Classroom Work

Self-introduction

Your name, student ID number, major, and nationality;

Your impressions of Kunming, Yunnan (you may describe aspects such as the weather, food, culture, etc.);

What you hope to gain here?

Your future plans.

You may also share anything else you would like to say.



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Clinical Laboratory Diagnostics



Point-of-care Testing Technology and Miniaturized Detection



College of Life Science and Laboratory Medicine

Marissa Wells

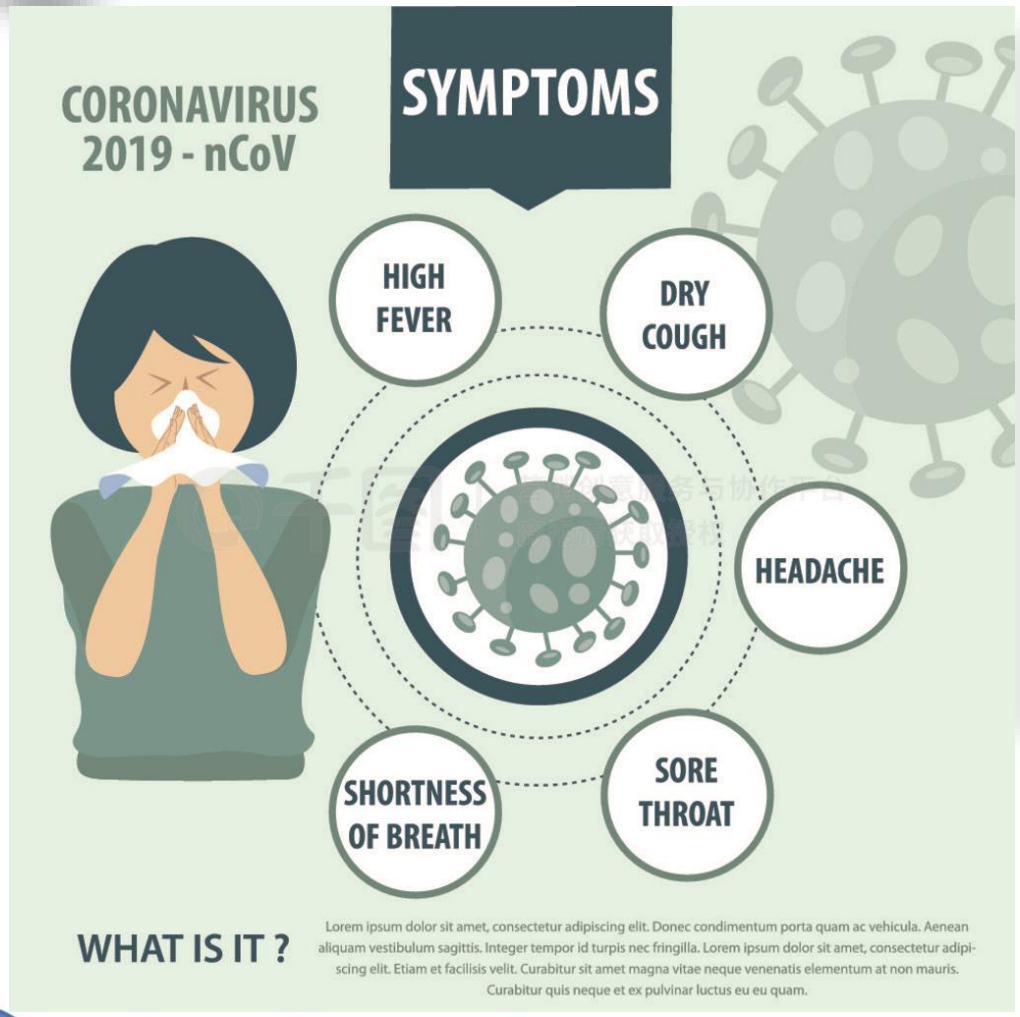
December 18, 2026

Learning Objectives and Requirements

- **Master: The concept of POCT, characteristics of POCT, and common technical methods of POCT.**
- **Be familiar with: Relevant technical principles of POCT, and key R&D points.**
- **Understand: Reagent development processes and performance evaluation of reagents.**
- **Scan: Literature related to POCT.**



Immunochromatographic Assay









无菌拭子



样本提取液



说明书



密封袋



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Definition and Characteristics

Definition:

- Point-of-care testing (POCT) refers to a testing method conducted at the sampling site using portable analytical instruments and corresponding reagents to obtain results rapidly. This type of testing can be performed by laboratory personnel or non-laboratory personnel (such as nurses, doctors, patients, family members, etc.) and is widely applied in various settings including large hospitals, primary care hospitals, community health stations, private clinics, as well as on-site locations like customs and disaster medical relief operations.



Definition and Characteristics

Characteristics:

- **Immediate:** Results can be obtained quickly, sometimes in less than a minute, and typically within half an hour at most.
- **On-site:** Test kits and some handheld devices are brought directly to the patient, allowing testing to be performed at the location.
- **Convenient:** The process from sample collection to result is streamlined and can often be completed with minimal steps.



Comparison of the Main Differences Between Clinical Laboratory Testing and POCT

Project	Clinical laboratory testing	POCT
Key Responsibilities	exact valuation	initial disease screening
Laboratory Personnel	professional laboratory personnel	Ordinary people can also do it
Turnaround Time	slow	fast
Specimen Identification	complicated	simple
Specimen processing	usually required	not usually required
Correction	frequent and tedious	not frequent and simple
Reagent	configuration required	available anytime
Consumables	relatively low	relatively high
Detecting Instrument	complicated	simple
Cost per Test	relatively low	relatively high
Quality of the experimental results	high	moderate

