



TEST REPORT

Report Number.....: CTG2510317188B-SR12AT

Tested by (name + signature).....: Iverson Chen

Iverson Chen

Reviewed by (name + signature).....: Alan Li

Approved by (name + signature).....: Aaron Zhai



Testing Laboratory

Name.....: Shenzhen CTG Testing Co., LTD.

Address.....: 3/F, Yongxing Plastic Plant, No.11. Waihuan Road, Shiyan Street, Bao'an District Shenzhen, Guangdong, China

Testing location.....: shenzhen CTG testing co.,ltd

Date of issue.....: 2025-10-31

Date of Test.....: 2025-10-24~2025-10-31

Applicant

name.....: Rosenthal Innovation Limited

Address.....: 9F, WINNING HOUSE, 72 - 76 WING LOK STREET, CENTRAL AND WESTERN DISTRICT, HONG KONG

Test specification:

Standard.....: EC Directive 98/79/EC

Non-standard test method.....: N/A

Test item

Test Item description.....: Pet Home Virus Test Kit

Trade Mark.....: N/A

Model and/or type reference.....: /

Manufacturer: Rosenthal Innovation Limited

Address.....: 9F, WINNING HOUSE, 72 - 76 WING LOK STREET, CENTRAL AND WESTERN DISTRICT, HONG KONG

Classification of installation and use : N/A



RESULTS:

Assessment Area	Standard / Requirement	Result	Evidence / Reference
Quality Management System	EN ISO 13485:2016	PASS	The QMS is established, implemented, and maintained. Certificate No.: QMS-VET-54321
Risk Management File	EN ISO 14971:2019	PASS	All identified hazards (biological, chemical, usability) have been addressed. Risk level is As Low As Reasonably Practicable (ALARP). Ref: RMF-VSR-F001-Rev1.5
Analytical Performance	Specificity: 100% for FHV vs. common feline pathogens (e.g., <i>C. felis</i> , <i>B. bronchiseptica</i>). Detection Limit: $\leq 10^{2.5}$ TCID ₅₀ /mL. Repeatability: 100% concordance (n=20).	PASS	Comprehensive analytical performance studies conducted. Report: PERF-VSR-F001-2023
Diagnostic Performance	Sensitivity: 98.5% (vs. PCR method) Specificity: 99.2% (vs. PCR method)	PASS	Clinical field study conducted with 300 feline samples. Report: CLIN-VSR-F001-2023
Stability & Shelf-Life	Real-time stability testing at 2-30°C.	PASS	Data supports a 24-month shelf life from the date of manufacture. Report: STAB-VSR-F001-2022
Labeling & Instructions for Use (IFU)	Directive 98/79/EC Annex I, §8 & EN ISO 18113-1	PASS	Labels and IFU clearly state "For Veterinary Use Only", intended use, species, sample type, limitations, and storage conditions. Provided in EN/FR/DE.
Biocompatibility	Evaluation of swab materials and buffer solution.	PASS	Materials are non-toxic and suitable for use on feline ocular/nasal mucosa. Report: BIO-VET-022

