Health Technology Review	
Technology Ref.:	HTA23077
Technology Name/Version/Model:	STANDARD™ E TB-Feron ELISA - STANDARD™ E TB-Feron ELISA - STANDARD™ E TB-Feron Control - TB-Feron Tubes 300
Approvals by International Bodies:	Saudi Food and Drug Authority (SFDA), Declaration of Confirmity (CE IVD)
Company name:	SD Biosensor, Inc
Agent in UAE:	Babirus Medical Equipment Trading L.L.C.
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Short Description of the Technology:	To measure the IFN-γ in samples, TB-Feron utilizes sandwich ELISA method using a specific to human IFN-γ antibody. It is designed especially for assessment of cell mediated immunity by measurement IFN-γ after cultivating heparin treated whole blood with stimulating antigen. The IFN-γ is a cytokine which is used as specific marker in cell-mediated immune response. When exogenous or endogenous antigens are added to the blood, antigen specific effector / memory T lymphocyte is rapidly re-stimulated to produce interferon gamma (IFN-γ). The stimulation technology of effector T lymphocytes in whole blood with specific antigens and the accurate IFN-γ measurement in a plasma, which are the basis of the TB-Feron ELISA technology. STANDARD E TB-Feron ELISA uses specialized blood collection tubes, which are antigen-sensitized. Incubation of the blood occurs in the tubes for 16 to 24 hours, after which, plasma is harvested and tested for the presence of IFN-γ produced in response to the peptide antigens. The test is performed in two stages. First, whole blood is collected into each of the blood collection tubes, which include a Nil tube, TB Antigen tube, and Mitogen tube. The Nil tube adjusts for background IFN-gamma level of sample. The TB Antigen tube contains TB-specific recombinant protein antigens (ESAT-6, CFP-10, and TB 7.7) to assess IFN-gamma responses in T cells from individuals infected with M.tuberculosis, but generally not from uninfected or BCG vaccinated people without disease or risk for latent TB infection. And the Mitogen tube can be used with the test as a positive control. This tube may also serve as a control for correct blood handling and incubation. These three tubes should be incubated at 37°C as soon as possible and within 16 hours of blood collection. Following 16to24hours Incubation period, the tubes are centrifuged, the plasma is collected and the amount of IFN-γ (IU/mL) measured by ELISA. A test is considered positive for

	an IFN-γ response to the TB Antigen tube that is significantly above the Nil IFN-γ (IU/mL) value. A low response to Mitogen (< 0.5 IU/mL) indicates an indeterminate result when a blood sample also has a negative response to the TB antigens. This pattern may occur with insufficient lymphocytes, reduced lymphocyte activity due to improper specimen handling, incorrect filling / mixing of the generate IFN-γ. The Nil sample adjusts for background, heterophile antibody effects, or non-specific IFN-γ in blood samples. The IFN-γ level of the Nil tubes is subtracted from the IFN-γ level for the TB Antigen tubes and Mitogen tubes (if used).

Health Technology Assessment Team Recommendation:	**Disapprove**

Summary of Review:

The technology is an in-vitro blood test to help for the diagnosis of human tuberculosis infection based on IGRA (Interferon Gamma Releasing Assay) method. IGRA method is the detection of IFN-γ produced by sensitized T lymphocytes upon exposure to mycobacterial antigens.

Advantages	Disadvantages
No risk on patients and healthcare professionals	The test is not recommended by WHO nor approved by FDA.
Help in diagnosing the Latent TB and preventing the disease progression.	More studies are required with larger sample size and assessment of reproducibility before it being comparable to the WHO approved tests
High performance with 95.0% total agreement	
Fast turn around time and High test efficiency	
Results from a patient single visit within 24 hours	

We recommend a **Disapprove of using this technology** for Market entry with the following conditions:

1. STANDARD™ E TB-Feron ELISA
2. More studies are required in a well-established healthcare provider in Abu Dhabi with larger sample size (for assessment of reproducibility).
3. Comply with human subject research regulations, including ethical Institutional review board (IRB) approval, apply for DOH IRB committee approval (to decide on the sample size and facility).
4. Re-submit the requirements to DOH after one year for further evaluation.
5. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
6. 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 "STANDARD™ E TB-Feron ELISA"

- **Population/ Intended User**;
  - to diagnose TB infection.
- **To be performed by**:
  - By medical lab technician/technologist.
- **Clinical Setting:**
  - **Hospitals, clinics, laboratories.**
- **Condition of use:**
  - As per manufacture instruction.
- **Exclusion criteria:**
  - Other conflicting medical issues.