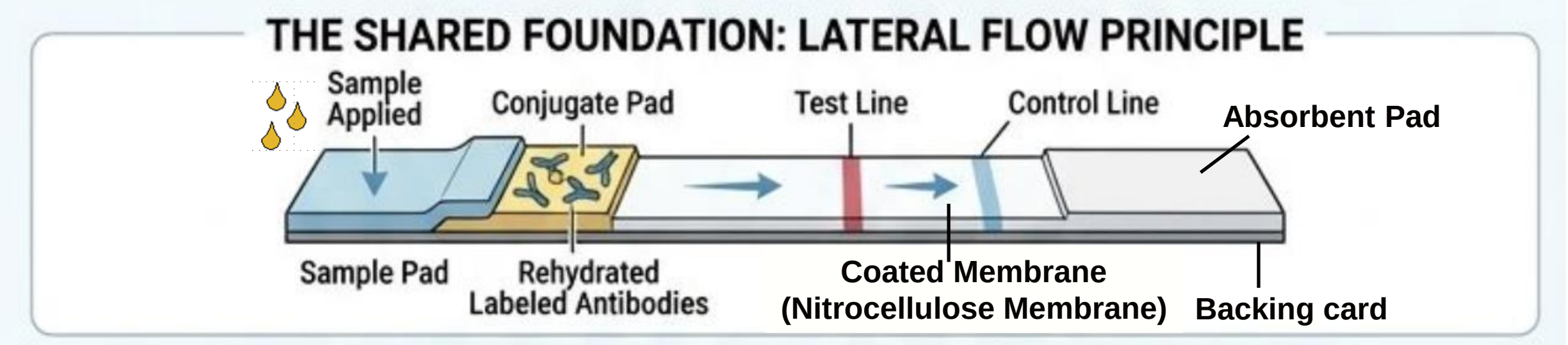


Methodological Classification of POCT

Technical Classification	Test Principle	Examples of Clinical Applications
Immunochromatography	immunological reaction	early pregnancy test strip
Dry chemical technology	color reaction, reflectometry, differential potential method	Uric acid test strip
Biosensor technology	identification of enzymes, antibodies, nucleic acids and other substances by optical and electrical methods	glucometer
Microfluidic chip technology	optical, electrical and mass spectrometry methods	triage heart failure/ myocardial infarction detector
Biochip technology	protein-protein interaction	magnetic sensitive immunoassay analyzer
Infrared spectrophotometry	optical means	infrared non-invasive blood glucose meter



Immunochromatographic Assay



The immunochromatographic test strip is primarily composed of a sample pad, a conjugate pad, a nitrocellulose membrane, an absorbent pad, a backing card, and various reagents applied to the strip, all laminated in sequential layers.



Components of the immunochromatographic test strip





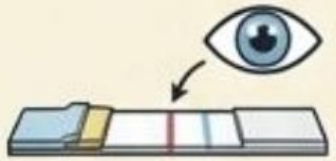


Immunochromatographic Assay

CORE DIFFERENCES IN TECHNOLOGY AND PERFORMANCE

COLLOIDAL GOLD

LABEL & SIGNAL:
Visible Color
Gold nanoparticles reflect & absorb light, creating a visible red/purple line.



DETECTION:
Visual Inspection or Simple Reader
Directly visible for qualitative result or optical density measurement.



SIGNAL-TO-NOISE:
Lower SNR
Signal against a light background, less contrast.



FLUORESCENT IMMUNOCHROMATOGRAPHY

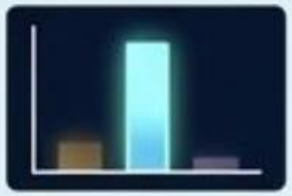
LABEL & SIGNAL:
Emitted Light
Fluorescent microspheres absorb light & emit a longer wavelength signal.



DETECTION:
Specialized Reader
Requires reader for excitation & precise emission measurement.



SIGNAL-TO-NOISE:
Higher SNR
Emitted signal against a dark background, high sensitivity.





Immunochromatographic Assay

SUMMARY TABLE

Feature	Fluorescent Immunochromatography	Colloidal Gold Immunochromatography
Label Type	Fluorescent microspheres/quantum dots	Gold nanoparticles
Detection Method	Specialized reader (emitted light)	Visual or simple reader (visible color)
Sensitivity	High (low detection limits)	Low to moderate
Result Type	Quantitative	Qualitative or semi-quantitative
Cost & Complexity	Higher cost, requires equipment	Lower cost, simple, rapid
Ideal Use Cases	Trace analyte, precise measurement	Rapid screening, point-of-care

MAKING THE RIGHT CHOICE

FOCUS: Rapid, Low-Cost Screening → COLLOIDAL GOLD (Simplicity, Speed)

FOCUS: Trace Amounts & Accuracy → FLUORESCENT (Superior Sensitivity, Reliable Quantitative Analysis)



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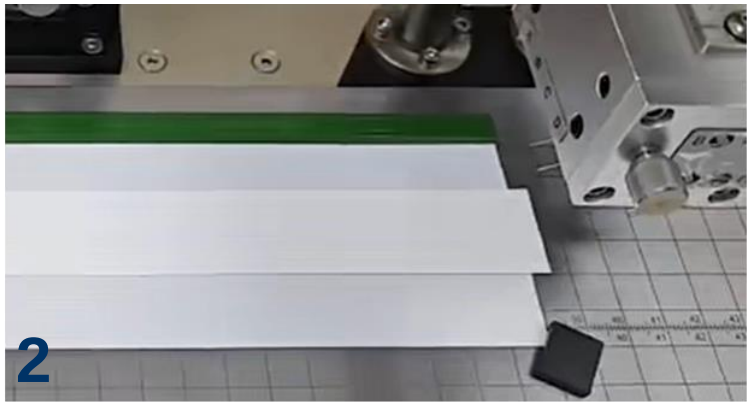


