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 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFIKAT




# Certificate

No. Q5 106240 0001 Rev. 01

**Holder of Certificate:** **Abbott Rapid Diagnostics Jena GmbH**  
 Orlaweg 1  
 07743 Jena  
 GERMANY

**Facility(ies):** Abbott Rapid Diagnostics Jena GmbH  
 Orlaweg 1, 07743 Jena, GERMANY  
  
 Abbott Rapid Diagnostics Jena GmbH  
 Löbstedter Straße 82, 07749 Jena, GERMANY  
  
 Abbott Rapid Diagnostics Jena GmbH  
 Löbstedter Straße 105, 07749 Jena, GERMANY

**Certification Mark:**



**Scope of Certificate:** Design, development, manufacture, distribution of in-vitro diagnostic products (reagents and instruments) and supporting products for immunological and nucleic acid based testing for the clinical areas of infectious diseases and hematology

**Applied Standard(s):** EN ISO 13485:2016  
 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)  
 DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** 713184815-03

**Valid from:** 2020-<sup>(10)(2e)</sup>

**Valid until:** <sup>(10)(2e)</sup> - <sup>(10)(2e)</sup>

**Date,** 2020-05-04 <sup>(10)(2e)</sup>  
<sup>(10)(2e)</sup>  
<sup>(10)(2e)</sup>