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Japan approves first gene panel testing system for Inherited Retinal Dystrophy

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Sysmex obtains manufacturing and marketing approval for its PrismGuide IRD Panel System

Sysmex Corporation has obtained manufacturing and marketing approval in Japan for its PrismGuide IRD Panel System that obtains information about the causative genes of inherited retinal dystrophy (IRD). Its approval marks Japan's first gene panel testing system for IRD.

IRD is a generic term for a series of inherited progressive diseases in which retinal dysfunction is caused by genetic mutations, including retinitis pigmentosa, Usher syndrome, and macular dystrophy, which are designated intractable diseases in Japan.

Severity and progression of symptoms for IRD vary depending on the causative gene. In recent years, gene therapy targeting the causative genes of IRD, which was previously considered untreatable, has been approved in Europe and the United States, and its development is progressing in Japan as well, indicating the emergence of new treatment possibilities.

The newly approved System, a combination medical device comprising a reagents kit and an analysis programme, is intended for use in obtaining comprehensive genome profilesfrom the blood of the patients diagnosed or suspected of having IRD to identify 82 types of genes causing IRD. Then, based on the analysis results obtained via the System, combined with subjective symptoms, clinical symptoms, and other relevant test results, each IRD patient's causative gene is comprehensively determined by an expert panel at a medical institution that meets the requirements stipulated by relevant academic associations.

If a treatment plan is determined based on an identified causative gene, a support plan for low vision care is mapped out, and genetic counseling is provided.