POLISH CENTRE FOR
TESTING AND CERTIFICATION
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BM.433.0058.2019/KW/MV/2023/0635 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 Anti-HCV Test, WB/S/P.
Anti-HCV Test can detect antibodies generated against proteins that are encoded by conserved sequences of CORE, NS3, NS4, NS5 parts of HCV genome. Performance evaluation is indicated below:

Sample Status	Sample Anti-HCV Status	S / P Sample Type			WB Sample Type		
		Study Number	Com. Assay	Result	Study Number	Com. Assay	Result
Positive samples (Including all available genotypes)	Positive	427	EIA	100 %	60	EIA	100 %
Blood donors	Negative	1145	EIA	100 %	100	EIA	100 %
Clinical samples	Negative	384	EIA	100 %	215	EIA	100 %
Pregnant women	Negative	280	EIA	100 %	30	EIA	100 %

Sensitivity: 99,9% [95% CI = 99,25% - 100%]; Specificity: 99,9% [95% CI= 99,83% - 100%]

The information in the IFU (version C08.TIHC.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-430/2019 and 1434-IVDD-431/2019.

Yours Sincerely,

Izabela Joanna Czeluśniak
2023.11.09 11:48:15 +01'00'

Coordinator for In Vitro Diagnostic Medical Device Certification Division

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