

**Supplementary Information**

**Establishment of ABEI-based direct chemiluminescence immunoassays for PIC, TAT, tPAIC, TM and  
the preliminary evaluation in thrombotic diseases**

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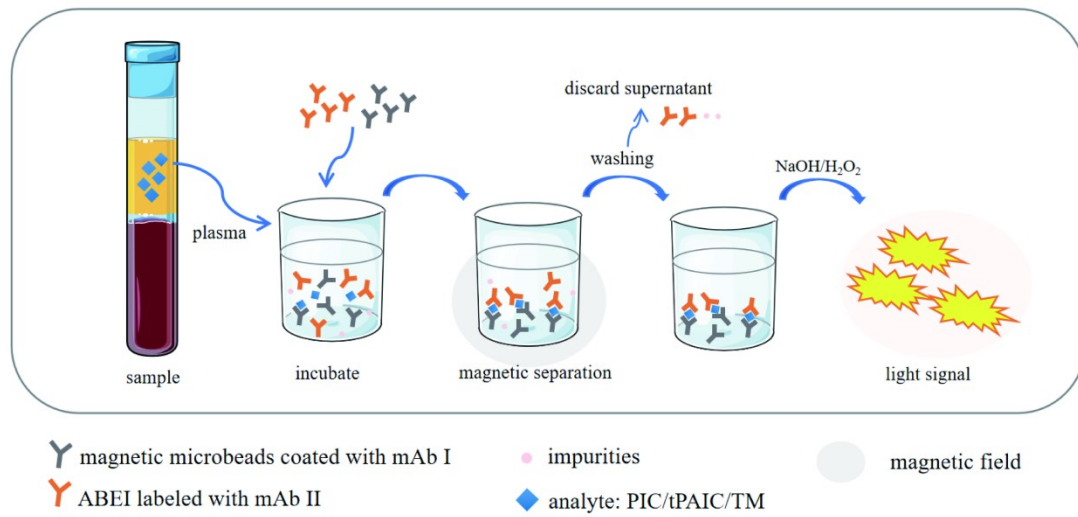
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**Supplementary Fig. S1** Schematic diagram of the “one step” quantitative detection of MAGLUMI PIC, tPAIC or TM CLIA test. Abbreviation: mAb, monoclonal antibody.

**Supplementary Table S1.** The LOB, LOD and LOQ of MAGLUMI PIC, TAT, tPAIC and TM CLIA reagents.

	Lot	LOB	LOD	LOQ
PIC (µg/mL)	1	<b>0.029</b>	<b>0.038</b>	0.044
	2	0.028	0.037	0.044
	3	<b>0.029</b>	<b>0.038</b>	<b>0.046</b>
TAT (ng/mL)	1	0.140	<b>0.279</b>	<b>0.356</b>
	2	<b>0.146</b>	0.272	0.350
	3	0.145	0.276	0.345
tPAIC (ng/mL)	1	0.388	0.638	0.907
	2	<b>0.393</b>	0.620	<b>0.934</b>
	3	0.370	<b>0.654</b>	0.801
TM (TU/mL)	1	0.386	<b>0.643</b>	0.807
	2	0.381	0.616	<b>0.895</b>
	3	<b>0.395</b>	0.628	0.877

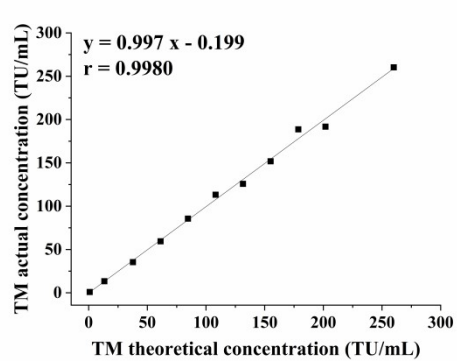
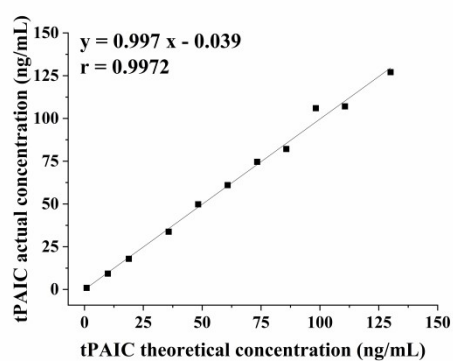
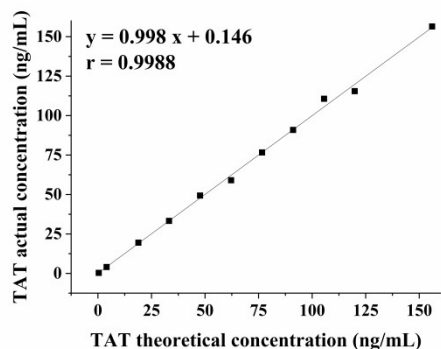
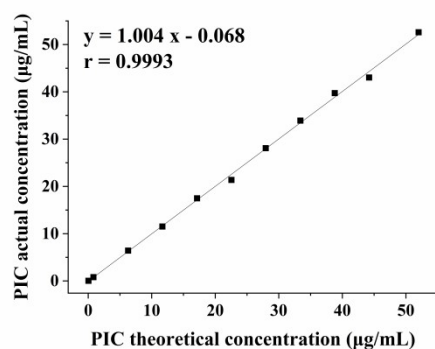
**Supplementary Table S2.** Precision of MAGLUMI PIC, TAT, tPAIC and TM CLIA reagents.

