Detection Kit of Type 1 Diabetes Mellitus with Autoimmune Marker GAD65 (Glutamic Acid Decarboxylase)

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Abstract: Incidence of Diabetes Mellitus (DM) progressively increasing it became a serious problem in Indonesia and it is a disease that government is priority to be addressed. The longer a person is suffering from diabetes the more likely to develop complications particularly diabetic patients who are not well maintained. Therefore, Incidence of Diabetes Mellitus needs to be done in the early diagnosis of pre-phase of the disease. In this pre-phase disease, already happening destruction of pancreatic beta cells and declining in beta cell function and the sign autoimmunity reactions associated with beta cell destruction. Type 1 DM is a multifactorial disease triggered by genetic and environmental factors, which leads to the destruction of pancreatic beta cells. Early marker of "beta cell autoreactivity" is the synthesis of autoantibodies against 65-kDa protein, which can be a molecule that can be detected early in the disease pathomechanism. The importance of early diagnosis of diabetic patients held in the phase of pre-disease is to determine the progression towards the onset of pancreatic beta cell destruction and take precautions. However, the price for this examination is very expensive (\$ 150/ test), the anti-GAD65 abs examination cannot be carried out routinely in most or even in all laboratories in Indonesia. Therefore, production-based Rapid Test Recombinant Human Protein GAD65 with "Reverse Flow Immunchromatography Technique" in Indonesia is believed to reduce costs and improve the quality of care of patients with diabetes in Indonesia. Rapid Test Product innovation is very simple and suitable for screening and routine inspection of GAD65 autoantibodies. In the blood serum of patients with diabetes caused by autoimmunity, autoantibody-GAD65 is a major serologic marker to detect autoimmune reaction because their concentration level of stability.GAD65 autoantibodies can be found 10 years before clinical symptoms of diabetes. Early diagnosis is more focused to detect the presence autontibodi-GAD65 given specification and high sensitivity. Autoantibodies- GAD65 that circulates in the blood is a major indicator of the destruction of the islet cells of the pancreas. Results of research in collaboration with Biofarma has produced GAD65 autoantibodies based Rapid Test had conducted the soft launch of products and has been tested with the results of a sensitivity of 100 percent and a specificity between 90 and 96% compared with the gold standard (import product) which worked based on ELISA method.

Keywords: diabetes mellitus, GAD65 autoantibodies, rapid test, sensitivity, specificity

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