

CERTIFICATE OF ANALYSIS

Product Name: Proflow C.difficile GDH	Lot Number: KBGDH010719A
Product Code: PL.3001	Expiration Date: 2020 01 31

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	SGDH060418 / 2019 08 31	Y
PL.3102 Proflow Sample Diluent	GDH021418/ 2019 08 31	Y
PL.3103 Proflow Positive control	CPGDH021418 / 2019 08 31	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

2019/01/24	<i>mawr</i>
Date	Quality Control

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