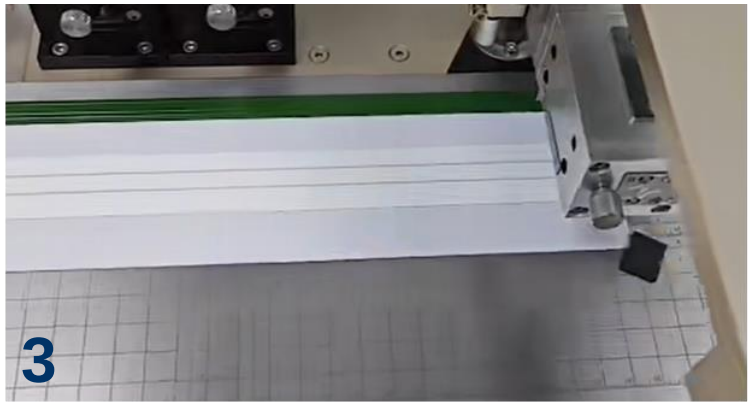
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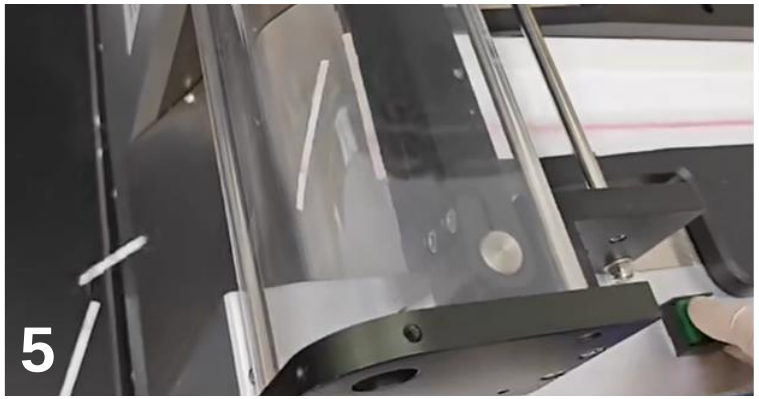
Assembly Process of the Test Strip















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Assay Formats for Immunochromatographic Tests

① Sandwich Assay:

Used for detecting large-molecule antigens.



② Competitive Assay:

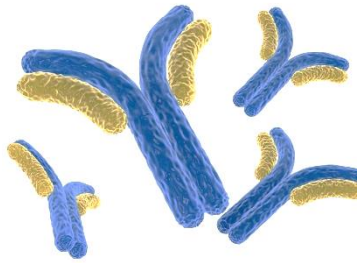
Used for detecting small-molecule antigens.







③ Indirect Assay:



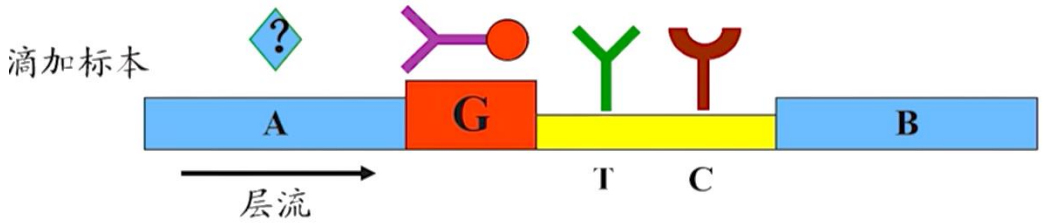
Used for detecting antibodies.



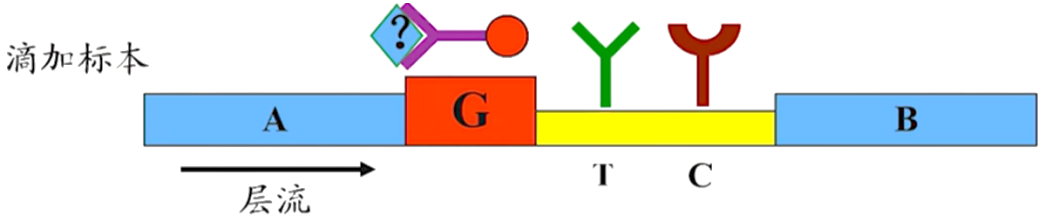
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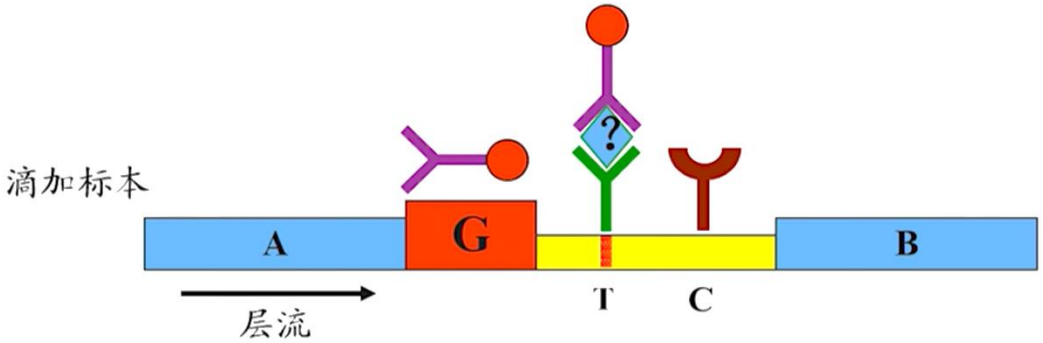
Sandwich Assay



