

Development of a Novel, Low-Cost, and Rapid Plasmonic Lateral Flow Assay for Point-of-Care Diagnoses of *N. gonorrhoeae* Infections

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The CDC and WHO report around 650,000 *Neisseria gonorrhoeae* (Ng) infections in the U.S and more than 80 million worldwide. Current diagnostic methods for Ng, mainly nucleic acid amplification tests (NAATs), are costly (at least \$60-90), limited to research settings and hospitals, and are time-consuming due to PCR usage. Therefore, there is an urgent need for a cheap and reliable diagnostic solution suitable for point-of-care settings to address the global rise of Ng infections. Plasmonic lateral flow assays (p-LFAs) present ultrabright and quantitative fluorescence-based approaches that overcome the limitations seen in standard colorimetric LFAs, such as qualitative measurements, poor sensitivity, and low accuracy. By conjugating plasmonic-fluor gold nanorods—7000 times brighter than traditional fluorophores—to detection antibodies, the Ng H8 lipoprotein antigen can be detected when it interacts with an H8 mAb. Paper-based LFA strips were created with a test line for H8 mAb and a control line with sheep IgG, all placed on a nitrocellulose membrane. An optimized 0.1% Triton X-100 buffer lyses the gonococcal membrane, releasing H8 into the solution. Urine samples from 44 Ng PCR-positive and 55 PCR-negative males were tested for clinical validation. Standard curves from solutions of 0-10⁷ CFU/mL were tested, resulting in a 10-fold lower detection limit in spiked urine than existing rapid antigen tests. p-LFAs have a manufacturing cost of <1 USD and meet WHO requirements for non-molecular bioassays, demonstrating a sensitivity of 93.2% and a specificity of 96.4%. When combined with portable LFA fluorescence readers, they could effectively address the need for accurate, affordable, and user-friendly diagnostic tests for Ng infections worldwide.

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