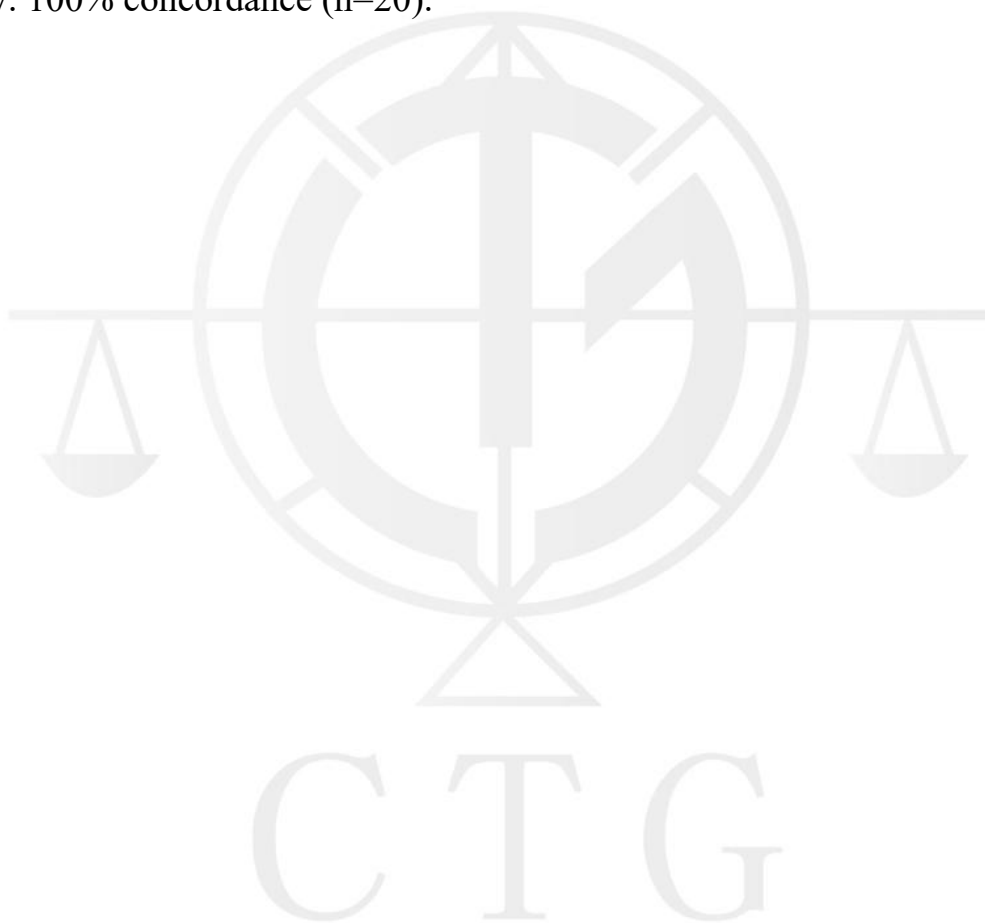


Assessment Area	Standard / Requirement	Result	Evidence / Reference
Software Validation	N/A	N/A	This is a manual, visually-read test device. No software is involved.

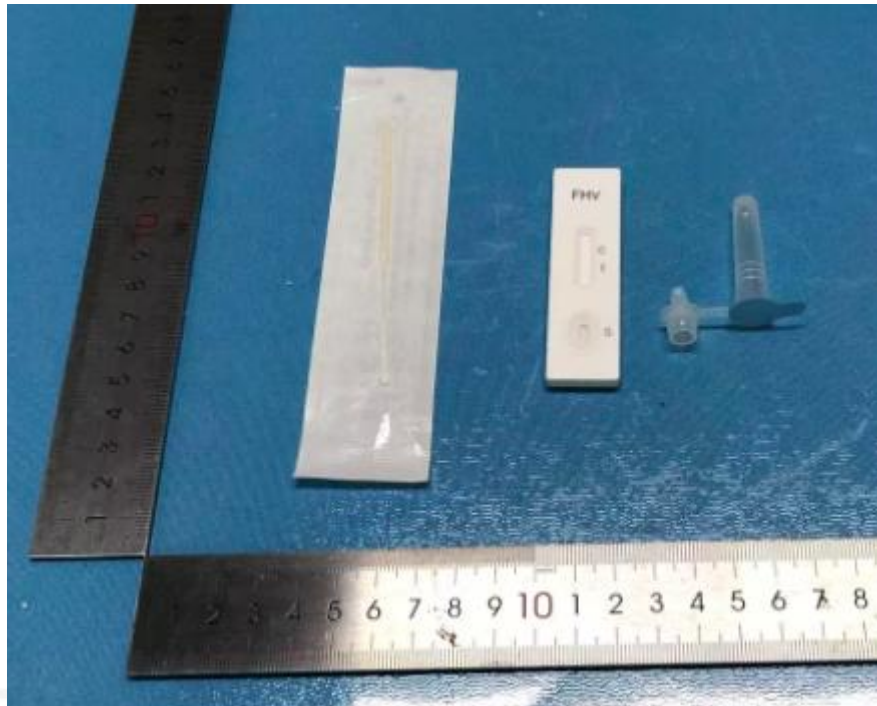
Specificity: 100% for FHV (Feline Herpesvirus-1) vs. common feline and canine pathogens (e.g., FCV, FCoV, C. felis, B. bronchiseptica).

Detection Limit: $\leq 10^{2.5}$ TCID₅₀/mL.

Repeatability: 100% concordance (n=20).



ANNEX A:Photo-documentation



*** End of Report ***

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dGeYEBw

CTG



SHENZHEN CTG TESTING CO.,LTD.

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