



# CERTIFICATE

**EC No 1434-IVDD-434/2019**  
**EC Design-Examination**

**Directive 98/79/EC on in vitro diagnostic medical devices**

Polish Centre for Testing and Certification certifies  
that manufactured by:

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

in vitro diagnostic medical devices, List A

**HBsAg Test**  
**Brands: Info®, Toyo®, Rapidan Tester®, Labmen®**

in terms of design documentation, comply with requirements of Annex IV section 4 to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 29.08.2019 to 28.08.2024

The date of issue of the Certificate: 29.08.2019

The date of the first issue of the Certificate: 29.08.2008



Application No: 56/2019  
Module: H6

Michał Pachowski, PhD  
President



Certificate No **1434-IVDD-434/2019**  
Issued under the Contract No MD-31/2019  
Bears the PCBC hologram.  
Warsaw, 29.08.2019



# CERTIFICATE

**EC No 1434-IVDD-435/2019**  
**Full Quality Assurance System**

**Directive 98/79/EC on in vitro diagnostic medical devices**

Polish Centre for Testing and Certification certifies  
that the quality assurance system in the organization:

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

for the design, manufacture and final inspection of in vitro diagnostic medical devices,  
List A

**HBsAg Test**  
**Brands: Info®, Toyo®, Rapidan Tester®, Labmen®**

complies with requirements of Annex IV excluding section 4 and 6 to Directive 98/79/EC (as amended)  
implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 29.08.2019 to 28.08.2024

The date of issue of the Certificate: 29.08.2019

The date of the first issue of the Certificate: 29.08.2008



Application No: 56/2019  
Module: H7

Michał Pachowski, PhD  
President



Certificate No **1434-IVDD-435/2019**  
Issued under the Contract No MD-31/2019  
Bears the PCBC hologram.  
Warsaw, 29.08.2019