N.A.G. – Test Requisition

INTRODUCTION

We believe you know what is best for your patient. But here are a few considerations that can inform your decision as to whether DNA testing with New Amsterdam Genomics (N.A.G.) is the best choice.

TEST OVERVIEW

N.A.G. analyzes the patient's exome, i.e. the coding region of all 22,000 genes of their DNA. This provides an extremely broad examination into the genomic factors affecting the patient's health. We assert we are the world's most advanced DNA test based on several key factors:

- Our database includes 480,000+ annotations associating DNA mutations with clinically relevant effects. They span the gamut from serious and lifesaving to simple diet, exercise, and lifestyle recommendations.
- Our computer algorithms automatically prioritize your patient's most important mutations (based on the quality of the science, the effect size, actionability, etc.) to keep you fast and efficient. A clinician can process the average patient's report in twenty minutes.
- Our web portal is constantly updated with the latest scientific information, so you are always up-to-date.
- We provide unlimited support to doctors, making sure they are exceptionally capable and confident in making use of DNA data.

TEST USES

45% of patients get a life changing result! That said, certain patients may be most likely to benefit:

- HEALTHY, BUT WANTS TO OPTIMIZE: We provide detailed risk assessments for age-related diseases plus personalized diet, exercise, and lifestyle suggestions – these help you devise a plan to optimize the patient's health and give them the best chance at living to age 100+.
- PERSONAL/FAMILY HISTORY OF CANCER: Cancer is modulated by 1000+ genes, so our test is vastly more comprehensive than a typical cancer gene panel. (See for example "Germline Mutations in Predisposition Genes in Pediatric Cancer" by J. Zhang et al.)
- MYSTERIOUS SYMPTOMS: Whole exome sequencing has shown substantial success in diagnosing unexplained symptoms in patients, and we have created special computational tools to investigate. (See for example "Clinical application of whole-exome sequencing across clinical indications" by K. Retterer et al.).

TEST REQUISITION

Here are two questions you may consider asking the patient.

Why does the patient want to be tested?

Our test is best for the categories listed in "Test Uses" and for other broad health questions. For instance, "Am I at risk of a problem as I age," "Will my children be at risk for genetic problems," "How can I optimize my health," and "What is my risk for heart problems" are all questions our test may help in answering.

On the other hand, a situation that may be less applicable for our test would be if the patient were interested in the presence or absence of a single specific mutation, but absolutely nothing else. In such a case, there are many other labs that can do that, and maybe you just prefer the cheapest one. As another example, if the patient is interested solely in their ancestry and not in their health, they can do a non-medical test like those which advertise on TV.

Does the patient have the emotional wherewithal to handle an impactful result?

N.A.G. provides powerful, clinical grade health information. However, this information should be handled with care. We do not want a patient to become depressed by learning something serious about their health. The goal is to have a patient feel empowered even if they have a major finding. Fortunately, science has found ways to reduce the risk of many diseases.

N.A.G. has options to mask clinical findings that are considered less medically actionable. They are called "Hide Unactionable" and "Comfortable and Fun." They are explained on the Patient Consent Form, and the patient can choose the one they feel most comfortable with.

Another psychological aspect to consider is whether a patient will be able to handle an impactful result rationally and responsibly. Our forms, reports, and marketing materials encourage patients to act rationally with serious results and seek out and follow doctor advice.

TEST LOGISTICS

The input specimen is saliva. We can ship a kit directly to a patient's house, and/or you can have kits at your office. The results typically return 5 weeks after we receive the sample in our lab. The results come in two forms: our paper report and web portal. The paper report contains the most important findings. It is usually just five pages long and can be covered in one office visit. The web portal presents the full details behind any finding (which is particularly useful if there is an important finding).

For general information, please see our website at http://www.nagenomics.com. Please direct questions to our Director of Support, Kristopher Faulend: kfaulend@nagenomics.com or (347) 507-8438. We are always here to support doctors, and we look forward to working with you!

Requisition Form for Doctors

GERMLINE TEST

Questions? order@nagenomics.com or (347) 901-9362

REQUIREMENTS CHECKLIST

- **Requisition Form for Doctors** (this form)
- **Patient Consent Form** (signed by the patient)
- **Saliva Submission Form** (only required if the patient produces their saliva outside your office)
- **Saliva sample**
- **Payment** (either from the patient using their Patient Consent Form or from you)

Send completed materials to order@nagenomics.com, our fax (347) 402-7487, or our mailing address.

