

## CE Technical Documentation Review Report

**Applicant:** **Labnovation Technologies, Inc.**  
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**Report Number:** 17054586 001

**Examination intent:** Examination the completeness of the Technical  
Documentation according to the requirements of the  
In Vitro Diagnostic Medical Devices Directive  
98/79/EC Annex III

**Product(s):** **Reagents for Hematology Analyzers Use**

**Type(s)/Model(s):** Various

**Classification:** Other IVD products  
(according to manufacturer's declaration)

**Examination period:** Jan. 29, 2016

**Review result:** During the examination of the provided Technical  
Documentation (Reagents for Hematology Analyzers  
Use, Revision 1.1, Dated Jan 14, 2016), no non-  
compliance according to the requirements of the In  
Vitro Diagnostic Medical Devices Directive 98/79/EC  
Annex III was detected.

TÜV Rheinland (Shenzhen) Co., Ltd.

Shenzhen, Feb. 01, 2016



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