

# The Development of a High Sensitive Home Diagnosis Kit for Group A Streptococcus Bacteria (GAS)

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Strep throat infects millions of people every year. Due to the similarity of symptoms between bacterial and viral infections, a rapid diagnosis test to identify Group A Streptococcus (GAS) from a different viral infection is necessary for proper treatment. Any delay in Strep A infection treatment may cause disease complications including secondary infections in the sinus and/or kidney of patients. Current Strep A diagnosis methods, such as bacteria culture and rapid antigen detection test (RADT), are not as sensitive and specific as molecular detection. Molecular detection is the ultimate tool to detect bacteria DNA, but it often needs to be performed in a hospital laboratory with necessary equipment. In this study, such molecular technologies were applied to develop a rapid, home-based bacteria DNA detection method. First, the Micro Extraction Technology (MET) was used to extract bacterial DNA on Flinders Technology Associates (FTA) filter paper. Second, isothermal DNA amplification by using Recombinase Polymerase Amplification (RPA) was performed by using Recombinase, SSB protein, and DNA polymerase. Third, amplified bacteria DNA was detected by lateral flow detection strip. This bacteria DNA assay has a sensitivity with about a 100X increase compared to RADT method. Furthermore, the limit of detection (LOD) is 100 copies of Strep A bacteria DNA. This assay is specific, shown by the negative results using similar microorganisms and the absence of cross reactions. Lastly, the assay is 100% reproducible by producing the same results throughout the 3 trials.