

November 20, 2024

Nobelpharma Co., Ltd.

Anti-GM-CSF Antibody Detection Kit “KBM LineCheck APAP” Launched

Nobelpharma Co., Ltd. (Headquarters: Chuo-ku, Tokyo, CEO & Managing Director: Jin Shiomura) and Kohjin Bio Co., Ltd. (Headquarters: Sakado-shi, Saitama, President and CEO: Takahito Nakamura) announced today that “KBM LineCheck APAP” (“Product”), an anti-GM-CSF antibody detection kit, will be launched on December 13, 2024.



Distributor: Nobelpharma Co., Ltd.

Manufacturer: Kohjin Bio Co., Ltd.

This Product is used to detect anti-GM-CSF antibody in serum to support the diagnosis of autoimmune pulmonary alveolar proteinosis (APAP).

This Product received the marketing approval as in vitro diagnostics on May 28, 2024 (authorization number: 30600EZX00015000) and the testing will be covered by insurance as of December 1, 2024.

[Listed Medical Insurance]

Test: Anti-GM-CSF antibody (D012 autoantibody test)

Insurance Point: 1,380 points

Applicable Insurance Point: D014 autoantibody test 43 anti-GM1IgG antibody/anti-GQ1bIgG 460 points, factor of rare disease doctor fee for two tests 150/100

Pulmonary Alveolar Proteinosis (PAP)

PAP is a general term for the diseases accompanied by abnormal accumulation of protein-like materials derived from surfactant (surface active material secreted in alveoli) in alveolar space, etc. Ninety (90) percent of these PAP's are APAP, which is the target of this Product.

PAP is listed as a designated intractable disease with the estimated number of patients, incidence rate, and prevalence rate of 730 – 770, 0.49 patients/year/million, and 6.2 patients/year/million respectively.

*Source: Pulmonary Alveolar Proteinosis Patient Association of Japan web site (<https://pap-net.jp/>)

While Nobelpharma received the marketing approval of “Sargmalin® for inhalation 250 µg,” a drug for APAP, on March 26, 2024, serum anti-GM-CSF antibody concentration is required to make a decision to use Sargmalin.

As this Product is for the detection of serum anti-GM-CSF antibody, the healthcare facilities across the nation can provide one-stop care by giving a diagnosis using this Product and treating patients with Sargmalin.

Nobelpharma and Kohjin Bio hope the launch of this Product hastens the diagnosis of APAP and will help as many patients as possible.

Nobelpharma

Nobelpharma was founded in 2003 with the mission, “Contribute to society by providing critical but neglected pharmaceuticals and medical devices.”

With the focus on developing new drugs and medical devices of unmet medical needs which were not developed by existing pharmaceutical companies, Nobelpharma has been, since 2008, developing and providing 20 new drugs and medical devices, mainly for intractable and orphan diseases, to the medical settings not only in Japan but also in USA, Europe and China.

Kohjin Bio Co., Ltd.

Kohjin Bio was founded in April 1981 and has been operating business mainly of production and sales of cell culture media, in-vitro diagnostics, and bacteria examination media as well as of cell processing. With the rapid expansion of global regenerative medicine market, we are recently undertaking to further expand the business in the global regenerative medicine market while focusing on the research and development of culture fluid used to grow cells.



<https://kohjin-bio.jp>

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