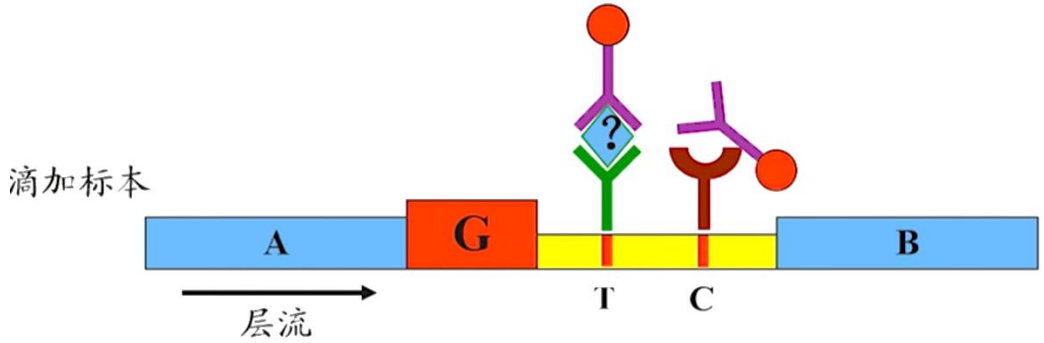
1



2



3

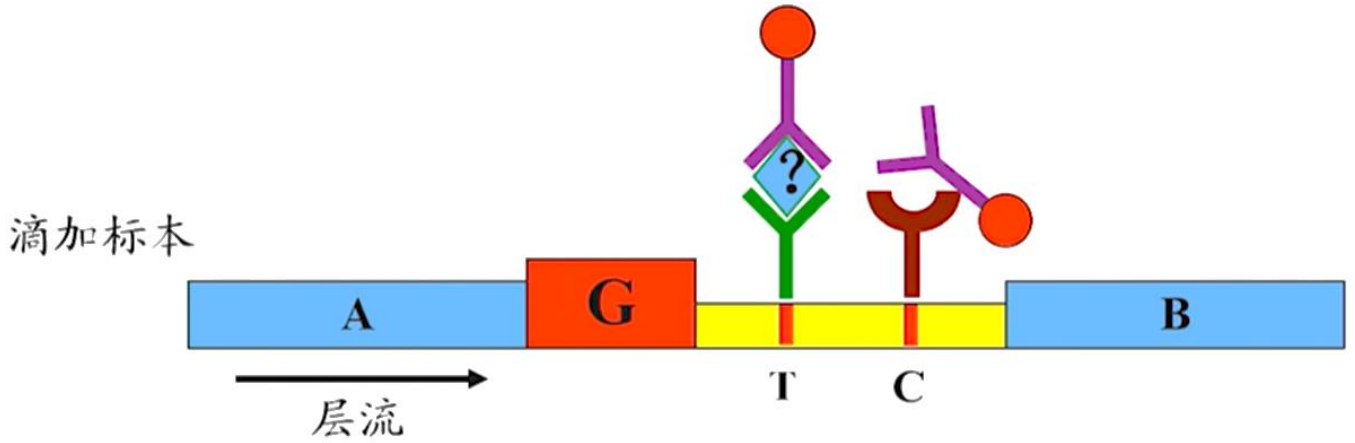


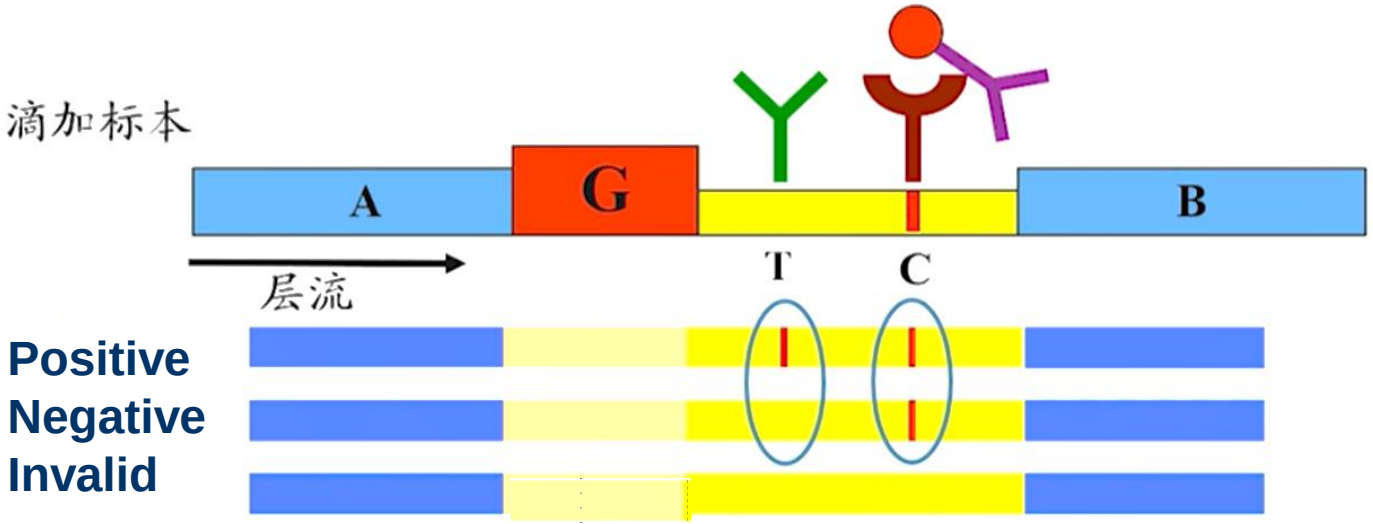
4



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Sandwich Assay





Positive
Negative
Invalid



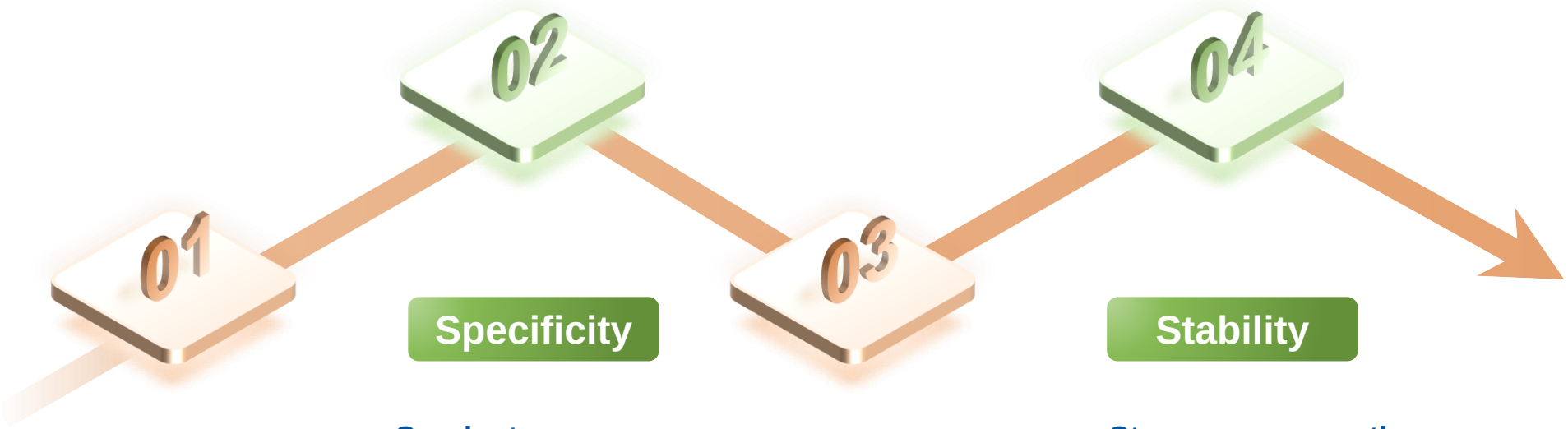
Study on Test Strip Process and Reaction System

1. Determination of coating concentrations for the test line and control line
2. Optimization of dispensing parameters for membrane coating
3. Establishment of drying parameters for the coated membrane
4. Optimization of preparation parameters for the conjugate pad
5. Construction of a standard curve
6. Determination of the optimal sample volume
7. Test for reaction time and strip stability



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Performance Evaluation of Test Strips



Sensitivity

Test three consecutive batches of reagents on serial samples to determine the limit of detection.

