

IVD5412 Performance Validation Report

Test 1: Low-Input DNA Recovery

Purpose: To evaluate micro-scale DNA recovery using RNase-free water spiked with 25 ng DL2000 DNA Marker.

Sample type	RNase-free water spiked with 25 ng DL2000 DNA Marker	
Sample input	200 µL	
Elution volume	50 µL	
Extraction method	Magnetic bead method	
Extraction time	35 minutes	
Detection method	Qubit	
Qubit Reading (ng/µL)	Recovered Amount (ng)	Recovery
0.436	21.8	87%
0.428	21.4	86%
0.442	22.1	88%
0.418	20.9	84%

Conclusion: Under the tested conditions, the kit recovered 20.9–22.1 ng DNA from a 25 ng input, corresponding to DNA recovery rates of 84–88%. The results indicate that IVD5412 supports recovery of low-input DNA targets. Minor losses may occur during binding, washing or elution from the magnetic particles.

Test 2: Macro-Scale DNA Marker Recovery and Short-Fragment Recovery

Purpose: To evaluate DNA marker recovery, short-fragment recovery and nucleic acid purity using porcine plasma or RNase-free water spiked with 250 bp DNA marker.

Sample type			Porcine plasma or RNase-free water spiked with 250 bp DNA marker		
Sample input			200 µL		
Elution volume			50 µL		
Extraction method			Magnetic bead method		
Extraction time			35 minutes		
Detection methods			Nanodrop and agarose gel electrophoresis		
Nucleic Acid (ng/µL)	Recovered Amount (µg)	Marker Recovery	A260/A280	A260/A230	Sample Type
38.4	1.92	87.3%	1.80	1.37	Porcine plasma
40.4	2.02	91.8%	1.81	1.40	
41.4	2.07	94.1%	1.80	1.35	
39.1	1.96	88.9%	1.81	1.43	RNase-free water
37.2	1.86	84.5%	1.83	1.52	
36.6	1.83	83.1%	1.86	1.58	

Macro-scale marker experiment

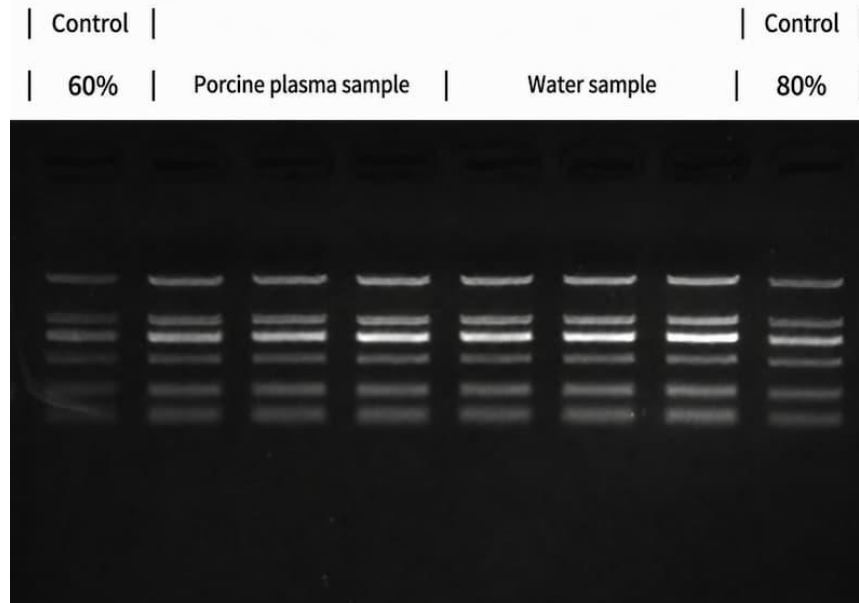


Figure 1. Agarose gel analysis of macro-scale DNA marker recovery from porcine plasma and RNase-free water samples.

Conclusion: The marker recovery rate exceeded 80% in both porcine plasma and RNase-free water under the tested conditions. Agarose gel electrophoresis supported recovery of DNA marker fragments after magnetic bead purification.

Test 3: RNA Recovery

Purpose: To evaluate RNA recovery using RNase-free water spiked with a defined RNA input.

Sample type		RNase-free water spiked with RNA		
Sample input		200 µL		
Elution volume		50 µL		
Extraction method		Magnetic bead method		
Extraction time		35 minutes		
Detection methods		Nanodrop and agarose gel electrophoresis		
Nucleic Acid (ng/µL)	Recovered Amount (µg)	Recovery	A260/A280	A260/A230
257.16	12.86	92%	3.44	2.87
252.51	12.63	90%	3.44	2.94
253.47	12.67	91%	3.40	2.97
256.70	12.84	92%	3.42	2.99

Conclusion: Under the tested conditions, the recovered RNA amount ranged from 12.63 to 12.86 µg, corresponding to RNA recovery rates of 90–92%. The results support RNA recovery using the IVD5412 magnetic bead workflow.

