SAFETY DATA SHEET

***Resistance**Plus*® GC

Issuing Date 08/09/2022

SECTION 1. IDENTIFICATION

1.1. Product Identifier

Product Name: ***Resistance**Plus*® GC

Catalogue Number:
2011001 (***Resistance**Plus*® $GC_{(610)}$ 100 test)
2011025 (***Resistance**Plus*® $GC_{(610)}$ 25 test)
2013001 (***Resistance**Plus*® $GC_{(550)}$ 100 test)
2013025 (***Resistance**Plus*® $GC_{(550)}$ 25 test)
2015001 (***Resistance**Plus*® $GC_{(675)}$ 100 test)
2015025 (***Resistance**Plus*® $GC_{(675)}$ 25 test)

1.2. Product Information

Intended Use: The ***Resistance**Plus*® GC kit is an in vitro multiplexed qPCR test that detects *Neisseria gonorrhoea* and associated genetic resistance determinants and susceptibility markers to quinolones (ciprofloxacin), in a one well reaction.

Components: 20x GC+gyrA Mix, 20x Control Mix 1 or 20x Control Mix 2 or 20x Control Mix 3, 2x ***Plex*** Mastermix, Nuclease Free Water The ***Resistance**Plus*® GC gyrA product is an in vitro multiplexed qPCR test that detects Neisseria gonorrhoea and associated genetic resistance determinants and susceptibility markers to quinolones (ciprofloxacin), in a one well reaction.

1.3. Recommended use and restrictions on use

Recommended Use: In vitro diagnostic (IVD)

Restrictions on Use: For professional users only

1.4. Details of the Supplier of the Safety Data Sheet

Manufacturer:
SpeeDx Pty. Ltd.
Suite 102, National Innovation Centre
4 Cornwallis Street
Eveleigh, NSW, 2015
Australia
Telephone: +61 (0)2 9209 4170

Authorized Representative:
MedEnvoy
Prinses Margrietplantsoen 33 – Suite 123
2595 AM The Hague
The Netherlands

For further information, please contact:
Email: tech@speedx.com.au
Website: www.plexpcr.com

1.5. Emergency telephone numbers

Emergency telephone: International: +61 (0)2 9209 4169 / For Australia: (02) 9209 4169

SECTION 2. HAZARDS IDENTIFICATION

2.1. GHS Classification

The product is a kit consisting of individual ingredients. The classification of the ingredients can be obtained from section 3. Section Label elements contains the resulting labelling for the kit.

2.2. GHS Label element

Not a hazardous substance or mixture.

2.3. Other hazards

No significant health effects are anticipated from routine use of this assay when following Universal Precautions and general safety laboratory practices. This kit is not considered hazardous as defined by the European Union (EU) Regulations, Commonwealth of Australia (NOHSC), Occupational Safety and Health Administration (OSHA) or the Canadian Workplace Materials Information System (WHMIS)

It is recommended that all users of this kit take suitable precautions when working with this product or indeed any biochemical reagent. Such precautions may include personal protective equipment, such as a laboratory coat, gloves and eye protection. This also includes good laboratory hygiene practices to avoid any and all accidental exposure to workplace materials. Universal precautions should be followed when working with any potentially infectious material.

Assay reagents contain IDTE Buffer which can cause severe eye irritation. It is recommended to use in a well-ventilated area and wear appropriate personal protective equipment such as gloves, protective eye wear and laboratory coat when handling reagents.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	Chemical Name	CAS #	EINECS #	Concentration (%)	Volume

SAFETY DATA SHEET (SDS) NOT REQUIRED FOR THIS KIT

The components of this kit are considered non-hazardous. The reagents contain <1% of a hazard classified component or <0.1% of a carcinogenic classified component, therefore, an SDS is not required in accordance with the following directives:

- European Union Regulations (EC) No. 1272/2008 and (EC) No. 1907/2006
- Commonwealth of Australia – [NOHSC:2011(2003) and NOHSC:1008(2004)]
- US Department of Labor – OSHA 29CFR1910.1200
- Canadian Workplace Materials Information System – WHMIS 2015

Other Information

Every effort has been made to adhere to the hazard criteria and content requirements of the U.S. OSHA Hazard Communication Standard, European Classification, Labelling and Packaging Regulation, European Registration, Evaluation, Authorization and Restriction of Chemicals Regulation, Canadian Controlled Products Regulations, UK Chemical Hazard information and Packaging Regulations, and UN Globally Harmonized System of Classification and Labeling of Chemicals.

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It is expected that the user is a professional who is familiar with and follows generally accepted safe handling procedures. SpeeDx is not liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages of any kind, even if SpeeDx Pty. Ltd. has been advised of the possibility of such damages.

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