Specificity

Conduct interference studies on potential cross-reacting substances and major interferents that may be present in the test samples.

Precision

Analyze both within-run precision and between-run precision.

Stability

Store three consecutive batches of products under different temperature conditions and periodically examine them to determine the shelf life.



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Summary

Basic Principles

- POCT
- Immunochromatographic Tests

Components

- Test Strip

Assay Formats

- Sandwich Assay
- Competitive Assay
- Indirect Assay

Applications

- Large-molecule antigen
- Small-molecule antigen
- Antibody



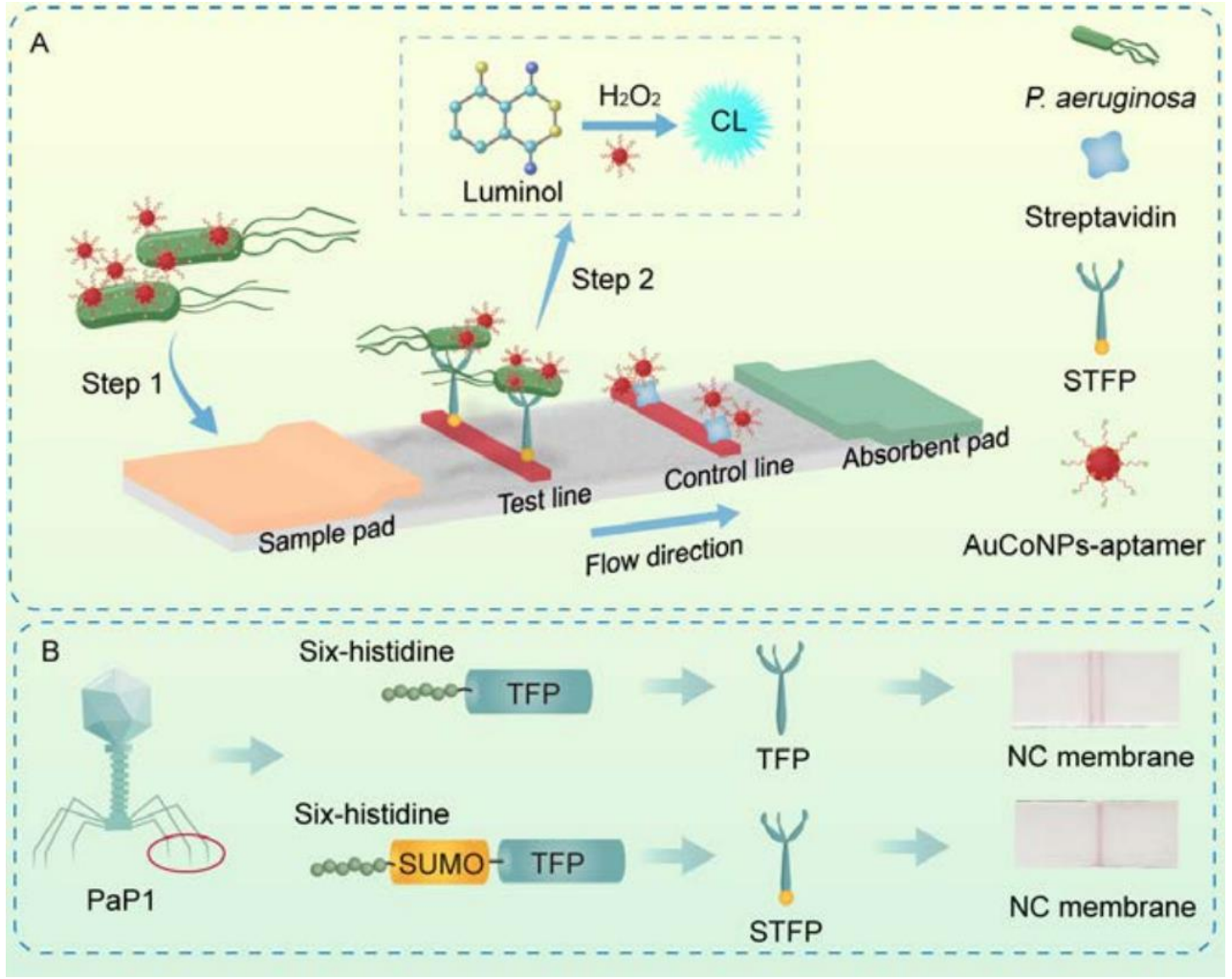
Classroom Work

1. What is POCT? What are its key characteristics? Analyze the main differences between POCT and traditional clinical laboratory testing methods.

