NeuroPoint Dx
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504 S. Rosa Road, Suite 150, Madison, WI 53719
Phone: (608) 441-8187 • Fax: (608) 646-7739 • Email: customercare@neuropointdx.com
www.neuropointdx.com • CLIA#52D2122420

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☐ Req.
☐ Sam. _____
☐ Pay. _____

NPDX ASD TEST REQUISITION FORM

PHYSICIAN

Healthcare Organization	**Phone**	**Secured Fax for Return of Test Results**
Address 1	**Address 2 (optional)**	
City	**State**	**Zip**
Requesting Physician	**NPI #**	
Physician Signature	**Date:**	

LAB

Laboratory (If Different from Above)	**Phone**	
Address 1	**Address 2 (optional)**	
City	**State**	**Zip**

PATIENT

Last Name	**First Name**	**Middle Initial**
Patient ID/MRN	**Sex** ☐ Male ☐ Female	**Date of Birth** _____/_____/_____ MM DD YYYY
Parent/Guardian Last Name	**Parent/Guardian First Name**	
Parent/Guardian Phone Number	**Parent/Guardian Email *(optional)***	

TEST

Test Name **NPDX ASD Test**	**# of Analytes** **32 Amines**	**ICD-10 Code(s):**

SPECIMEN

Specimen Type **Blood Plasma**	**Date of Last Food Intake** _____/_____/20_____ Month Day Year	**Time of Last Food Intake** **AM** **PM**
Note: The patient must fast for 12 hours prior to blood draw.		
Specimen Collection Date _____/_____/20_____ Month Day Year	**Specimen Collection Time** **AM** **PM**	

PAYMENT

Method of Payment ☐ Credit Card ☐ Check* ☐ PayPal **Make checks payable to: **NeuroPointDX***	**Card Type** ☐ Master Card ☐ Visa ☐ Discover	
Payment Amount	**Name on Card**	
Credit Card Number	**Card Expiration:** _____/_____ Month / Year **Security Code:** _____	
Signature for Credit Card Payment		

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(OPTIONAL) CONSENT FOR USE OF LEFTOVER SAMPLE

TITLE: NeuroPointDX Biomarker Discovery and Test Performance Evaluation from Clinical Samples

PROTOCOL NO.: None
WIRB® Protocol #20183304

SPONSOR: NeuroPointDX, a division of Stemina Biomarker Discovery, Inc.

INVESTIGATOR: Robert Burrier, PhD
504 S. Rosa Road, Suite 150
Madison, Wisconsin 53719
United States

PHONE NUMBER(S): Robert Burrier, PhD
(608) 204-0104

Samples You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant. In this consent form "you" generally refers to the research subject. If you are being asked as the parent or guardian to permit the subject to take part in the research, "you" in the rest of this form generally means the research subject.

Why is this research being done? The purpose of this research is to utilize the remaining blood samples after the diagnostic testing your physician ordered is completed. These samples will be used to confirm the accuracy of autism spectrum disorder markers and to potentially identify new metabolite biomarkers. We want to compare behavioral and metabolic tests to better understand autism spectrum disorder.

How long will I be in this research? NeuroPointDX will keep the leftover sample indefinitely, but you will not have to do anything additional for your participation.

What happens to me if I agree to take part in this research? Your physician is ordering an experimental test from NeuroPointDX that will require a routine blood draw. We are asking that you consent to allow us to study any remaining blood sample after the diagnostic testing your physician ordered is completed.

These samples will be used to confirm the accuracy of autism spectrum disorder biomarkers (a biological molecule found in blood or other bodily fluids that is a sign of a condition or disease) and to potentially identify new biomarkers.

There is a possibility that your biomarker profile may qualify you to participate in additional clinical research and NeuroPointDX may contact you to see if you would be interested in participating in this research. Your decision at that time is independent of this consent and will not affect any other care or decisions regarding your medical care.

To complete this research study, the lab performing these tests, NeuroPointDX or the sponsor, Stemina Biomarker Discovery, Inc, may require additional information about you such as medical history, diet, and supplement/vitamin use. We also may ask if other family members have been diagnosed with autism. We may compare behavioral tests that you may have taken to the metabolic tests to better understand the diagnosis of autism spectrum disorder.

These samples will be tested at: NeuroPointDX, a division of Stemina Biomarker Discovery, Inc.
Contact Person: Robert Burrier, Ph.D (bburrier@neuropointdx.com)

Could being in this research hurt me? While the leftover sample will be de-identified, there is a chance that your confidentiality will not be maintained.

Will it cost me money to take part in this research? There is no cost to you for allowing NeuroPointDX to use the leftover sample.

