| Health Technology Review | |
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| **Technology Ref.:** | HTA23076 |
| **Technology Name/Version/Model:** | Oxford Immunotec T-SPOT. TB test, version: TB.300 |
| **Approvals by International Bodies:** | CE Mark, FDA and MoHaP (UAE) |
| **Company name:** | Al Fahim Healthcare Solutions L.L.C-Branch of Abu Dhabi |
| **Agent in UAE:** | Salih Zain |
| **Email:** | salih@alfahimhealth.com |

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| **Short Description of the Technology:** | Oxford Immunotec T-SPOT. TB test is a diagnostic test for tuberculosis (TB) infection. It's designed to detect immune responses to Mycobacterium tuberculosis, the bacteria that causes TB, by measuring the response of T cells in the blood. |

| **Health Technology Assessment Team Recommendation:** | **Approve** |
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**Summary of Review:**

The immune response to infection with Mycobacterium tuberculosis (MTB) is mediated predominantly through T cell activation. As part of this response, T cells are sensitised to MTB antigens and the activated effector T cells, both CD4 and CD8, produce the cytokine interferon-gamma when stimulated by these antigens. The T-SPOT.TB test uses T-SPOT technology, a modified version of the enzyme-linked immunospot (ELISPOT) methodology to enumerate M. tuberculosis-sensitised T cells by capturing interferon-gamma in the vicinity of CD4 and CD8 T cells from which it was secreted.

IGRAs are in vitro blood tests that measure interferon-gamma released by circulating lymphocytes in whole blood during overnight incubation with exposure to M. tuberculosisspecific antigens (ELISA based) or the number of T-lymphocytes producing interferon-gamma (ELISPOT based). In 2011, WHO issued recommendations on the use of IGRAs for the diagnosis of TB infection, including the Oxford Immunotec T-SPOT.TB (T-Spot) assays.

| Advantages | Disadvantages |
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| International bodies approval: CE Mark, FDA and MoHaP (UAE) | The test is generally more expensive than the traditional TB skin test. |
| In 2011, WHO issued recommendations on the use of IGRAs for the diagnosis of TB infection, including the Oxford Immunotec T-SPOT.TB (T-Spot) assays. | The test requires laboratory facilities and trained personnel, which might not be readily available in resource-limited settings. |

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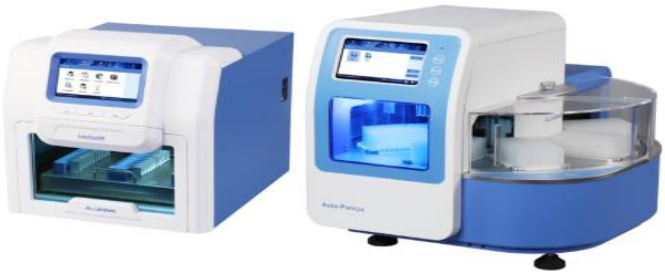
| High Sensitivity and Specificity, leading to more accurate detection of TB infection. | |
| Unlike the skin test, T-SPOT.TB is not influenced by prior Bacillus Calmette-Guérin (BCG) vaccination, reducing the chances of false-positive results. | |
| It requires only one patient visit, which is more convenient and efficient compared to the skin test that requires multiple visits. | |

We recommend an **approval of using this technology** for Market entry with the following conditions:

1. Approval of Oxford Immunotec T-SPOT. TB test, version: TB.300.
2. The T-SPOT.TB test should be performed by laboratory technicians who are skilled in handling blood samples and conducting immunological assays in a clinical or laboratory setting.
3. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
4. Provision of regular updates and reports about the product to DOH upon request.

**Moreover,** DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

**Technology Image**



## Population, setting and intended user for Technology "Oxford Immunotec T-SPOT. TB test"

- **Population/ Intended User**;
  - Individuals with possible exposure to TB.
  - Healthcare workers exposed to TB patients.
  - Immigrants from TB-endemic regions.
  - Immunocompromised Individuals.

- Patients Before Initiating Immunosuppressive Therapy.
- Residents and employees of high-risk settings such as prisons, homeless shelters, or nursing homes.

- **To be performed by**:
  - Laboratory technicians who are skilled in handling blood samples and conducting immunological assays.
- **Clinical Setting:**
  - Hospitals, clinics, or specialized laboratories are equipped to handle blood samples and conduct immunological assays.
- **Condition of use:**
  - As per the manufacturer's instructions.
- **Exclusion criteria:**
  - Not suitable for patients who recently received live vaccines.