2. Briefly describe the structure of a colloidal gold immunochromatographic test strip.



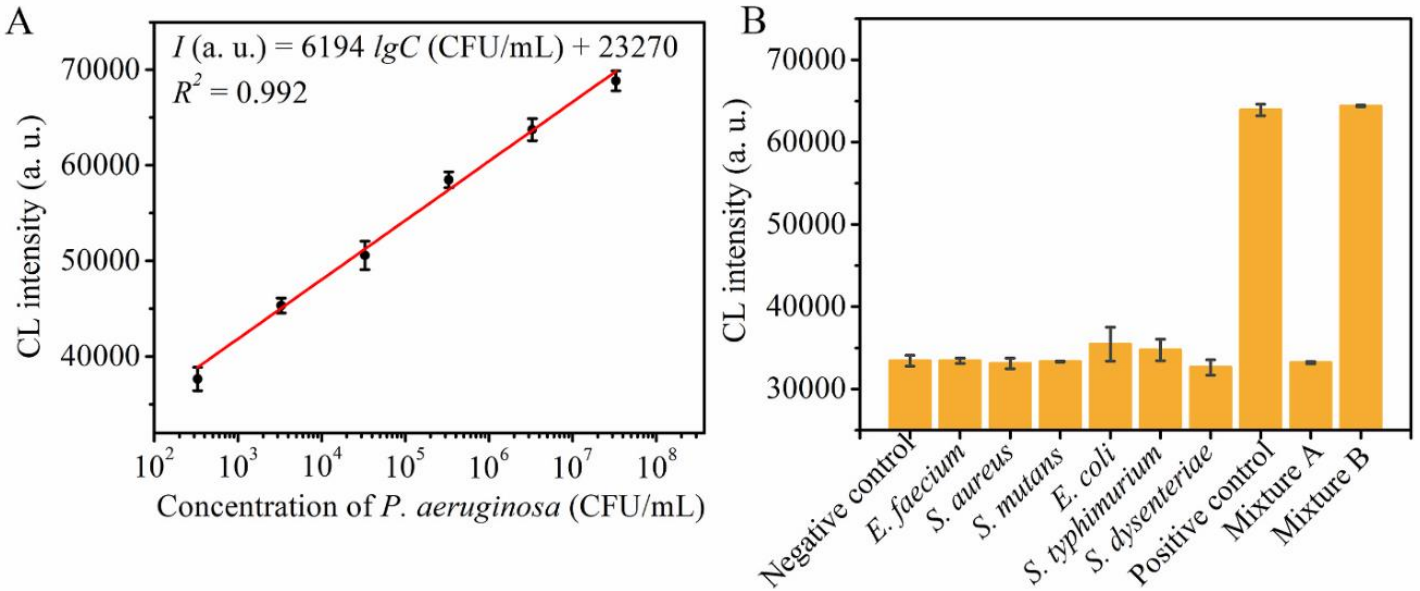
Literature Study

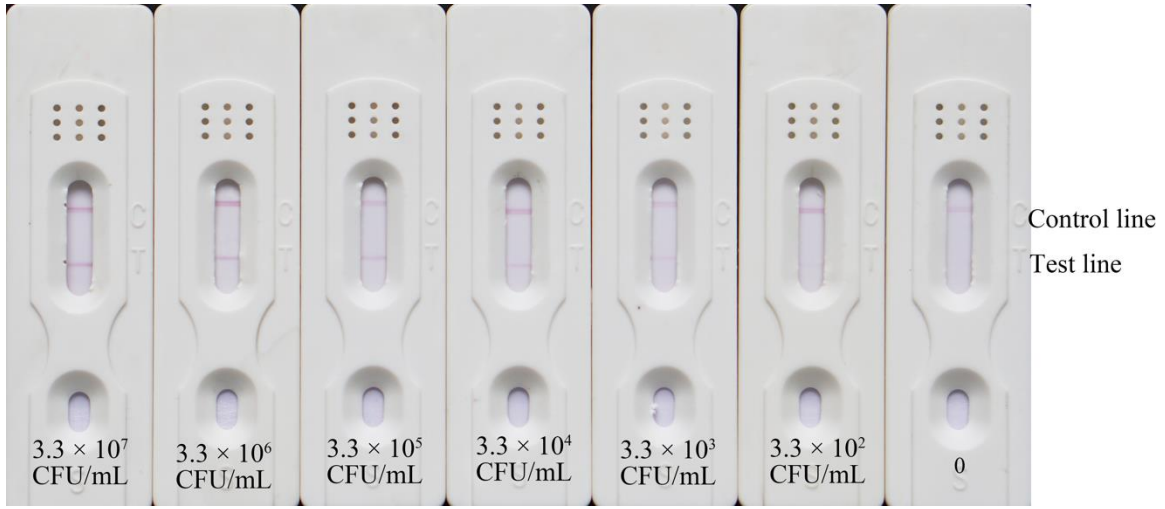


Biosens. Bioelectron. **2022**, 216, 114637



Literature Study

