

FOR IMMEDIATE RELEASE:

GENEX begins whole-genome molecular testing service for people concerned about rare, intractable “Nanbyo” diseases

- A genetic analysis report to support a physician’s diagnosis is available for less than 40,000 yen -

TOKYO, December 22, 2022 – GENEX, Inc. (headquarters: Tokyo; Representative Directors and Presidents: Ken Yagi and Atsushi Iida; hereinafter, GENEX) is pleased to announce that it will begin sales of GENEX’s Whole-Genome Test (launch commemorative price: 39,800 yen tax-exclusive, 43,780 yen tax-inclusive) aimed at people or their loved ones who are concerned about rare, intractable diseases. Sales are limited to the first 100 customers.

Service features

1. Examines all three-billion nucleotides (A/G/T/C letters) of human DNA and detects millions of genetic variants that all people have. A re-analysis of the sample can be performed to reflect future technological advances and new findings.
2. Looks for sequences that match any genetic variants experts consider disease-causing, and provides a detailed report. Additional information about risk factors related to nationally designated intractable diseases (“Nanbyo”) is provided to better support possible access to medical attention.
3. Testing using a saliva sample can be conducted easily, anywhere, at any time, at an affordable price for individuals.

Genetic analysis technology has matured to a point where it is now possible for individuals to obtain their entire genetic (whole-genome) information. On the other hand, there are several unresolved ethical, legal and social issues, such as the right to know vs. the right not to know, the psychological burden of being aware of one’s disease risk and the impact on the family. Therefore, except for certain research and medical reasons, there have been no services to meet the needs of those who want more detailed information to act upon, such as individuals who suspect they have a rare, intractable disease and their families.

GENEX has begun accepting applications for a new testing service that enables individuals 18 years and older to obtain their whole-genome information and learn their genetic risk for rare, intractable diseases. Users who agree to the terms and conditions of the service send a saliva sample and will receive a genetic analysis report several months later. The report provides detailed and easy-to-understand explanations of disorders that could be associated to the detected genetic variants. If a physician suspects that the patient may have a related disease, the physician can then decide to conduct separate tests necessary for a diagnosis (the GENEX test is a direct-to-consumer genetic test which is for non-diagnostic use).

GENEX’s Whole-Genome Test: <https://genex.co.jp/gt/>

This service has three differentiating factors. The first is the transparency of results. Errors in genetic analysis are inevitable and it is impossible to predict the fate of an individual. Even evaluations by experts can change with the evolution of research. With full awareness of the limitations of this technology, GENEX provides information with a focus on supporting physicians who may experience difficulties diagnosing rare, intractable diseases. We provide data to support how reliable the information is and as needed, re-analyze the information. This is the first attempt in Japan* to report whole-genome information directly to users with such a set of evidence as consumer service.

*Based on a GENEX survey as of December 19, 2022

The second differentiating factor is high quality and ease of use. Through its joint research with Japan's leading mitochondrial disease research consortium, GENEX has developed a high level of expertise in rare disease genomics. In addition, GENEX has been conducting patient-involved verification tests in the second half of this year and striving to respond to the needs of patient advocacy groups, such as the desire for patients to share their test results with their physicians.

The third differentiating factor is the low burden of testing. Users need only to send in a saliva sample and no blood test or biopsy is required. This is good news for users who live in rural areas without close access to core hospitals or who wish to avoid the physical strain of medical tests. In addition, while the going price of similar tests is in the 100,000 to several-hundred-thousand-yen range, the price of GENEX's test has been set to just less than 40,000 yen, making it affordable for those who may not be able to receive cost subsidies.

To ensure the quality of this distinct service, the commemorative price will be available to the first 100 customers only (scheduled for the end of March 2023).

To resolve societal issues

Patients with rare, intractable diseases often spend years getting a definitive diagnosis and treatment protocol. Usually, the diagnostic process involves performing various tests and only after the physician has narrowed down the focus, obtaining genetic information. Alternatively, GENEX believes that whole-genome information can be positioned as an effective preliminary screening measure before medical treatment. In other words, by first objectively identifying possible disease candidates before making any medical judgments, subsequent medical testing and diagnosis can be conducted more efficiently.

Genomic medicine and diagnostics exemplifies that research activities and medical practices are sometimes inseparable, and currently it is sustained by busy, devoted physicians and researchers with limited funds and personnel. Fortunately, discussion about legislation to prevent discrimination and other downside risks related to genomic medicine is accelerating. With the popularization of telemedicine, which is helping to bridge regional disparities in access to medical care, the social environment behind genomic medicine is improving. While national and local government ensure universal health coverage in Japan, companies like us will not only be able to benefit people who are otherwise inaccessible to such added services, but also help lead to improved allocation of resources for research and medical care.

For a future society where individuals can own, think about and act upon their own data, GENEX seeks to be a responsible pioneer in promoting the use of whole-genome information and nurturing a healthy environment by venturing into fields like diagnostic decision support. We look forward to hearing from like-minded patient advocacy groups, clinics, medical institutions, and companies and organizations involved in disease awareness.

About GENEX, Inc.: The company was established in August 2019 as a start up to plan and operate genome and healthcare-related data platforms with Monex Group, Inc., Sugi Holdings, Co., Ltd., Kaken Pharmaceutical Co., Ltd., and others as shareholders.

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