

SickIED: Low-Cost, Point-of-Care, Sickle Cell Screening Device for Use in Low-to-Middle Income Countries



Anjali Shah, Dr. Xuanhong Cheng, Department of Bioengineering, Lehigh University, Bethlehem, PA

Abstract

Sickle cell disease (SCD) is a hereditary disease that is prevalent in many sub-Saharan African countries as well as many parts of South-Eastern Asia. Its prevalence is widespread due to its ability to grant resistive immunity to malaria, complicating the truly devastating nature of the blood condition. When diagnosed, the condition is treatable, restoring quality of life and maintaining the patient's resistance to malaria. 50-90% of individuals in Sub-Saharan Africa die before the age of five, due to the lack of testing to reliably determine the cause of death. Current diagnostic methods are not feasible for the low-resource settings where SCD is most prevalent, so the development of a **low-cost point-of-care diagnostic device for SCD is vital**.

The device under development is a sandwich binding lateral flow device for increased specificity and intensity of binding. An intended reference point for the first implementation of this device is Sierra Leone, but a successful device will be integrated into other settings where SCD is prevalent, including Sub-Saharan Africa and South-Eastern Asia. **This device has the potential to make a large impact in these low-income countries, since early diagnosis of SCD can allow preventative prophylaxis penicillin treatments which can significantly reduce mortality due to infection, a common side effect.**¹

Background

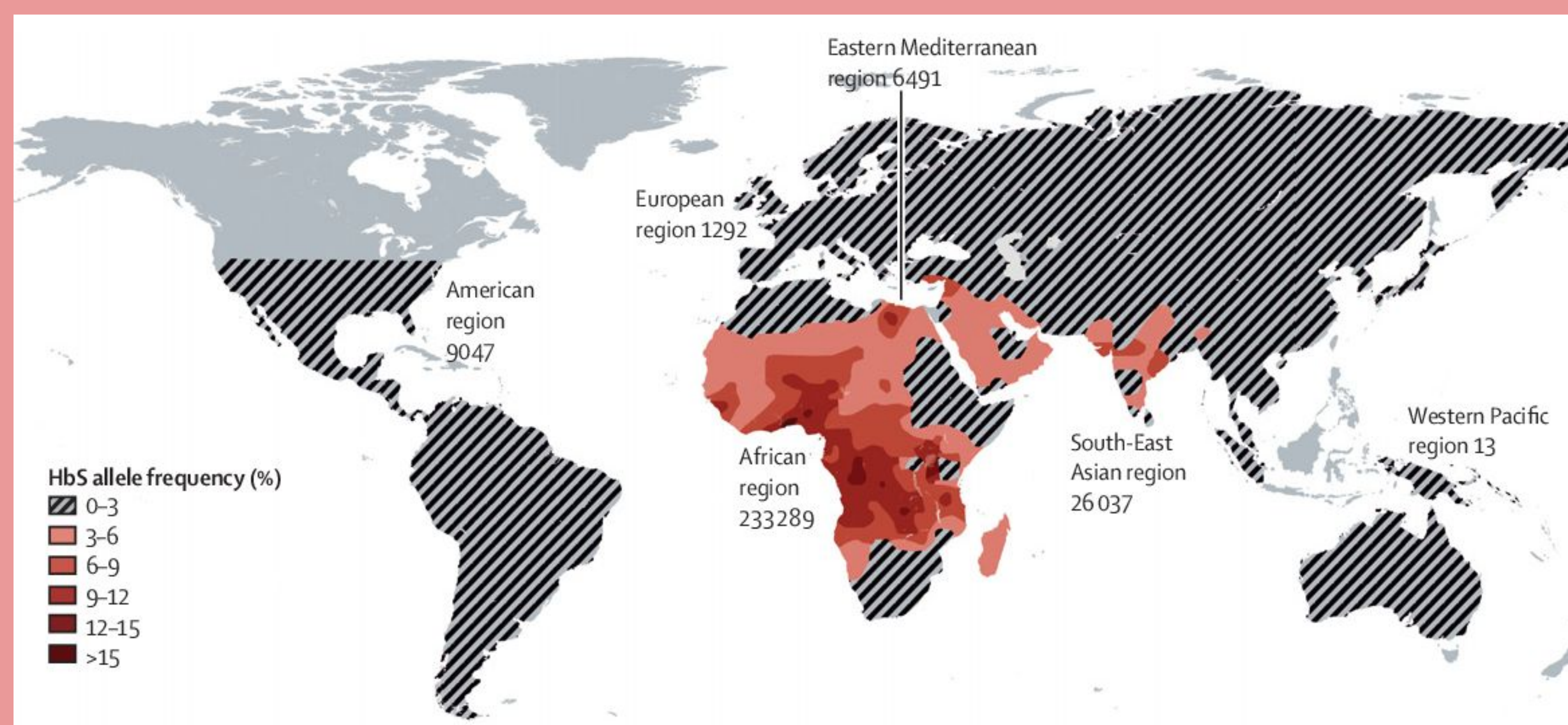


Figure 1: Prevalence of HbS Allele World Map

SCD develops when an abnormal variant of hemoglobin called HbS is present, causing red blood cells to become rigid and crescent-shaped that can aggregate and block blood flow. Carriers of the sickle cell trait have one copy of the sickle cell gene, while people with sickle cell disease have two copies of the sickle cell gene. Symptoms include:³

- Pain episodes
- Swelling of hands and feet
- Difficulty with vision
- Increased susceptibility to infection
- Can be fatal

Current Developmental Stage and Looking Ahead

The Device

A sandwich structure lateral flow test strip, as designed below, will provide ideal specificity and sensitivity to a device that is cost-effective for low-resource areas and accepts whole blood. The device works through a series of three steps and uses a wash step to eliminate a phenomenon called the Hook effect, or the oversaturation of hemoglobin, to decrease nonspecific binding in the antibody-antigen complex.

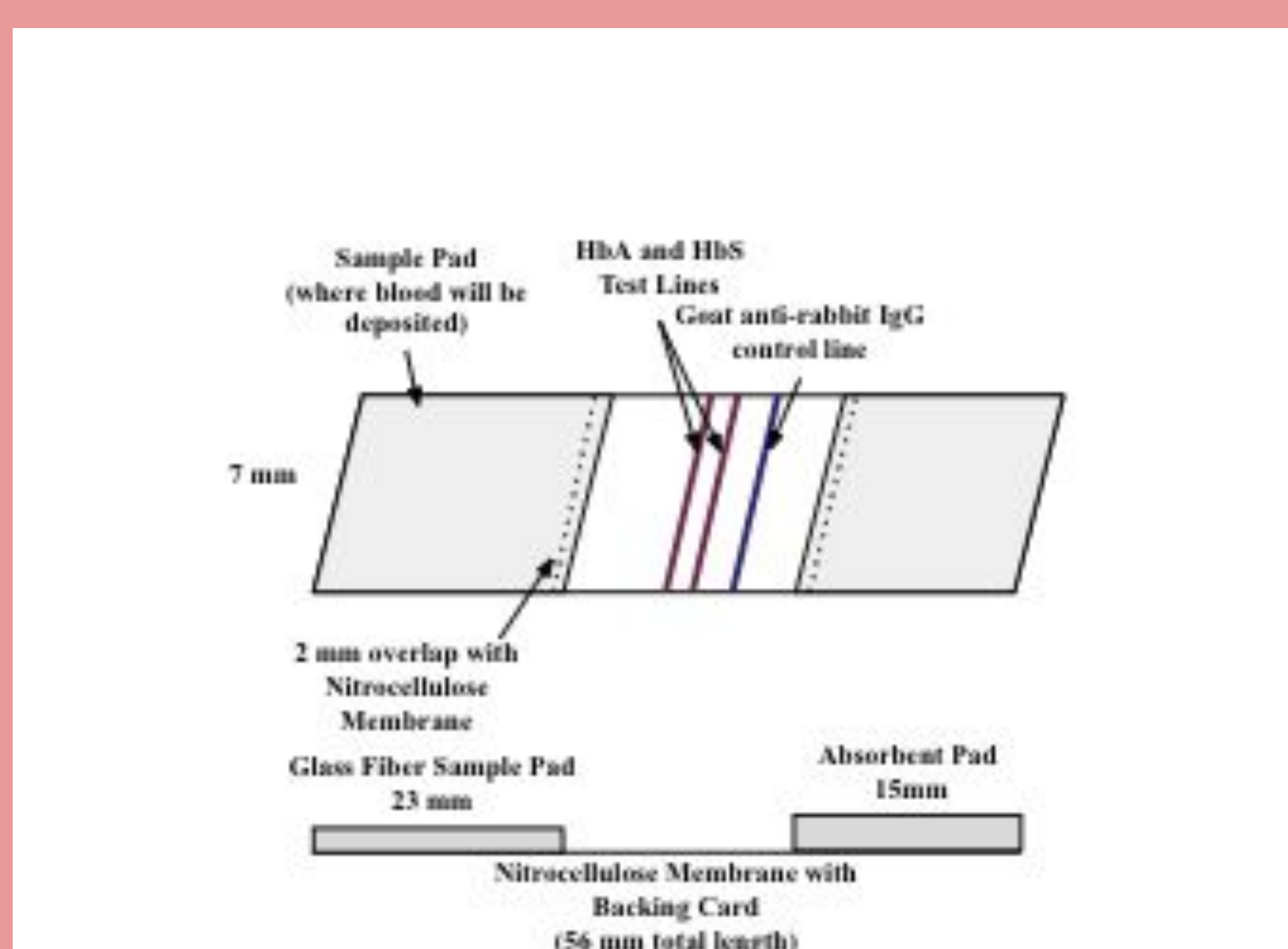


Figure 2: Proposed Test Strip Design

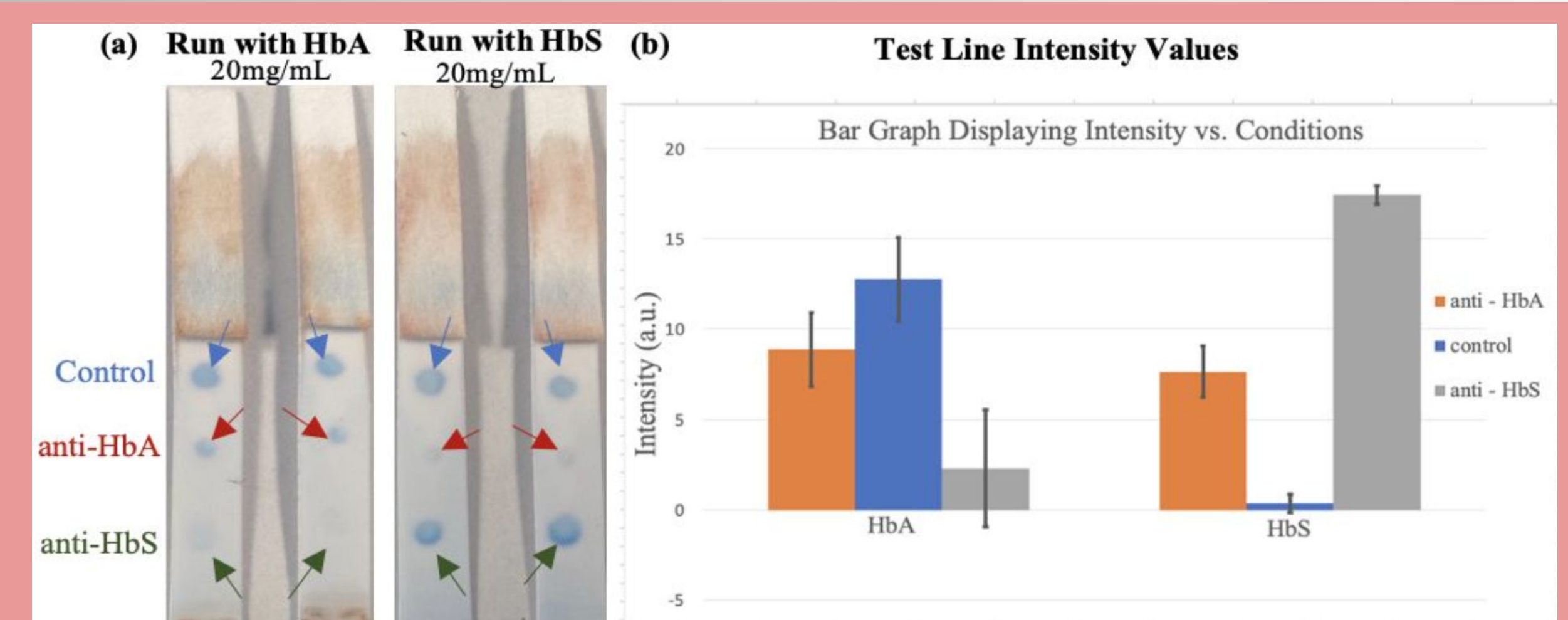


Figure 3: Test Line Intensity Values of the SickIED Lateral Flow Device

A working prototype of the device that is able to recognize antigens and produce accurate results has been developed by the team. The **current goal is to further optimize the device through increasing the specificity and sensitivity of the device and increasing the color intensities of the test lines to produce clear, accurate diagnostic results**. Experiments to increase the sustainability and affordability of the device are also conducted. **ImageJ** computer software is utilized to quantify the test line intensities and create a standardized system for evaluating the saturation of color. Having visited Sierra