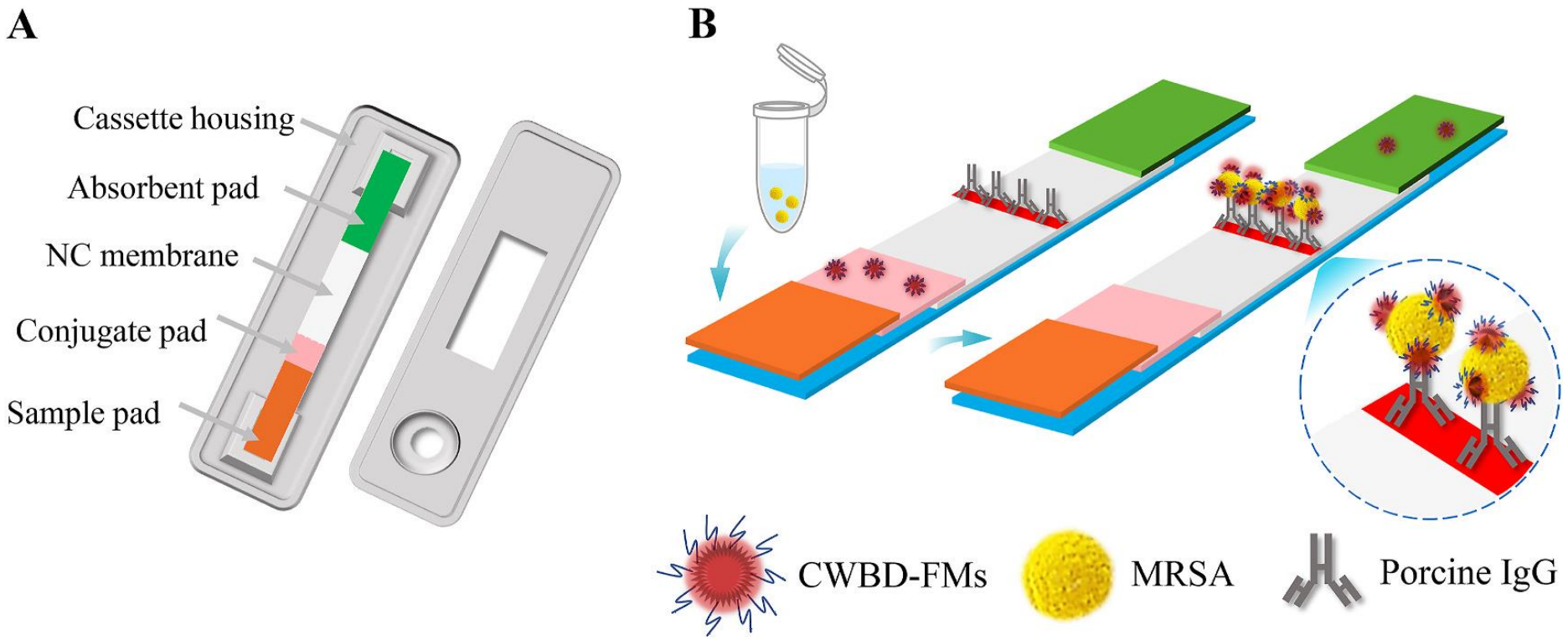






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Literature Study

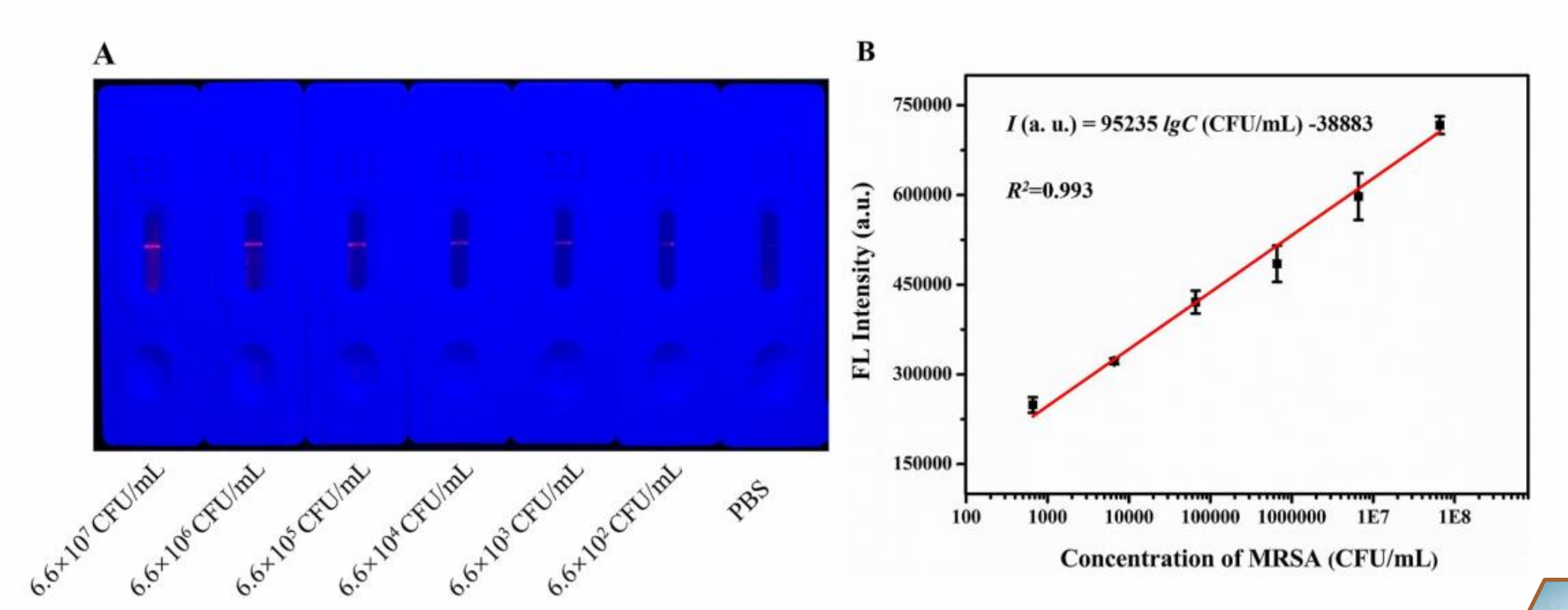




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Biosens. Bioelectron. **2021**, 182, 113189

