



**SD BIOSENSOR INC.**

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**STATEMENT**

Date: 16<sup>th</sup>, August, 2022

To whom it may concern,

We, SD BIOSENSOR, having the facility premises in A-28F~29F, ICT Valley 58-1, Giheung-ro, Giheung-gu, Yongin-si, Gyeonggi-do, 16976, REPUBLIC OF KOREA, registered at Chamber of Commerce at Suwon, represented by its Managing Director Rafe Seo.

Declare hereby, that:

1. The Clinical Performance characteristics values of **STANDARD™ E TB-Feron ELISA Test Kit** (REF: 07TBFA10 and 07TBFA30C) based on IGRA principle **were validated** in strict compliance with the updated and consolidated World Health Organization (WHO) recommendations / guidelines for programmatic management of Latent tuberculosis infection..
2. The Clinical Performance characteristics (Sensitivity and Specificity) values of STANDARD™ E TB-Feron ELISA Test Kit (REF: 07TBFA10 and 07TBFA30C) was found to be **98.03%** and **98.55%** respectively.
3. The Clinical Performance characteristics values of **STANDARD™ E TB-Feron ELISA Test Kit** are placed on our corporate web page and can be easily verified by accessing the following link:

[https://www.sdbiosensor.com/product/product\\_view?product\\_no=113](https://www.sdbiosensor.com/product/product_view?product_no=113)

← → ↻ 🔒 [sdbiosensor.com/product/product\\_view?product\\_no=113](https://www.sdbiosensor.com/product/product_view?product_no=113)

Specification	
Sensitivity	98.03%
Specificity	98.55%

4. There should be no doubt about the quality, authenticity of clinical performance values and compliance of **SD BIOSENSOR** brand products (the REF numbers are mentioned above) with the statements mentioned above.

Thus, we declare under our sole responsibility that, the STANDARD™ E TB-Feron ELISA Test kit (REF: 07TBFA10 and 07TBFA30C), which was offered in frames of the procurement project No: 21056258 from 09/06/2021 by SC IMUNOTEHNOMED S.R.L. completely meets the tender requirements.

With kind regards,

Name & Surname: Rafe Seo

Position: IGRA Business Leader

Authorized signature & Stamp:

