Genedrive®
Speed to result
Rapid molecular detection of *Mycobacterium tuberculosis*
and rifampicin resistance (MTB/RIF)
Tuberculosis is one of the deadliest diseases in the world and India is the country with the highest burden of TB, with World Health Organisation (WHO) statistics for 2014 giving an estimated incidence of 2.2 million cases of TB for India out of a global incidence of 9.6 million. It is estimated that about 40% of the Indian population is infected with TB bacteria, the vast majority of whom have latent rather than active TB.

Common symptoms of TB include **coughing**, **sneezing**, **fever** and **night chills**, the ambiguity of these symptoms makes early diagnosis and treatment a difficult target to achieve.

WHO notes that the deaths due to TB are preventable yet 2014 reported 1.3 million mortalities.

Some studies suggest that the biggest barrier to prevention and cure of TB is the lack of proper diagnostic capacity. The subcontinent bears the burden of 2 million TB sufferers annually, the disease claims 2 lives every 3 minutes, killing a total of 1000 people daily.

TB can affect anyone regardless of their socio-economic status, lifestyle and region. Both government and private bodies note that TB control and management is becoming a critical issue. When diagnosed at a preliminary stage and treated properly, TB can be controlled and eliminated completely.

“**23% OF GLOBAL TB CASES ARE REPORTED IN INDIA**”

“**LARGE INCREASE IN DRUG RESISTANT TB CASES IN INDIA**”
Hindustantimes, Feb 2015 and Biomed Research International

India needs an affordable, early and accurate diagnosis to get ahead in the race against TB.

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**Genedrive®**
A powerful technology for accurate and affordable TB diagnosis

Genedrive® is a unique, affordable, rapid PCR based device for the rapid detection of MTB/Rif.

**Advantages of Genedrive®**
- Simultaneous detection of *Mycobacterium tuberculosis* and rifampicin resistance
- Fast turn around time ~ 75 minutes
- User friendly, simple to use
- Compact design for easy portability
- Lyophilised reagents stable at room temperature

Clear, unambiguous results

600g, 12x18x10cm, 12V DC, 15-40°C operating range

Single button operation

Three-prong assay cartridge with lyophilised amplification-detection mix
**Simple and easy to use**

**01**
Collect patient sample & process on sample processing cassette.

Sample processing must always be performed inside a biological safety cabinet.

**02**
Load MTB/RIF cartridge.

**03**
Insert cartridge and start.

![Image of a biological safety cabinet](image1.png)

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**Genedrive®**
Display of results

**01**
Positive. This indicates the presence of a mutation associated with resistance to rifampicin treatment.

**02**
Positive. Unable to determine rifampicin resistance status.

**03**
Positive. The patient is likely to be sensitive to rifampicin treatment.

**04**
Negative.
The expert’s choice for tuberculosis testing

Competitive advantages of the Genedrive® system over traditional TB testing methods.

<table>
<thead>
<tr>
<th>Afforable</th>
<th>Fast TAT</th>
<th>Ease of operation</th>
<th>Drug sensitivity</th>
<th>Detection</th>
</tr>
</thead>
<tbody>
<tr>
<td>✔️</td>
<td>✔️</td>
<td>❓*</td>
<td>❓*</td>
<td>✔️</td>
</tr>
</tbody>
</table>

*Varies depending on instrument

Ordering Information

Please quote the codes shown below when placing your order.

- **Genedrive - XGDv1.0**
- **MTB/RIF ID Assay Kit - G13200201**

**Xcelris Labs Ltd**
Xcelris Labs Limited is ISO 9001:2008 & DSIR certified; India’s leading Genomics research organisation. Our focus is on delivering innovative solutions across domains such as Human Health, Nutrition, Genetics, Animal science, Agriculture and the Environment. We offer a comprehensive portfolio of Genomics research and Medical Genetics testing services through our expertise in Next Generation Sequencing (NGS) technology and data analysis capabilities.

