



TB Patch

A non-invasive skin patch test used to diagnose active TB infection.

- Transdermal and non-invasive, no needles required
- No whole blood or sputum collection required
- No central laboratory required
- Can be applied and read by trained personnel, but does not require a doctor or a nurse in settings where these professionals are limiting
- More specific than existing TB skin tests

Overview

The TB Patch is a conventional point-of-care test used to diagnose active TB infection without laboratory processing. The patch is applied to the skin and delivers MPT-64, a protein specific to bacteria that cause TB. In patients with active TB infection, a localized immune response consisting of erythema and/or vesiculation appears less than 4 days after application.

Accurate diagnosis of active TB infection enables physicians to avoid wasting time, resources and medicine treating false positive cases.

Sequella has conducted demonstration and pivotal trials in Africa, South America, and the Philippines. Product life cycle strategy involves developing the Generation 1 Patch with vial MPT-64 and an adhesive bandage (*Fig. 1 above*); Generation 2 with MPT-64 incorporated into adhesive patch (*Fig. 2 above*); and Generation 3 with integrated MPT-64 to detect active TB and recombinant PPD proteins (rPPD) to detect latent TB in same patch adhesive (*Fig. 3 above*).

Alliance and Market Opportunities

Market Need. Far more people in the U.S. are suspected of having TB than those with confirmed cases. Physicians estimate that, for every case of confirmed TB, 10 to 20 "TB suspect" patients undergo the CDC-recommended diagnostic regimen. Currently, treatment is hindered by inadequate diagnostic technology, test complexity, and duration.

In the U.S., there are 15 to 30 million people with latent TB at high-risk for developing active TB disease and approximately 15,000 new confirmed cases of active TB disease annually. While there is a common misperception that TB only infects the poor or homeless, the total U.S. high-risk population is far wider and includes the following segments:

- **Opportunistic Infection:** Persons with HIV/AIDS, or who inject illicit drugs (~ 4 to 6 million)
- **Chemically-Induced TB:** Persons on anti-TNF drugs or α -interferon for rheumatoid arthritis, Crohn's disease, ankylosing spondylitis, or psoriasis (~4 to 6 million)
- **Healthcare:** Physicians, staff and patients in hospitals and nursing homes and facilities for the elderly (~3 million)
- **Public Welfare:** Prison and jail employees, homeless shelter workers and residents,
- **Foreign-born:** Persons from developing or TB high-burden countries (~3 million)

Sequella Licensing Opportunity

Biologic, Diagnostic: Pivotal Trials

Therapeutic Focus: Tuberculosis (TB)

The TB Patch has no special handling, refrigeration, or incubation requirements. Results from the TB Patch can be obtained in less than 4 days. In comparison to existing TB diagnostics, the TB Patch is differentiated by the following attributes:

| Product | Type of Infection | Specimen Collection | Admin. Method | Specimen Handling | Results TAT | Relative Cost | Sensitivity | Specificity |
|--------------------------|-------------------|------------------------------|---------------------|--|------------------------------|---------------|-------------|-------------|
| Mantoux PPD | Latent | None | Needle | POC (point of care) | 48-72 hrs | Medium | Low | Low |
| QFT-Gold | Latent | Whole blood draw | "In tube" sampling | Minimizes blood handling | ~24 hrs | High | High | High |
| AFB Smear | Active | Sputum generated | None | Lab processed; Special handling requirements | 3-7 days | Medium | Medium | Medium |
| AFB Culture | Active | Sputum generated | None | Lab processed; Special handling requirements | Several lab readings, ~6 wks | High | Med/High | Med/High |
| Sequella TB Patch | Active | No specimen collected | Non-invasive | POC convenience | < 4 days | Low | High | High |

Clinical Status

The TB Patch has completed demonstration and pivotal trials in Africa, South America, and the Philippines. The TB Patch has successfully confirmed high rates of specificity demonstrating its superiority compared to current tests.

| Phase | Study | Design | Subjects | Clinical Results |
|---------|---------------------|--------------------------------------|----------|----------------------------------|
| Pilot | Philippines (1998) | Dose – Finding | 96 | Sensitivity 98% Specificity 100% |
| Pilot | Philippines (2001) | Dose – Finding | 77 | Sensitivity 88% Specificity 100% |
| Pivotal | Cape Town (2003/04) | Dose – Finding, Blinded, Prospective | 96 | Sensitivity 65% Specificity 96% |
| Pivotal | Philippines | Blinded, Prospective | 130 | 2008 |

Regulatory and Development Background

Regulatory. The TB Patch may be regulated as a biologic, biopharmaceutical, or device in non-US markets, and as a biologic in the U.S.

Development/Technical Background. Sequella manufactures recombinant MPT-64, or rMPT-64, in E. coli, a bacterial host conducive to large-scale manufacturing. Sequella established that the rMPT-64 protein is potent and efficacious for detection of active TB. Sequella produces the TB Patch recombinant protein under Good Manufacturing Practices (GMP). Peer-reviewed articles are available.

Intellectual Property. Sequella has 18 issued and pending patents in Canada, the U.S., Europe, Australia, and China, for Patch composition, methods, and use.

The TB Patch is currently available for partnering worldwide.

For information on
alliance opportunities, contact:

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