

CERTIFICATE OF ANALYSIS
PROFLOW C. difficile TOX A-B ®
Cat # PL.3002

LOT NUMBER : **K20TAB041014**
MANUFACTURING DATE **03/2014** EXPIRATION DATE : **2015-03-31**

Item	Lot Number	Expiration Date	Conformity
			Yes/No
Tests Immunoquick Tox A/B	STAB041014	2015-03-31	Yes
Extraction buffer	DILTAB041014	2015-03-31	Yes

Appearance of active components

Description	Appearance
Tests	20 devices conditioned under individual pouches
Extraction buffer	1 vial containing 20 mL of colourless liquid (unit dose)

Test performance

Test sample	Expected results	Obtained results	Comments
Negative sample	Negative	Negative	PASS
Low Tox A Positive Sample (100 ng/mL)	Positive	Positive	PASS
Med Tox A positive sample (600 ng/mL)	Positive	Positive	PASS
Low Tox B Positive sample (10 ng/mL)	Positive	Positive	PASS
Med Tox B positive sample (60 ng/mL)	Positive	Positive	PASS
High Tox B positive sample (120 ng/mL)	Positive	Positive	PASS

The batch above was tested and approved according to validation criteria and meets the quality characteristics. This product has been designed and validated to demonstrate a detection limit specification of 10 ng/mL for Toxin A and 1 ng/mL for Toxin B.

Date :
Approved by:

16/04/2014
Quality departement: Thierry PAPER