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CERTIFICATE OF ANALYSIS

Product Name: Proflow C.difficile GDH	Lot Number: KBGDH021817
Product Code: PL.3001	Expiration Date: 2018 07

Additional Information

Test conditions: As defined in the IFU. Storage conditions: 2-30°C The product is intended for in vitro use only.

Quality Control Testing

<u>Item</u>	<u>Lot/Expiry</u>	<u>Conformity</u>
PL.3101 Proflow C.diff GDH Test Device	SGDH021817 / 2018 07	Y
PL.3102 Proflow Sample Diluent	GDH120616/ 2018 07	Y
PL.3103 Proflow Positive control	CPGDH120616 / 2018 08	Y

Appearance of active components

Test Device Devices conditioned under individual pouches
 Sample Diluent 21 ml colourless liquid in bottle
 Positive control 0.5 ml colourless liquid in dropper bottle

Test performance

The above lots were tested and approved according to validation criteria and meet the quality characteristics.

Release

2017/02/27	<i>mawr</i>
Date	Quality Control

Canada ☎ 800 268 2341 Fax 905 731 0206
 20 Mural Street, Unit #4, Richmond Hill, Ontario,
 L4B 1K3
 support@pro-lab.com

U.S.A. ☎ 800 522 7740 Fax 800 332 0450
 21 Cypress Blvd., Suite 1070, Round Rock,
 Texas 78665-1034
 ussupport@pro-lab.com

U.K. ☎ 0151 353 1613 Fax 0151 353 1614
 3 Bassendale Road, Bromborough, Wirral,
 Merseyside CH62 3QL
 uksupport@pro-lab.com