SECTION 1. IDENTIFICATION

1.1. Product Identifier
Product Name: ResistancePlus® GC
Catalogue Number: 2011001 (ResistancePlus GC(610) 100 test)
2011025 (ResistancePlus GC(610) 25 test)
2013001 (ResistancePlus GC(550) 100 test)
2013025 (ResistancePlus GC(550) 25 test)

1.2. Product Information
Intended Use: The ResistancePlus® 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.
Components: 20x GC+gyrA mix, 20x Control Mix 1 or 20x Control Mix 2, 2x Plex Mastermix, Nuclease Free Water

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 G16
National Innovation Centre
Australian Technology Park
4 Cornwallis Street
Eveleigh, NSW, 2015
Australia
Telephone: +61 (0)2 9209 4170

Authorized Representative: Medical Technology Promedt Consulting GmbH
Altenhofstrasse 80
66386 St. Ingbert
Germany

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) Directives, 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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Component</th>
<th>Chemical Name</th>
<th>CAS #</th>
<th>EINECS #</th>
<th>Concentration (%)</th>
<th>Volume</th>
</tr>
</thead>
</table>

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 Directives 67/548/EC and 1999/45/EC
- 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 Communities Safety Data Sheets Directive, Canadian Controlled Products Regulations, UK Chemical Hazard information and Packaging Regulations, and UN Globally Harmonized System of Classification and Labeling of Chemicals.

The information presented in this document is based on the most current information available. We make no warranty of accountability, appropriateness for a particular purpose, expressed or implied, with respect to products described or data or information provided. SpeeDx Pty. Ltd. assumes no liability resulting from the use of such products, data or information. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material, including compliance with all applicable laws and regulations regarding purchase, use, storage and disposal.

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.

END DOCUMENT