POLISH CENTRE FOR
TESTING AND CERTIFICATION
www.pcbc.gov.pl

BM.433.0056.2019/KW/MV/2023/0634 Warsaw, 09.11.2023

TÜRKLAB Tibbi Mal. San. Tic. A.Ş.
ITOB 10017 Sokak No: 2,
Tekeli – Menderes Izmir, Turkey

To Whom it May Concern,

Please be kindly informed that Polskie Centrum Badań i Certyfikacji S.A. (hereinafter "PCBC" or "Polish Centre for Testing and Certification") performed evaluation of the comparative study of IVD Device HBsAg Test, WB/S/P.
HBsAg Test can detect all subtypes of Hepatitis B virus surface antigens. Performance evaluation is indicated below:

Sample Status	Sample HBsAg Status	S / P Sample Type			WB Sample Type		
		Study Number	Com. Assay	Result	Study Number	Com. Assay	Result
Naturally acute or chronic infected	Positive	473	EIA	100 %	411	EIA	100 %
Blood donors	Negative	1143	EIA	99,8 %	100	EIA	100 %
Clinical samples	Negative	297	EIA	100 %	225	EIA	100 %
Pregnant women	Negative	280	EIA	100 %	30	EIA	100 %

Sensitivity: 99,9% [95% CI = 99,58% - 100%]; Specificity: 99,90% [95% CI= 99,65% - 99,99%]
Analytical Sensitivity: Cut-off: 0,26 IU/mL

The information in the IFU (version C08.TIHBG.02; date: 25.07.2023; Rev. 00) for Test It brand had been reviewed and remain true and valid.
Test manufactured by TÜRKLAB Tibbi Mal. San. Tic. A.Ş. and covered by EC Certificates 1434-IVDD-434/2019 and 1434-IVDD-435/2019.

Yours Sincerely,

Digitally signed by Poiata Vitalie
Date: 2024.11.08 16:50:13 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Izabela Joanna Czeluśniak
2023.11.09 11:47:26 +01'00'

Coordinator for In Vitro Diagnostic Medical Device Certification Division