Note: NIH provides this sample for educational purposes to demonstrate how access plans could be prepared in different contexts and conform to the requirements of the IRP Access Planning Policy. This sample is not intended to be used as a template, and its use does not guarantee approval by NIH.

The technology described in this plan is hypothetical and does not intentionally reflect any current or former NIH license. The sample stands alone, outside the context of a full license or application, but applicants may cross-reference information from other parts of their application in their access plan. This sample reflects an access plan prepared before FDA approval of the licensed product (or a foreign equivalent). NIH would maintain the confidentiality of such an access plan, along with other license information and reports, as permitted by applicable law.

Sample Access Plan – Rapid Diagnostic – Lyme Disease

Basic information:
Type of license: non-exclusive
Licensed product contemplated: diagnostic test for Lyme disease
Type of product: diagnostic

I. Product description

We aim to develop a diagnostic test for Lyme disease that allows for rapid detection and, ultimately, earlier treatment to mitigate Lyme disease symptoms and disease progression. Current gold standard diagnosis involves two-step serologic testing, meaning individuals with suspected cases must travel to a healthcare provider or lab service for initial testing and it can take weeks to return results. Even then, those tests may yield false negatives for up to 4 to 6 weeks after infection, and the tests may return false positive results in patients with other conditions like rheumatoid arthritis or other infection.[1] We aim to develop an over-the-counter rapid diagnostic test that can detect the bacteria that causes Lyme disease, during the earliest stages of infection, providing rapid diagnosis. The diagnostic test will serve as an early indicator for patients to seek appropriate follow-up care and antibiotics.

II. Anticipated patient population

Initially, we will focus on patients in the U.S. who live in regions where Lyme is more prevalent, but we are seeking a global license that would allow future expansion to other markets. There were over 89,000 cases of Lyme disease in the U.S. reported to the CDC in 2023. However, this could be an underestimate, as other studies suggest 476,000 cases of Lyme each year and some cases are likely never reported or diagnosed.[2] The Northeast, mid-

[1] CDC. 2024. Testing and Diagnosis for Lyme Disease. https://www.cdc.gov/lyme/diagnosis-testing/index.html
[2] CDC. 2025. Lyme Disease Surveillance Data. https://www.cdc.gov/lyme/data-research/facts-stats/index.html

Atlantic, and upper Midwest have the highest concentrations of black-legged ticks, which corresponds with higher rates of Lyme disease. Rates are also high in Europe, with over 200,000 cases per year,[3] and ticks that spread Lyme disease are found worldwide.

People who work or spend substantial time outdoors, in areas where ticks are found, may have a higher risk of Lyme transmission. This could include those who work outdoors (e.g., park rangers, farmers) and who spend recreation time outside (e.g., park visitors, summer campers). We plan to direct product testing and deployment strategies to meet their needs.

III. Other tools, facilities, or unique resources necessary for use of the product

While our goal is to make it easier to access Lyme diagnostics, customers will still need to be able to get to a facility where our product is sold. Additionally, our diagnostic test merely identifies Lyme disease; it cannot prevent or treat the condition. If someone using our product tests positive for Lyme, they may need confirmatory testing and treatment from a healthcare provider. Our proposed access strategies may help address these challenges.

IV. Access Strategies

Licensing

- We are seeking a non-exclusive license to this technology. A non-exclusive license promotes patient access to NIH inventions by permitting competition and parallel innovation, which in turn drive **affordability**, **availability**, **acceptability**, and **sustainability** in the Lyme diagnostics market. Other companies can use this technology in the same field of use and/or region to create multiple products that compete on price and quality, and other products may address similar challenges in different ways to support a broader range of patients.
- In the event we exit the market before expiration of the licensed patents, we will seek out other manufacturers/suppliers to **sustain** production and **availability** of the diagnostic test. We commit to license all intellectual property and know-how needed to make the product under those circumstances. To demonstrate our diligence, we will continue to submit progress reports to NIH, detailing our efforts to identify another manufacturer/supplier, for the remaining patent term.

Product design & customer engagement

- We will focus on developing a diagnostic test that utilizes self-collected specimens for easy at-home self-administration (**acceptability**), which can open more avenues to market the product and remove previous barriers to Lyme diagnostic tests (**availability**). We will start customer interviews within the first year of our license.

[3] CDC. 2021. Comparison of Lyme Disease in United States and Europe. *Emerging Infectious Diseases,* Vol. 27, No. 8. ISSN: 1080-6059

Distribution

- We intend to distribute to pharmacies, garden centers, farming supply stores, outdoor retailers, as well as online retailers and telehealth providers, promoting convenient **availability**, especially for those in rural areas across the U.S.
- We will engage with organizations including the National Parks Service, the U.S. Forest Service, state park systems, the National 4-H Council, the YMCA, and professional organizations representing outdoor professionals. Agreements could include selling our product in park shops and/or selling to certain organizations at a reduced cost, all promoting **availability** and **affordability**. To maximize the benefit of these partnerships, we will initiate conversations prior to FDA approval such that arrangements are in place before or shortly after market entrance.

Marketing

- We will engage with patients and physicians to produce suitable educational materials (e.g., packaging labels, insert information, instructions with illustrations, etc.) in multiple languages. Our test kits will include QR codes and link to government websites where patients can learn more about Lyme disease and find options for follow-up care. Together, these strategies promote **acceptability** of our product. We will develop materials before FDA approval and revisit them every 5 years.

V. Alternatives

We intend to make choices informed by and responsive to end user preferences when possible, including post-market improvements to our product like increased accuracy, earlier detection, faster readout, and longer shelf stability. We will continue to update NIH, in annual progress reports, about the status of these and other access strategies—as evidenced by, e.g., user uptake relative to need and our continued engagement around end user preferences. We also commit to adapt our proposal to promote access to our product as our R&D evolves. For example, if our product ultimately must be administered by a healthcare provider (instead of a self-administration) or if uptake is low, we will revisit this plan and incorporate strategies that could touch on transportation challenges, pricing and insurance coverage, and other related barriers.