



**EC CERTIFICATE No. 1434-IVDD-56/2016**

**EC Design-Examination**

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

PCBC certifies that the design documentation relating to in vitro diagnostic medical device, List A:

**HBsAg Test**

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

manufactured by:

**TÜRKLAB Tibbi Mal. San. Tic. A.Ş.  
ITOB 10031 Sokak No: 15 Tekeli Menderes  
Izmir, Turkey**


was examined by PCBC according to Annex IV p. 4 Directive 98/79/EC (with subsequent amendments) transposed into the Polish law and comply with the essential requirements of the Directive.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**



  
**Anna Wyroba**  
Vice President of PCBC

**CE 1434**

PCBC Notified Body  
23A, Kłobucka Str., PL-02-699 Warsaw

# POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A.

POLISH CENTRE FOR TESTING AND CERTIFICATION



## EC CERTIFICATE No. 1434-IVDD-57/2016

Full Quality Assurance System

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

PCBC certifies quality assurance system in company:

**TÜRKLAB Tıbbi Mal. San. Tic. A.Ş.**  
**ITOB 10031 Sokak No: 15 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 the requirements of Annex IV excl. 4, 6 Directive 98/79/EC  
(with subsequent amendments) transposed into the Polish law. The audit of the quality  
assurance system carried out by PCBC has provided evidence of the above.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**



  
**Anna Wyroba**  
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Application No. 45/2016  
Contract No. MD-18/2016

Module H7