Reagent for Lateral Flow Immunoassays for PoC Testing of Disease Markers

21-015

This technology is a LFI antigen testing reagent buffer that provides strong analytical sensitivity, and can also be produced domestically from available chemicals.

Lateral flow immunoassay (LFI) antigen testing for infectious disease is a rapid, low-cost method of diagnosis. An LFI consists of a sample pad that collects and transmits the tested sample to another pad with immobilized affinity capture conjugate beads. A critical component of the LFI is the reagent buffer, which performs multiple tasks to ensure the LFI runs correctly. First, the reagent buffer prepares the sample for analysis by extracting the analyte of interest without denaturing the specific analyte-ligand binding sites required for the immunological reactivity. Next, the reagent buffer must properly re-hydrate the dry LFI strip to improve fluid flow rate performance. Additionally, the reagent buffer must rehydrate and mix the conjugate beads with the sample analyte. Finally, the reagent buffer must prevent non-specific hydrophobic interactions in the reaction matrix, to both improve the diagnostic signal and improve the clarity of the diagnostic signal (reduction of non-specific background signal). Common reagent buffers typically contain surfactants/chemical detergents, blocking proteins, polymers, and other materials that interfere with hydrophobic binding. The SARS-CoV-2 virus generates thousands of copies of protein antigens per virus. These antigens are indicative of active infectious because the virus is replicating at high rates. Therefore, developing a reagent buffer to extract and neutralize SARS-CoV-2 antigens is of high importance.

This technology is a novel reagent buffer for LFI specifically designed for rapid LFI COVID- 19 antigen testing. The reagent buffer consists of a zwitterionic sulfonic solution, a nonionic surfactant solution, and a buffer solution, in which the reagent buffer has a pH range of about 7.0 to about 8.0 and a circular dichroism with an absorbance peak more than 0 at 190 nm and 225 nm. The reagent buffer can be configured to be a reagent buffer for a LFI for detection of COVID-19. Other COVID-19 LFI antigen testing reagent buffers utilize different chemical compositions that fail to provide a strong analytical sensitivity or lack the ability to be produced domestically.

- Provides a LFI antigen testing reagent buffer that delivers strong analytical sensitivity compared to other COVID-19 reagent buffers.
- Can extract and neutralize SARS-CoV-2 antigens from a sample.
- Can be produced domestically.

<u>Stage of Development</u>
Research Prototype

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