Test 4: Viral DNA/RNA Extraction Performance

Purpose: To evaluate viral nucleic acid extraction from porcine plasma spiked with defined RNA virus and DNA virus targets, followed by fluorescence quantitative PCR analysis.

Sample type	Porcine plasma spiked with RNA virus or DNA virus
Sample input	200 µL
Elution volume	100 µL

Extraction method	Magnetic bead method
Extraction time	35 minutes
Detection method	Fluorescence quantitative PCR

DNA Virus Model: Hepatitis B Virus

Input Level	Ct Value 1	Ct Value 2
High concentration (10 ⁵)	24.19	24.38
Medium concentration (10 ⁴)	27.75	27.97
Low concentration (10 ³)	32.23	32.63

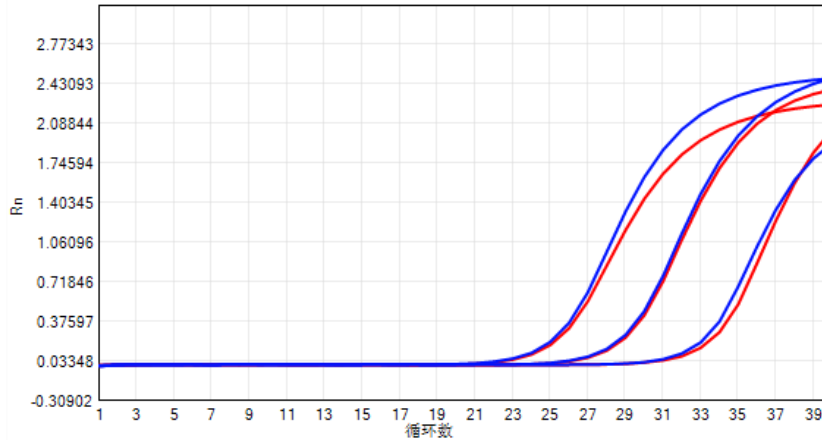


Figure 2. Fluorescence quantitative PCR amplification curves for the DNA virus model.

RNA Virus Model: Newcastle Disease Virus

Input Level	Ct Value 1	Ct Value 2
High concentration (10 ⁵)	22.59	21.96
Medium concentration (10 ⁴)	28.15	27.58
Low concentration (10 ³)	32.92	32.16

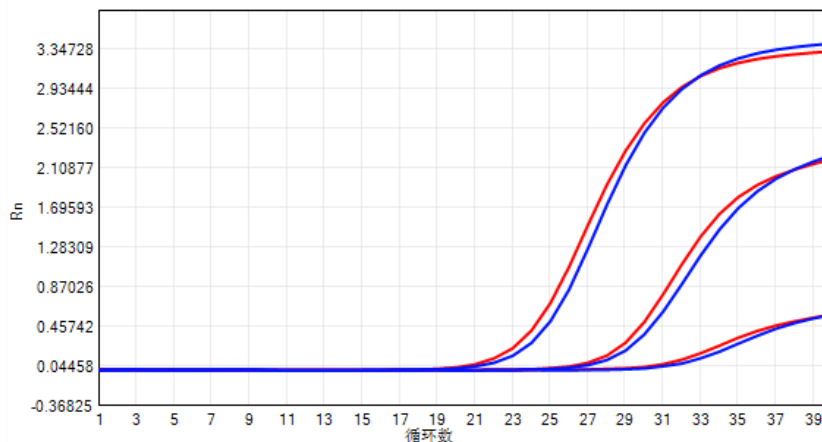


Figure 3. Fluorescence quantitative PCR amplification curves for the RNA virus model.

Conclusion: After extraction with IVD5412, both DNA virus and RNA virus targets produced concentration-dependent Ct gradients across high, medium and low input levels. The results indicate that the extracted viral nucleic acids were compatible with fluorescence quantitative PCR detection under the tested conditions.

Overall Conclusion

Across the simulated recovery and virus-spiked plasma tests, IVD5412 recovered DNA and RNA targets with recovery rates above 80% under the tested conditions. DNA marker recovery, RNA recovery and qPCR amplification of both DNA virus and RNA virus targets support the use of MagPure Viral DNA/RNA Kit for viral nucleic acid extraction from plasma, serum and related low-cell-content biological samples.