Abbreviation: CV, coefficient of variation; C1, control 1; C2, control 2.

Analyte	Sample	Mean (n=180)	Within-Run (%CV)	Between-Run (%CV)	Between-Day (%CV)	Between-Lot (%CV)	Within-Lab (%CV)	Reproducibility (%CV)
PIC (µg/mL)	1	0.824	3.03%	1.09%	1.82%	0.85%	3.76%	3.76%
	2	5.149	2.37%	1.63%	1.03%	0.45%	3.09%	3.28%
	3	21.051	1.93%	1.32%	1.11%	0.95%	2.75%	2.84%
	C1	0.997	3.11%	1.30%	1.81%	0.90%	3.91%	4.11%
	C2	9.873	2.83%	1.56%	1.16%	1.02%	3.59%	4.31%
TAT (ng/mL)	1	3.808	2.76%	1.73%	1.13%	0.42%	3.47%	3.57%
	2	20.667	2.31%	0.87%	1.76%	1.23%	3.27%	3.55%
	3	101.937	1.97%	1.35%	0.92%	0.72%	2.66%	2.95%
	C1	5.001	3.20%	1.86%	1.82%	1.18%	4.28%	4.42%
	C2	51.127	2.55%	1.08%	1.48%	1.38%	3.43%	4.21%
tPAIC (ng/mL)	1	10.276	2.66%	1.49%	1.68%	1.45%	3.77%	3.86%
	2	39.638	2.56%	0.93%	1.08%	0.96%	3.08%	3.16%
	3	79.837	1.94%	1.59%	0.45%	0.67%	2.64%	3.30%
	C1	5.013	2.91%	1.04%	1.92%	1.06%	3.79%	5.29%
	C2	19.915	2.77%	1.05%	1.21%	0.55%	3.24%	3.29%
TM (TU/mL)	1	5.153	3.18%	0.72%	1.71%	0.80%	3.76%	3.94%
	2	15.648	2.08%	1.87%	0.20%	0.70%	2.89%	3.09%
	3	102.659	2.07%	1.15%	0.59%	0.67%	2.53%	2.90%
	C1	9.966	2.70%	2.51%	0.76%	1.31%	3.98%	4.04%
	C2	49.921	2.43%	0.26%	1.66%	0.52%	3.00%	3.08%

**Supplementary Table S3.** Analytical recovery tests of MAGLUMI PIC, TAT, tPAIC and TM CLIA reagents.

Analyte	added concentration	Measured value			Recovery rate (%)		
		Lot1	Lot2	Lot3	Lot1	Lot2	Lot3
PIC (µg/mL)	0	0.504	0.509	0.518	/	/	/
	0.8	1.297	1.311	1.317	99.13	100.25	99.88
	3	3.560	3.514	3.589	101.87	100.17	102.37
	30	30.509	30.716	30.337	100.02	100.69	99.40
TAT (ng/mL)	0	0.496	0.493	0.497	/	/	/
	4	4.552	4.443	4.513	101.40	98.75	100.40
	10	10.128	10.264	10.614	96.32	97.71	101.17
	90	91.973	88.711	89.767	101.64	98.02	99.19
tPAIC (ng/mL)	0	4.717	4.462	4.482	/	/	/
	3	7.508	7.414	7.411	93.03	98.40	97.63
	9	13.332	13.613	13.620	95.72	101.68	101.53
	75	79.826	80.523	80.685	100.15	101.41	101.60
TM (TU/mL)	0	4.015	4.201	4.134	/	/	/
	4	7.955	8.103	8.033	98.50	97.55	97.48
	13	16.758	16.751	16.980	98.02	96.54	98.82
	150	153.168	151.802	153.364	99.44	98.40	99.49



**Supplementary Fig. S2** Representative graphs of linearity using one lot for the detection of PIC (0.45-52.00 µg/mL), TAT (0.36-156.00 ng/mL), tPAIC (0.90-130.00 ng/mL) and TM (0.90-260.00 TU/mL).