In recent years Xcelris Labs has gained a strong foothold by developing their genetic testing portfolio for Cancer, Infectious diseases, Cardiology diseases and Hereditary diseases in humans. Xcelris Labs partners with more than 1000 major research institutions and hospitals in India and abroad.

www.xcelrislabs.com

**Epistem Ltd**
Epistem is an established, ISO 13485 certified, biotechnology company with headquarters in Manchester, UK and facilities in the US. Founded on ground-breaking research in epithelial stem cell biology, Epistem has evolved into a dynamic and successful enterprise enabling advances in medicine through the provision of innovative services and pioneering products. In recent years Epistem has focused on the development of the Genedrive® molecular device. The Genedrive® was developed as an affordable next generation genotyping and sequence analysis device, providing rapid detection in approximately 75 minutes. The first test developed on the Genedrive® is MTB/RIF which allows small/medium laboratories to test for TB thus speeding up diagnosis and treatment and improving prognosis.

www.epistem.co.uk
www.genedrive.com
# General Specifications

<table>
<thead>
<tr>
<th>Method</th>
<th>Real time PCR with post-PCR melting curve analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Performance characteristics</td>
<td>Maximum thermal transition rate: 4°C/sec heating, 1.2°C/sec cooling</td>
</tr>
<tr>
<td>Software operating system</td>
<td>Microsoft .Net Micro Framework v4.1</td>
</tr>
<tr>
<td>Analysis time</td>
<td>75 minutes</td>
</tr>
<tr>
<td>Result output</td>
<td>Display: 10.6x6.7 LCD display (9.7x5.7cm visible)</td>
</tr>
<tr>
<td></td>
<td>Printer: Printer Optional</td>
</tr>
<tr>
<td>External communication</td>
<td>Mini B-USB port</td>
</tr>
<tr>
<td>Dimensions</td>
<td>12cm x 18cm x 10cm</td>
</tr>
<tr>
<td>Weight</td>
<td>600g</td>
</tr>
<tr>
<td>Mains power supply</td>
<td>Input: 100-240V 1.2A 50/60Hz AC</td>
</tr>
<tr>
<td></td>
<td>Output: 12V 8.33A DC</td>
</tr>
<tr>
<td>Uninterruptable power supply (optional):</td>
<td>Input: 100-240V 1.2A 50/60Hz AC</td>
</tr>
<tr>
<td></td>
<td>Mains output: 12V 8.33A DC</td>
</tr>
<tr>
<td></td>
<td>Battery output: 11.1V 7500mAh (sufficient for 2 test operations)</td>
</tr>
<tr>
<td>Operating conditions</td>
<td>15°C to 40°C humidity &lt;75% non-condensing</td>
</tr>
<tr>
<td>Pack size</td>
<td>1 unit</td>
</tr>
</tbody>
</table>

## Assay

<table>
<thead>
<tr>
<th>Assay type</th>
<th>Mycobacterium tuberculosis &amp; rifampicin resistance (MTB/RIF) test</th>
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</thead>
<tbody>
<tr>
<td>Packing</td>
<td>1x1 test, 1x25 tests, 1x50 tests, 1x100 tests</td>
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<tr>
<td>Storage temperature</td>
<td>2°C to 28°C</td>
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<td>Shelf life</td>
<td>12 months</td>
</tr>
</tbody>
</table>

Marketed in India and SAARC countries* (Bangladesh, Sri Lanka, Nepal, Pakistan, Myanmar, Bhutan, Maldives, Afghanistan) by:

Xcelris Labs Ltd
Old Premchand Nagar Road, Opp. Satyagrah Chhavani, Bodakdev, Ahmedabad-380015, India. Tel.: +91-79-66197777 | Fax: +91-79-66309341
e-mail: medicalgenetics@xcelrislabs.com • www.xcelrislabs.com

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MTB / RIF ID Cartridge is an In Vitro Diagnostic Medical Device intended for use with the Genedrive® instrument. For professional use only.

*Subject to local approval