VOLUNTARY SUMMARY OF SAFETY AND PERFORMANCE (SSP) – KarbaDia

(for transparency purposes – not a formal SSP under IVDR Article 29)

1. Introduction

Under Regulation (EU) 2017/746 (IVDR), a Summary of Safety and Performance (SSP) is required only for Class C and D devices (Article 29 and Annex XIV).

Although KarbaDia Rapid Test is classified as a Class B in vitro diagnostic medical device, GaDia SA voluntarily provides the following summary of key safety and performance information to promote transparency for professional users and stakeholders.

This document is informative only and is not intended to fulfil the formal SSP obligations defined under Article 29 IVDR.

2. Summary of Safety and Performance (SSP)

Requirements based on IVDR Article 29	Potential regulatory sources
Device identification and general information	
Name or trade name including any model number or version	KarbaDia (KAR-025)
Manufacturer (name and address)	GaDia SA Route de l'Ile-au-Bois 1A 1870 Monthey Switzerland
Manufacturers single registration number (SRN), if available	CH-MF-000031123
Basic UDI-DI	7649990065KARMM
Intended purpose of the device	
Intended purpose and indications	KarbaDia is a non-automated rapid immunochromatographic test intended to be used for the qualitative detection of KPC-type, NDM-type, IMP-type, VIM-type and OXA-48-type carbapenemase in bacterial colonies. The assay is for professional use only and can aid in the diagnosis of KPC-type, NDM-type, IMP-type, VIM-type and OXA-48-type carbapenemase resistant strains. The test should be used in conjunction with other diagnostic procedures, such as genetic analysis, susceptibility testing and other microbial analysis.

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Target populations	Bacterial colonies on agar plate suspected to be Carbapenem resistance Enterobacteriaceae. Bacteria can be isolated from human body fluids or other sources.
Contraindications (limitations)	Not for near-patient or home use. Results are qualitative and must be interpreted alongside culture, susceptibility, and molecular testing.
Device description	
Device description	Lateral-flow immunochromatographic assay with five specific test lines (K, N, I, V, O) and one control line (C). Each line contains immobilized monoclonal antibodies targeting a carbapenemase family. A visible red control line confirms sample migration and reagent integrity.
Description of other devices and products intended to be used in combination with the device (as applicable)	Materials Required but Not Supplied 1. Timer 2. Inoculation loop (5 µl) 3. Optional: Pipettes and sterile tips 4. Optional: Disposable sterile micro-centrifuge tubes (1.5 ml)
Standards Reference	
Harmonised standards and Common Specifications (CS) applied	IVDD 98/79/EC (CE-marking under transition) EN ISO 13485:2016 EN ISO 15223-1:2021 EN ISO 17511:2021 ISO 14971:2019 ISO 18113-1:2009 ISO 18113-2:2009 ISO 20417:2021 ISO 13975:2003 ISO 13612:2002 ISO 23640:2011 ISO 20916:2019 IEC 62366-1:2015+A1:2020

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Summary of the Performance Evaluation

A total of 212 clinical isolates were collected from European hospitals (81%) and American hospitals (15%) in 2019 and 2020, including 19 carbapenemase- negative isolates (9%) and 193 (91%) carbapenem-resistant Enterobacterales (CRE) with various carbapenemase types. These were collected from various infection sources including respiratory, urinary tract, intra-abdominal and chorionic villus sampling. Molecular analysis was performed on all isolates and MIC determination on discordant results. The isolates were cultivated on blood agar for 24h at 37°C and analysed with KarbaDia rapid test. The primary end point was to assess the diagnostic performance of KarbaDia Rapid test (GaDia SA, Monthey, Switzerland) using cultivated bacterial colonies. The second end point was to assess the capacity of the test to detect specific variants and non-fermenter isolates. The usability of the test and feedbacks from user are also collected for the usability study. Vassarstats online tool (www.vassarstats.net) was used to calculate sensitivity (SE), specificity (SP), positive and negative predictive values (PPV, NPV), 95% confidence intervals, median, and Interquartile range (IQR); while significance (p-values) was calculated using student t test for independent samples with equal variances. Statistical significance was defined as $p < 0.05$.

KPC	+	-	**Sensitivity**	**100%**	(CI95%: 87-100%)
+	32	0	**Specificity**	**100%**	(CI95%: 97-100%)
-	0	180	**PPV**	**100%**	(CI95%: 87-100%)
			NPV	**100%**	(CI95%: 97-100%)
OXA	+	-	**Sensitivity**	**98%**	(CI95%: 90-100%)
+	58	2	**Specificity**	**99%**	(CI95%: 95-100%)
-	1	149	**PPV**	**97%**	(CI95%: 87-99%)
			NPV	**99%**	(CI95%: 96-100%)
NDM	+	-	**Sensitivity**	**97%**	(CI95%: 89-99%)
+	65	1	**Specificity**	**99%**	(CI95%: 95-100%)
-	2	139	**PPV**	**98%**	(CI95%: 91-100%)
			NPV	**99%**	(CI95%: 94-100%)
IMP	+	-	**Sensitivity**	**93%**	(CI95%: 66-100%)
+	14	0	**Specificity**	**100%**	(CI95%: 98-100%)
-	1	190	**PPV**	**100%**	(CI95%: 73-100%)
			NPV	**99%**	(CI95%: 97-100%)
VIM	+	-	**Sensitivity**	**100%**	(CI95%: 85-100%)
+	29	0	**Specificity**	**100%**	(CI95%: 97-100%)
-	0	183	**PPV**	**100%**	(CI95%: 85-100%)
			NPV	**100%**	(CI95%: 97-100%)

Carbapenemase Type	Variants detected (previous study)	Variants detected (this study)
KPC	KPC-1, KPC-2, KPC-3, KPC-74	KPC-2, KPC-3, KPC-4, KPC-27
OXA	OXA-23 OXA-163, OXA-181, OXA-232	OXA-48(c), OXA-48 Type(u) OXA-181(c), OXA-232(c) OXA-244(c)
NDM	NDM-1, NDM-5, NDM-7	NDM-1, NDM-2, NDM-5, NDM-6, NDM-7
IMP	IMP-1, IMP-3, IMP-4, IMP-6, IMP-10, IMP-25, IMP-26, IMP-30, IMP-34, IMP-38, IMP-40, IMP-42	IMP-1, IMP-4, IMP-6, IMP-7, IMP-10, IMP-26
VIM	VIM-1, VIM-2, VIM-4, VIM-5, VIM-9, VIM-10	VIM-1, VIM-2

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The main finding of this evaluation study, using an unmatched case control design including 91% (184/203) carbapenemase positive isolates is that the diagnostic performance of KarbaDia RDT on bacterial isolates is high and depend of the carbapenemase type detected. The sensitivity varied between 93% and 100% with lower sensitivity with IMP type, when comparing with genetic and MIC assay. In term of specificity, the diagnostic specificity is between 99% and 100%, similar to other rapid tests.
Summary of the Post-Market Performance Follow-Up
PMPF activities are defined in 240-PLA-PMPF Plan. In 2023, an external evaluation at Maurizio Bufalini Hospital (Cesena, Italy) confirmed full concordance on 25 clinical samples with reference PCR. Findings integrated into PMS Report 2023 and PER.

Metrological traceability	
Metrological traceability of assigned values	No quantitative assigned values; internal control line ensures procedural validity and reagent integrity.
Users	
User Profile	Intended for trained clinical microbiology or infection-control laboratory professionals familiar with culture-based techniques and biosafety requirements.
User Training	Appropriate training in sample collection, biosafety and in the use of rapid tests.
Device Risks Information	
Residual risks and undesirable effects	Possible contamination when handling infectious material; risk of misinterpretation if IFU not followed; potential false negatives with low-enzyme-expression strains. Mitigated through clear IFU, controls, and operator training.
Warnings and precautions	1. Read the instruction for use carefully before using the test. 2. Clearly identify the sample ID on the test cassettes. 3. This product is for in vitro diagnostic and professional use only. 4. Do not reuse the test 5. Do not use the test after expiry date 6. Read the test results within the specific time to avoid wrong interpretation. 7. Do not use the components from different batches or different types of reagents.

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	8. Properly dispose the specimen and used materials following the local biohazardous disposal regulation. 9. Use protective equipment when using the test and handling samples as they may contain infectious agents, human or animal components. 10. Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Performance and Safety Conclusions

The KarbaDia Rapid Test demonstrates high diagnostic accuracy, with sensitivity and specificity above 93% and 99% respectively across major carbapenemase families.

Ease of use and short result time (≈15 min) support rapid infection-control decisions in laboratory settings.

No new or unexpected risks were identified during PMPF activities or market use in 2022-2023.

The benefit-risk ratio remains favourable and the product continues to meet the General Safety and Performance Requirements (Annex I IVDR).

Regulatory Status

Regulatory framework: Currently CE-marked under IVDD 98/79/EC during transition; technical documentation aligned with IVDR 2017/746 (Class B).

Notified Body involvement: Class B conformity assessment – Technical Documentation and PMS system reviewed by Notified Body.

PMS/PMPF schedule: PMS Report updated annually; PMPF Report performed when new performance data, design changes, or emerging risks arise (as per Article 78 IVDR).

Disclaimer

This document is provided voluntarily by GaDia SA to ensure transparency and user awareness.

It does not constitute a formal Summary of Safety and Performance (SSP) as required for Class C or D devices under Article 29 IVDR.

All data originate from the validated Performance Evaluation Report (234-REC), PMS/PMPF Reports, and Risk Management File.