Leone in August 2022 with the team for **fieldwork**, a perceptions and prevalence study of SCD was thoroughly conducted amongst medical professionals, patients, and other community members. **Next steps** include the clinical trials phase of testing the device with patient blood samples, connecting manufacturing partners, and preparing for upcoming fieldwork in Sierra Leone. The long term goal is to implement the device throughout the Sierra Leone healthcare system and eventually other countries worldwide.

Acknowledgements

- ¹Cober, M. P., & Phelps, S. J. (2010). Penicillin prophylaxis in children with sickle cell disease. *The Journal of Pediatric Pharmacology and Therapeutics*, 15(3), 152-159.
- ²Sierra Leone News: One in four carry the sickle cell disease trait. (2017, March 16). Retrieved March 2, 2019, from <https://awoko.org/2017/03/15/sie-rra-leone-news-one-in-four-carry-the-sickle-cell-disease-trait/>
- ³Sickle cell anemia. (2018, March 08). Retrieved March 2, 2019, from <https://www.mayoclinic.org/diseases-conditions/sickle-cell-anemia/symptoms-causes/syc-20355876>
- ⁴Wirth, J. P., Rohner, F., Woodruff, B. A., Chiwile, F., Yankson, H., Koroma, A. S., . . . Hodges, M. H. (2016). Anemia, Micronutrient Deficiencies, and Malaria in Children and Women in Sierra Leone Prior to the Ebola Outbreak - Findings of a Cross-Sectional Study. *Plos One*, 11(5). doi:10.1371/journal.pone.0155031