PATIENT INFORMATION

Name:

Date of Birth: _____/_____/_____ Sex (circle): Male Female

Clinical Diagnoses and/or ICD Codes (as applicable):

If you are investigating a particular problem, please provide details to facilitate interpretation of our test results. Please send us, as available: patient clinical history and notes, family history and pedigree, and previous test results.

ORDERING PHYSICIAN INFORMATION

Name:

Institution: Fax Number:

Email Address: Mobile Number:

Email address and mobile number are only for emergencies and to verify your website access.

FIRST TIME PHYSICIAN

If we already have your information from a previous order, you can leave this section blank.

NPI #: Department:

Mailing Address:

SAMPLE INFORMATION

Specimen Type (circle): Oragene Saliva Kit Data from Previous Sequencing

If submitting saliva, complete the following line ***-or-*** *have the patient use the Saliva Submission Form.*

Collection Date: _____/_____/_____ N.A.G. Label: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

GERMLINE TRIO (optional add-on)

Leave this section blank unless you are testing a trio (additional cost applies for trio testing).

MOTHER'S SPECIMEN

Mother's Full Name:

Specimen Type (circle): Oragene Saliva Kit Data from Previous Sequencing

Collection Date: _____/_____/_____ N.A.G. Label: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Affected by Same Problem as Patient (circle)? Yes No N/A

FATHER'S SPECIMEN

Father's Full Name:

Specimen Type (circle): Oragene Saliva Kit Data from Previous Sequencing

Collection Date: _____/_____/_____ N.A.G. Label: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Affected by Same Problem as Patient (circle)? Yes No N/A

TEST LIMITATIONS

Patients are given a copy of the text in this section on their consent form.

Next Generation Sequencing, a technology upon which this test is based, is limited in the detection of certain mutation types such as large rearrangements, copy number variation mutations, mutations involved in tri-allelic inheritance, mitochondrial genome mutations, epigenetic effects, trinucleotide repeat expansions, and X-linked recessive mutations in females who manifest disease due to skewed X-inactivation.

Genomic sequencing is an advanced technology, but, by its statistical nature, it is not 100% accurate. Every result on the test report has a small probability of error. Generally, these errors can arise in one of three ways. First, it is not possible to capture and sequence 100% of the human exome. There are some genes, portions of genes, and closely related pseudogenes that may not be covered by this test. We expect to be able to evaluate approximately 90-95% of an exome, as presently defined. Second, if an area of the genome has been sequenced, the base pairs within may be

decided incorrectly, which may impact downstream analysis. Third, science's understanding of the relationship between the genome and health is incomplete and evolving. For example, it is possible that different results on my report have different things to say about the same condition. It is also possible that one scientific finding may be modified or overridden by a later finding (e.g. one source may report a mutation is pathogenic and another may report benign). Different labs use different methodologies for resolving conflicts among scientific findings and thus may legitimately produce different conclusions. N.A.G. uses a different standard for reporting variants than the ACMG. N.A.G. does not vouch for the scientific validity of any external source a report references.

PHYSICIAN REVIEW

I understand the limitations of this test. I have decided this test is appropriate for this patient. I believe the patient or their guardian has a sufficient understanding of the test. If the patient's biological sample was collected in my presence, I confirm it was collected correctly. I agree to accurately represent the N.A.G. test to the patient and assist the patient in interpreting their test results. If there are important results that I am unable to advise about, I will refer the patient appropriately. I allow the patient or their guardian to view the test results directly, after my consultation. I understand N.A.G. reports can help understand a patient's health, but they are not the only information that should be used to make a care decision. Notwithstanding anything else expressly stated or implied, doctors always have final and independent judgment as to how to care for a patient.

Physician Signature: X_____ Date: _____

This test is regulated by the Clinical Laboratory Improvement Amendments Act and has not been evaluated by the FDA. Here our CLIA certificate. A larger view is at http://nagenomics.com/CLIA-Certificate.pdf.

CENTERS FOR MEDICARE & MEDICAID SERVICES
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF COMPLIANCE

LABORATORY NAME AND ADDRESS
NEW AMSTERDAM GENOMICS CAMBRIDGE LAB
45 PROSPECT ST
CAMBRIDGE, MA 02139

CLIA ID NUMBER
22D2084314

EFFECTIVE DATE
11/24/2023

LABORATORY DIRECTOR
ISRAA A. LAKLOUK

EXPIRATION DATE
11/23/2025

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.
This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Gregg Brandush, Director
Division of Clinical Laboratory Improvement & Quality
Quality & Safety Oversight Group
Center for Clinical Standards and Quality

We look forward to giving you valuable information about your patient!