**Supplementary Table S4.** Interference from supplement of hemoglobin, triglyceride and bilirubin.

analytes	Levels	Lot	bilirubin		hemoglobin		lipid emulsion	
			10 mg/dL	20 mg/dL	250 mg/dL	500 mg/dL	500 mg/dL	1000 mg/dL
PIC	Low	Lot1	-3.98%	0.53%	-1.46%	-1.99%	0.13%	1.35%
		Lot2	1.20%	0.40%	0.27%	0.40%	1.20%	0.40%
		Lot3	1.35%	1.48%	1.07%	-0.13%	4.64%	4.10%
	Medium	Lot1	-1.78%	-0.89%	-0.59%	1.83%	-2.70%	-0.16%
		Lot2	0.81%	0.67%	-1.45%	0.68%	3.85%	1.06%
		Lot3	-0.57%	-3.54%	3.02%	-0.53%	1.41%	0.98%
	High	Lot1	0.58%	-0.50%	4.04%	2.27%	-4.09%	-2.51%
		Lot2	-1.71%	0.04%	0.82%	-1.52%	-2.58%	-1.08%
		Lot3	0.44%	2.16%	0.53%	0.30%	-0.29%	3.06%
TAT	Low	Lot1	0.61%	-2.69%	1.01%	0.57%	-4.85%	-3.32%
		Lot2	2.92%	3.06%	-4.50%	-1.16%	-2.31%	-0.18%
		Lot3	-0.37%	-0.60%	0.68%	-0.03%	-2.76%	-1.84%
	Medium	Lot1	-4.28%	-0.04%	3.04%	2.06%	-2.67%	-0.69%
		Lot2	-1.98%	-0.57%	-2.72%	2.52%	-0.35%	0.54%
		Lot3	2.38%	2.40%	1.22%	3.18%	0.46%	1.59%
	High	Lot1	0.51%	0.14%	1.77%	-0.74%	-0.23%	-0.43%
		Lot2	-3.32%	-1.32%	-2.64%	-0.78%	3.13%	2.52%
		Lot3	-1.19%	1.33%	-4.89%	-3.30%	-0.96%	-2.97%
tPAIC	Low	Lot1	2.40%	0.01%	-2.04%	-2.16%	0.76%	0.79%
		Lot2	1.87%	1.42%	-3.37%	-3.91%	-2.03%	-2.90%
		Lot3	3.51%	2.97%	3.88%	2.85%	0.91%	2.57%
	Medium	Lot1	-2.05%	0.58%	-1.56%	0.99%	1.17%	-0.15%
		Lot2	3.42%	3.39%	0.60%	-0.26%	1.61%	3.75%
		Lot3	-0.75%	0.53%	-4.57%	0.75%	1.25%	-0.13%
	High	Lot1	2.39%	0.52%	-0.09%	-2.52%	-3.06%	-0.79%
		Lot2	-2.60%	-2.83%	-2.23%	1.48%	2.05%	1.47%
		Lot3	-2.32%	0.66%	2.15%	2.85%	-1.95%	-0.37%
TM	Low	Lot1	-2.19%	-1.13%	-1.93%	-1.59%	-1.30%	-0.09%
		Lot2	-3.22%	-2.09%	-0.51%	1.18%	2.20%	2.41%
		Lot3	-1.55%	-0.33%	1.19%	4.41%	1.13%	0.32%
	Medium	Lot1	-1.47%	0.68%	-2.23%	-2.34%	3.15%	2.69%
		Lot2	1.27%	4.02%	-0.39%	-0.68%	-0.03%	-2.78%
		Lot3	-1.53%	0.45%	0.76%	0.80%	2.73%	0.83%
	High	Lot1	2.19%	1.85%	-5.47%	-4.49%	-2.91%	-3.61%
		Lot2	1.92%	-2.31%	-2.54%	-1.23%	1.77%	1.44%
		Lot3	-2.63%	-1.83%	-2.75%	0.25%	-2.21%	-1.03%

Variable	AUC (95%CI)	Sensitivity (%)	Specificity (%)	Youden Index
PIC	0.788 (0.702-0.858)	64.0	81.8	0.458
TAT	0.798 (0.713-0.867)	82.0	66.7	0.487
tPAIC	0.835 (0.755-0.898)	70.0	95.5	0.655
TM	0.844 (0.765-0.905)	80.0	81.8	0.618
PIC+tPAIC	0.915 (0.849-0.959)	84.0	92.4	0.764
PIC+TAT+tPAIC+TM	0.913 (0.846-0.957)	86.0	90.9	0.769

**Supplementary Table S5.** ROC analysis of thrombosis markers for DIC diagnosis.

Variable	AUC (95%CI)	Sensitivity (%)	Specificity (%)	Youden Index
PIC	0.713 (0.624-0.791)	60.0	74.1	0.341
TAT	0.806 (0.725-0.872)	73.9	79.3	0.532
tPAIC	0.673 (0.582-0.754)	80.0	55.2	0.352
TM	0.561 (0.469-0.651)	73.9	46.6	0.204
PIC+TAT+tPAIC	0.839 (0.762-0.899)	73.9	81.0	0.549
PIC+TAT+tPAIC+TM	0.841 (0.764-0.900)	73.9	79.3	0.532

**Supplementary Table S6.** ROC analysis of thrombosis markers for IS diagnosis.