

SECTION 1. Product identification		
1.1. Trade name	RESIST-3 O.O.K. K-Set Code: K-15R4	
1.2. Manufacturer	Coris BioConcept, CREALYS Science Park, Rue Guillaume Fouquet, 11 5032 Gembloux, Belgium. Ph: +32/81 719 917 ; Fax: +32/81 719 919 ; E-Mail: <a href="mailto:info@corisbio.com">info@corisbio.com</a> - Web Site: <a href="http://www.corisbio.com">www.corisbio.com</a>	
1.3. Kind of use	<i>In vitro</i> Rapid Diagnostic Test for the detection of OXA-48, OXA-163 and KPC carbapenemases on bacterial colony. <b>FOR MEDICAL DIAGNOSTIC USE ONLY</b> For details, see insert	
SECTION 2. Health hazard data/risk identification		
Main exposure risks and symptoms	None with dried strip	
	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%; text-align: center;">Buffer</td> <td>Contact with eyes: Irritation, tears. Contact with skin: Irritation. Ingestion: Not considered particularly toxic or dangerous upon ingestion in conditions.</td> </tr> </table>	Buffer
Buffer	Contact with eyes: Irritation, tears. Contact with skin: Irritation. Ingestion: Not considered particularly toxic or dangerous upon ingestion in conditions.	
SECTION 3. Composition, information on ingredient		
3.1. Classification	<i>In vitro</i> Diagnostic device	
3.2. Components	<p><b>Laminate:</b> Active matrix → nitrocellulose + mylar Plastic backing → Polyester</p> <p><b>Absorbent paper:</b> Sample PAD → glass fiber Absorbent paper → cellulose paper</p> <p><b>Release matrix:</b> Conjugate PAD → glass fiber</p> <p><b>LY-A buffer:</b> Salts → restricted information Additive(s) → restricted information Conservative → Sodium Azide (&lt;0.1%) pH → 7.5 Molarity → restricted information</p>	
3.3. Biologicals	<p><b>Specific reagent:</b> Anti-OXA-48 → mouse monoclonal antibody (purified) directed against one first epitope of the OXA-48 carbapenemase and variants (but not the OXA-163 variant) Anti-OXA-48/163 → mouse monoclonal antibody (purified) directed against one second epitope of the OXA-48 carbapenemase and variants (including OXA-163) Anti-KPC → mouse monoclonal antibody (purified) directed against one epitope of KPC carbapenemase.</p> <p><b>Control reagent:</b> Antichickens goat polyclonal antibody (purified by precipitation) Antimouse goat polyclonal antibody</p> <p><b>Conjugate:</b> Anti-OXA-48 antigen: mouse monoclonal antibody (purified) gold colloid coupled Anti-KPC : mouse monoclonal antibody (purified) gold colloid coupled Chicken IgY: chicken polyclonal gold colloid coupled</p>	
3.4. Hazardous substance	Sodium Azide : < 0.1%                      CAS: 26628-22-8	
3.5. Packaging material	Box → cardboard	

	Buffer bottle → polyethylene-polypropylene Pouch → polyethylene aluminium foil plastic Sampling Tube → polypropylene - GPPS – polyurethane K-SeT → ABS
<b>3.6. Other information</b>	Latex free
<b>SECTION 4. Emergency and first aid procedures</b>	
<b>4.1. Contact with eyes</b>	Buffer: Immediately flush eyes thoroughly with water.
<b>4.2. Contact with skin</b>	Buffer: Immediately wash skin with soap and large volume of water.
<b>4.3. Ingestion</b>	Buffer: If swallowed, wash out mouth with water provided the person is conscious; seek medical advice (showing this document when possible); never give anything by mouth to an unconscious person; never try to make an unconscious person vomit.
<b>SECTION 5. Fire hazard data</b>	
<b>5.1. Flammability</b>	Contains combustible materials.
<b>5.2. Extinguishing</b>	Water, carbon dioxide, dry chemical powder or polymer foam. Use extinguishing media appropriate to surrounding fire conditions.
<b>5.3. Special Fire Fighting procedures</b>	For fires involving this material, do not enter any enclosed or confined fire space without proper protective equipment. This may include self-contained breathing apparatus to protect against the hazardous effects of normal products of combustion or oxygen deficiency.
<b>SECTION 6. Accidental release measures</b>	
<b>6.1. Precautionary measures</b>	Wear appropriate protective clothing (refer to point 8).
<b>6.2. Environment Precautions</b>	Buffer: Avoid flushing away in drainpipes. Collect samples in plastic bag and submit to sterilization procedures
<b>6.3. Released or spilled material</b>	Sweep up and collect in appropriate container for waste disposal (refer to point 13) clean the floor and all other contaminated objects with water.
<b>SECTION 7. Handling and storage</b>	
<b>7.1. Handling</b>	Wear appropriate protective clothing (refer to point 8); eliminate rapidly from eyes skin and clothes; wash hands and any other exposed zone with water and mild soap before eating, drinking, smoking and leaving workplace.
<b>7.2. Storage</b>	Store at room temperature, not above 30°C and not below 0°C.
<b>7.3. Additional information</b>	Refer to point 10.
<b>SECTION 8. Exposure controls and personal protection</b>	
<b>8.1. Hands protection</b>	Laboratory gloves.
<b>8.2. Skin protection</b>	Laboratory coat.
<b>8.3. Eyes protection</b>	Safety goggles.
<b>8.4. Ingestion</b>	Do not eat, drink or smoke during use.
<b>SECTION 9. Physical and chemical properties</b>	
<b>9.1. Form</b>	Strip → Dried; Buffer→ Liquid
<b>9.2. Critical temperature</b>	Min. 4°C - Not above 30°C; Do not frozen components.
<b>9.3. pH</b>	See point 3.2

<b>9.4. Vapour pressure</b>	Nil
<b>9.5. Solubility</b>	Nil
<b>9.6. Smell</b>	Nil
<b>SECTION 10. Stability and reactivity data</b>	
<b>10.1. Dangerous reaction</b>	Particular dangerous reactions not known.
<b>10.2. Dangerous properties</b>	Particular dangerous properties not known.
<b>10.3. Hazardous combustion or decomposition products</b>	Nature of decomposition products not known.
<b>SECTION 11. Toxicological information</b>	
<ul style="list-style-type: none"> <li>- Collect samples and used sticks in plastic bag and submit to sterilization procedures</li> <li>- Rinse carefully polluted bench</li> </ul>	
<b>SECTION 12. Ecological information</b>	
<ul style="list-style-type: none"> <li>- Data not available for stick</li> <li>- Avoid flushing away in drainpipes</li> </ul>	
<b>SECTION 13. Disposal considerations</b>	
<ul style="list-style-type: none"> <li>- Collect samples and used sticks in plastic bag and submit to sterilization procedures</li> <li>- Rinse carefully polluted bench</li> <li>- Contact a licensed professional waste disposal service to dispose of this material. Observe all federal state and regulations. Emptied bottles and vials may retain product residues: handle as if they were full.</li> </ul>	
<b>SECTION 14. Transport information</b>	
Non classified.	
<b>SECTION 15. Regulatory information</b>	
From the European Communities Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CPL), this product is not hazardous and does not contain hazardous ingredients at concentrations used.	
<b>SECTION 16. Other information</b>	
<p>Contents and format of this Safety Data Sheet comply with the European Communities Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).</p> <p>The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Coris BioConcept shall not be held liable for any damage resulting from handling or from contact with the above product.</p>	