diagnostic markers for ASD. In addition, lower concentrations of AVP and lower gene expression of its receptor could predict the severity of social symptoms associated with ASD. This finding could be used to develop laboratory assays for clinical diagnostics and prognostics as well as companion diagnostics for therapeutic development.

## **Stage of Research**

The inventors have performed multiple studies which demonstrate that patients with autism have different concentrations of neuropeptides or their receptors compared to neurotypical controls. Specifically, they found that patients with autism have lower concentrations of arginine vasopressin (AVP) in cerebrospinal fluid and the AVP concentration can also predict the severity of social behavioral symptoms. In a different study, the inventors could correctly classify 84% of participants (patients with ASD and controls) using blood-based analysis of AVP, oxytocin and their receptors. In this study, neuropeptide receptor gene expression was strongly associated with ASD symptom severity, such that lower levels expression predicted greater social impairments and stereotyped behavior in children with ASD.

## **Applications**

- **Diagnostics for autism**, with potential applications for:
  - clinical diagnostics for ASD in new patients with behavioral symptoms

- predicting the severity of ASD symptoms
- predicting likelihood of ASD in at-risk patients
- companion diagnostics for ASD drug development

## Advantages

- **Objective laboratory-based test** - currently the diagnosis of autism is made using subjective behavioral criteria, this biomarker could provide the first objective analysis

## Publications

- Oztan, O., Jackson, L. P., Libove, R. A., Sumiyoshi, R. D., Phillips, J. M., Garner, J. P., ... & Parker, K. J. (2018). [Biomarker discovery for disease status and symptom severity in children with autism](#). *Psychoneuroendocrinology*, 89, 39-45.
- Karen J. Parker, Joseph P. Garner, Ozge Oztan, Erna R. Tarara, Jiang Li, Valentina Sclafani, Laura A. Del Rosso, Katie Chun, Sean W. Berquist, Michael G. Chez, Sonia Partap, Antonio Y. Hardan, Elliott H. Sherr and John P. Capitanio, ["Arginine vasopressin in cerebrospinal fluid is a marker of sociality in nonhuman primates"](#). *Science Translational Medicine*, May 2, 2018, Vol. 10, Issue 439.
- ["Scientists find possible autism biomarker in cerebrospinal fluid"](#), *Stanford Medicine*, News Center. Article written by Erin Digitale, May 2, 2018.

## Innovators

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