

CERTIFICATE OF ANALYSIS
ProFlow™ C.difficile GDH
Cat #PL.3001_K20

LOT NUMBER : K20GDH100113A EXPIRATION DATE : 2015-04-30
MANUFACTURING DATE: 10/10/2013

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	CPGDH120913	2015-06-30	Yes

Appearance of active components

Description	Appearance
Tests	20 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:

03/01/2014
Quality department: Rachel WEILL SELLAM