Will being in this research benefit me? We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to you include new diagnostic testing and treatments that may be developed which could benefit you and others with autism spectrum disorder.

What other choices do I have besides taking part in this research? This research is not designed to diagnose, treat, or prevent any disease. Your alternative is to not take part in the research.

What happens to the information collected for this research? Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research for the purpose of conducting the research, including: the research sponsor,

Stemina Biomarker Discovery, Inc; people who work with the research sponsor to monitor the data; government agencies, such as the Food and Drug Administration; as well as the Independent Review Board (IRB) that reviewed this research.

We may publish the results of this research. However, no patient information will be published, and all patient information will be maintained in accordance with privacy regulations including HIPAA. We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy as information that has already been disclosed, may be re-disclosed and no longer protected by privacy laws.

Who can answer my questions about this research? If you feel that the research has hurt you, or you have questions, concerns, or complaints, talk to the research team at (608) 204-0104. This research is being overseen by an Independent Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies to protect the rights and welfare of research subjects. If you have questions, concerns, or complaints that are not being answered by the research team; you cannot reach the research team; you want to talk to someone else about the research; or you have questions about your rights as a research subject, please contact: Western Institutional Review Board® (WIRB®), 1019 39th Avenue SE, Suite 120, Puyallup, Washington 98374-2115; Telephone: 1 (800) 562-4789 or (360) 252-2500; E-mail: Help@wirb.com

What happens if I agree to be in this research, but I change my mind later? The decision to participate in the research is up to you. If you decide not to participate in the research or participate in the research and later change your mind, you will not be penalized nor will you lose any benefits that you are otherwise entitled to. The results from the blood draw and any research that has been conducted on your blood samples cannot be cancelled or withdrawn from use. However, you can tell your physician that you do not want any information or more information shared with NeuroPointDX or Stemina Biomarker Discovery, Inc. from the time that you decide to withdraw from the study. You can also request that no further research be done on your samples if they have not been stripped of your personal identifiers (de-identified).

Will I be paid for taking part in this research? You will not be paid for taking part in this research.

Financial Disclosures Dr. Robert Burrier owns non-publicly traded equity in Stemina Biomarker Discovery, Inc., and the study coordinator Jacqueline Hind has earned consulting fees for the company. Please feel free to ask any questions.

Authorization to Use Your Health Information for Research Purposes Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. This form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and as required or allowed by law. Please read it carefully before signing it.

Do I have to sign this authorization form? No, you do not have to sign this authorization form, but if you do not sign this authorization, you will not be able to participate in the study. If you do not participate, your physician will still receive the metabolic test results that were ordered from NeuroPointDX as part of your standard of care.

When will my authorization expire? Your authorization for the use and/or disclosure of your health information will end on December 5, 2023 or when the research project ends, whichever is earlier.

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Please choose all that apply:

☐ I consent to allow my physician to disclose medical history from my medical record (if you do not allow this sharing of information, you cannot participate in the study).

☐ I consent to the use of my blood samples for future research in autism spectrum disorders.

☐ I do not consent to my samples being saved for future research.

Assent Instructions:

- All children are required to assent, unless the clinician determines that the capability of the child is so limited that the child cannot reasonably be consulted.
- If assent is obtained, have the person obtaining assent document assent on the consent form.

I consent to me or my child participating in this research study. I am not giving up any of my legal rights by signing this form.

Name of minor for whom consent is signed _____

Printed name of parent or legal guardian of participant _____

Signature of parent or legal guardian of participant _____ Date _____

Signature of person obtaining consent _____Date: _____

☐ I have explained the study to the extent compatible with the subject's capability, and the subject has agreed to be in the study.

☐ The subject is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted.

_____ _____

Signature of person obtaining assent Date

Case Report Form with Optional Consent for Use of Leftover Sample

NeuroPointDX Biomarker Discovery and Test Performance Evaluation from Clinical Samples
Version 1.0, December 6, 2018

To Be Completed by Clinician

Patient Name: _____

Indicate medical diagnosis (check all that apply):

[ ] Typically developing

[ ] Formal neurological condition medical diagnosis not yet obtained

[ ] Neurological condition (please indicate all relevant conditions)

- [ ] Autism Spectrum Disorder

  Method of Diagnosis (ADOS, DSM-V, etc.): _____

- [ ] Developmental delay (not Autism Spectrum Disorder)

  Method of Diagnosis (DAS-II, MSEL, etc.): _____

- [ ] Other:_____
- [ ] Other:_____
- [ ] Other:_____

For NeuroPointDX use only:

Sample ID: