

Product certificate of analysis

Number: DNK-JL-ZL-083-20250904-01

Version number: 04

Product name: Carbapenem Resistant Enterobacteriaceae Test Kit (LFA)

Date of inspection: 03/09/2025

Specification: 40 tests/kit

Lot number: 250901-HW

Expiry Date: 28/02/2027

Quantity: 106 kits

Production Date: 01/09/2025

Inspection items	Standards	Results	Assessment
Appearance	Test Cassette should be smooth, The material and content should attached and complete, Extraction Buffer no-Leakage. The components of the kit should be complete, no broken, the label should be clean.	Meet the requirements	Qualified
Physical Testing	Width of membrane strip: greater than 3.0mm.	Meet the requirements	Qualified
	Liquid migration speed: not less than 10 mm/min.	Meet the requirements	Qualified
Conformance rate with negative sample	Detect 10 negative samples of internal reference products, Coincidence rate should be 10/10.	10/10	Qualified
Conformance rate with positive sample	Detect 10 positive samples of internal reference products, Coincidence rate should be 10/10.	10/10	Qualified
The lowest detection limit	Three minimum detection limit reference materials in the internal reference materials of the enterprise were tested respectively, and each reference material was tested three times. L1 test results should be negative, and	L1 is negative, L2 and L3 are positive.	Qualified

	L2 and L3 test results should be positive.		
Repeatability	Take the same batch of reagents and repeatedly determine the repetitive reference materials in the internal reference materials of the enterprise for 10 times, all of which should be positive and have uniform chromaticity.	All results are positive and the color rendering is uniform.	Qualified
Inspector	Duan Mingzhu		
Conclusion	丹娜(天津)生物科技股份有限公司 产品检验专用章 Product qualified Approver : Li Huichun Date:03/09/2025		