

# Executive Summary

## Recombinant HCV Colloid Gold Test Strip

### (application of multiepitope fusion antigen)

#### **Project Description**

Recombinant HCV Test Strip is an easy and real-time clinical screening device. The key to the technology of Colloid Gold Test Strip lies in its high qualitative and sensitive antigens. The major epitopes of the third generation recombinant HCV antigens are integrated into one protein through Genetic Engineering, therefore decreases the non-specific reaction of unnecessary amino acid sequences and intensively strengthens antigenicity. As a result, the increase of the amount of absorbed antibodies by unit antigen leads to the Test Strip sensitivity increase by two to four times. Meanwhile, manufacturing and labeling single fusion antigen has largely reduced both costs and procedures.

#### **Product characteristics and technical level**

The recombinant HCV fusion antigen is generated through Recombinant Genetic Engineering, based on the protein structure characteristics and antigen immunology. The main epitopes of structural protein Core, B cell epitope of Envelop E 1 and E 2, epitopes of non-structural protein NS3, NS4 and NS5a and other important epitope genes are connected by flexible spacers and constructed into a artificial gene sequence containing all important HCV antigenicities. This sequence was cloned into the expression vector, constructing a high expression cell strain (engineering bacteria). Recombinant HCV antibody test strip technique applies Colloid Gold labeled HCV proteins, which is bound with positive antibody in the blood sample, forming a mauve band on the nitrocellulose test strip. Chromatography Colloid Gold test strip technique was applied in the diagnosis of early pregnancy and HBV in the early 90s', which has the same specificity, accuracy and sensitivity as ELISA. We apply HCV multiepitope fusion polypeptide labeled test strip, which has similar sensitivity as the third generation HCV ELISA kit and can replace ELISA method to popular test.

Company applies advanced Colloid Gold test strip manufacturing facilities, which can accurately quantify and tag antigen or antibody onto the test strip and processes high quality control standards.

#### **Market Prospects**

China is HC high incidence area, infection accounts for 40% of world total, equivalent to approximately 50 million. HC symptoms are not obvious, but they tend to be chronic. HC has been the major cause for cirrhosis and liver cancer. The blood transfusion infection is very high. At the moment, blood screening is the major tool for the government to control HCV transmission. Recombinant HCV antibody test strip is most powerful for blood screening, which has a annual demand up to billions strips, ten times more than ELISA Kits. But there is large market blank for the current Colloid Gold Test Strip material source, and domestic organizations are unable to obtain stable supply. Our technique would meet high remand from both domestic and international markets; economic cycle has been estimated at more than 10 years. Our company is at the early development stage, and our high quality and high-yield engineering bacteria has great potential to lead the market with competitive technical and pricing advantages.

#### **Competitor Analysis**

HC's slow pathogenesis, deferment and low virus titer requires high test sensitivity. None of Colloid Gold test strips have been approved by SFDA due to the sensitivity problem. The domestic second generation HCV ELISA Kit is able to diagnose 80% of all patients, 10% lower than the foreign products, such as Ortho and Abott. The third generation ELISA adds NS5 antigen for early diagnosis, but its sensitivity has not been much improved.

#### **Investment and Cooperation**

10 million RMB for manufacturing facilities, GMP Plant, Clinical Trial and SDA Document Number Application.

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