

**CERTIFICATE OF ANALYSIS**  
**ProFlow™ C.difficile GDH**  
**Cat # PL.3001\_KB**

LOT NUMBER : KBGDH100113

EXPIRATION DATE :

2015-04-30

Item	Lot Number	Expiration Date	Conformity
			Yes/No
Device ProFlow C. difficile GDH	SGDH100113	2015-04-30	Yes
Migration buffer	DILGDH100113	2015-04-30	Yes
Positive control	CPGDH100113	2015-04-30	Yes

**Appearance of active components**

Description	Appearance
Tests	Devices conditioned under individual pouches
Migration buffer	21 mL colourless liquid in bottle
Positive control	0,5 mL colourless liquid in dropper

**Test performance**

Test sample	Expected results	Obtained results	Comments
Migration buffer	Negative	Negative	PASS
Positive control	Positive	Positive	PASS
1,56 ng/mL GDH ** cut-off	Positive	Positive	PASS

\*\* Recombinant antigen

The batch above was tested and approved according to validation criteria and meets the quality characteristics.

Date :  
Approved by:

06/11/2013  
Quality department: Rachel Sellam