Literature Study

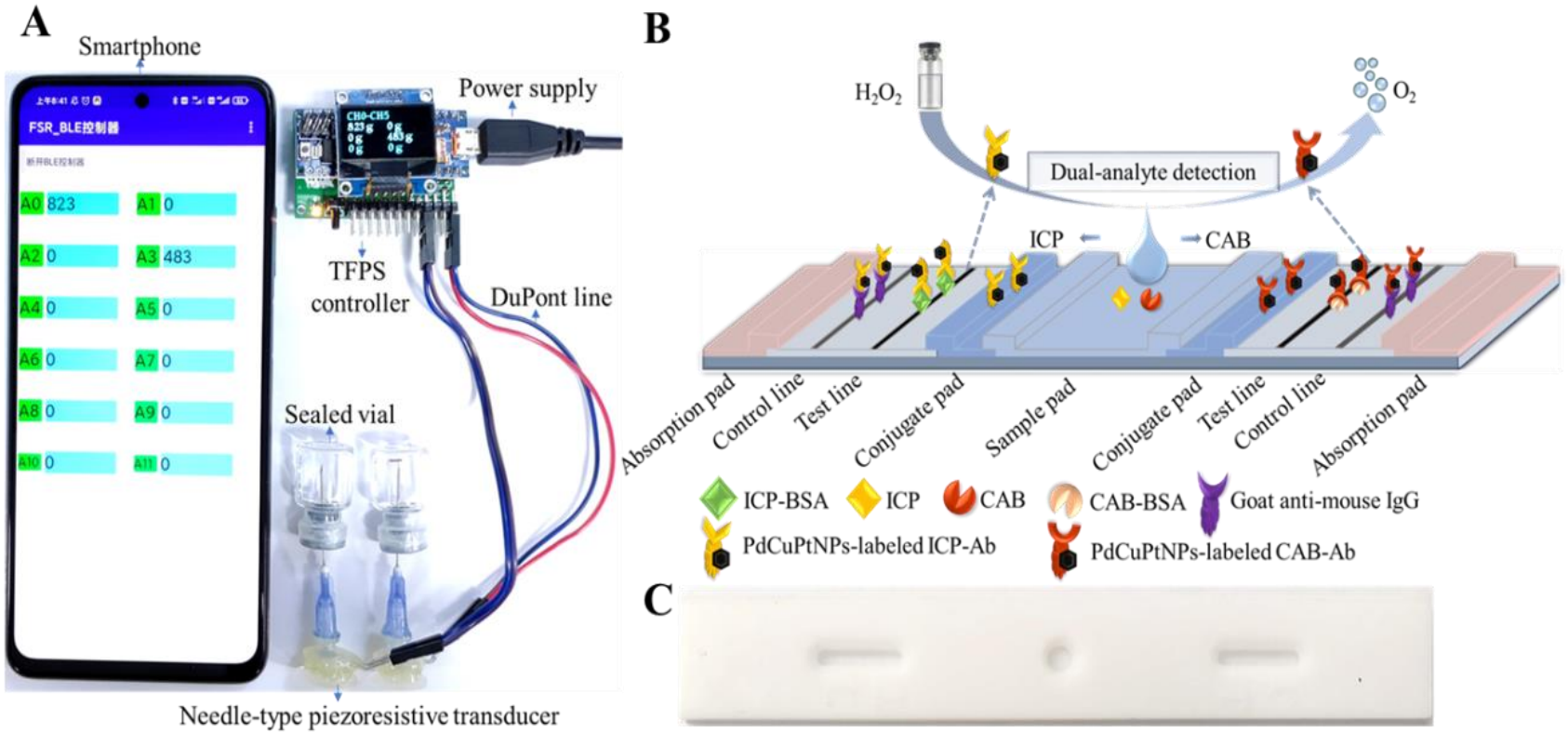




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Biosens. Bioelectron. **2021**, 182, 113189

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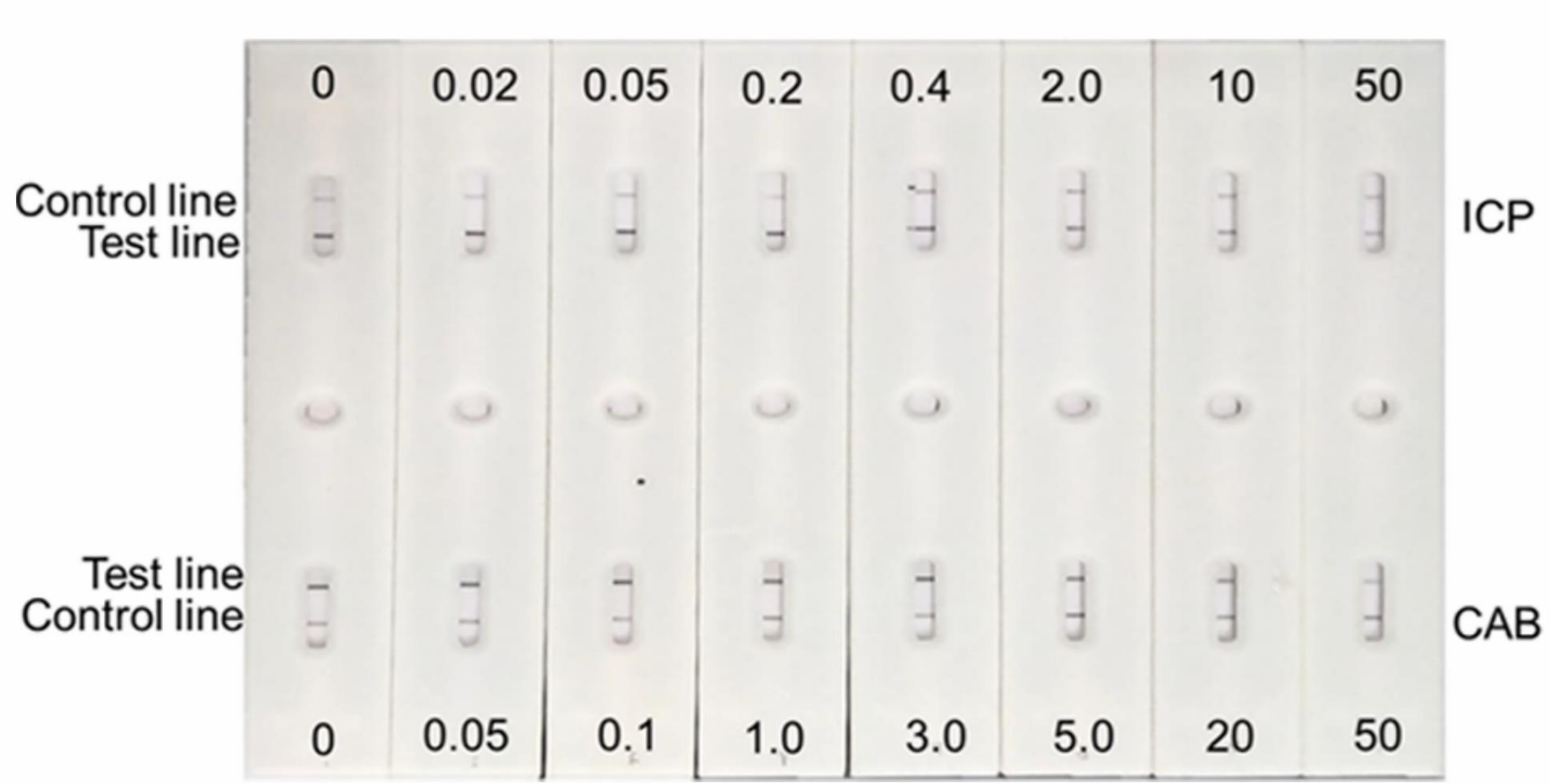


Anal. Chem. **2023**, 95, 1359–1365



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Literature Study

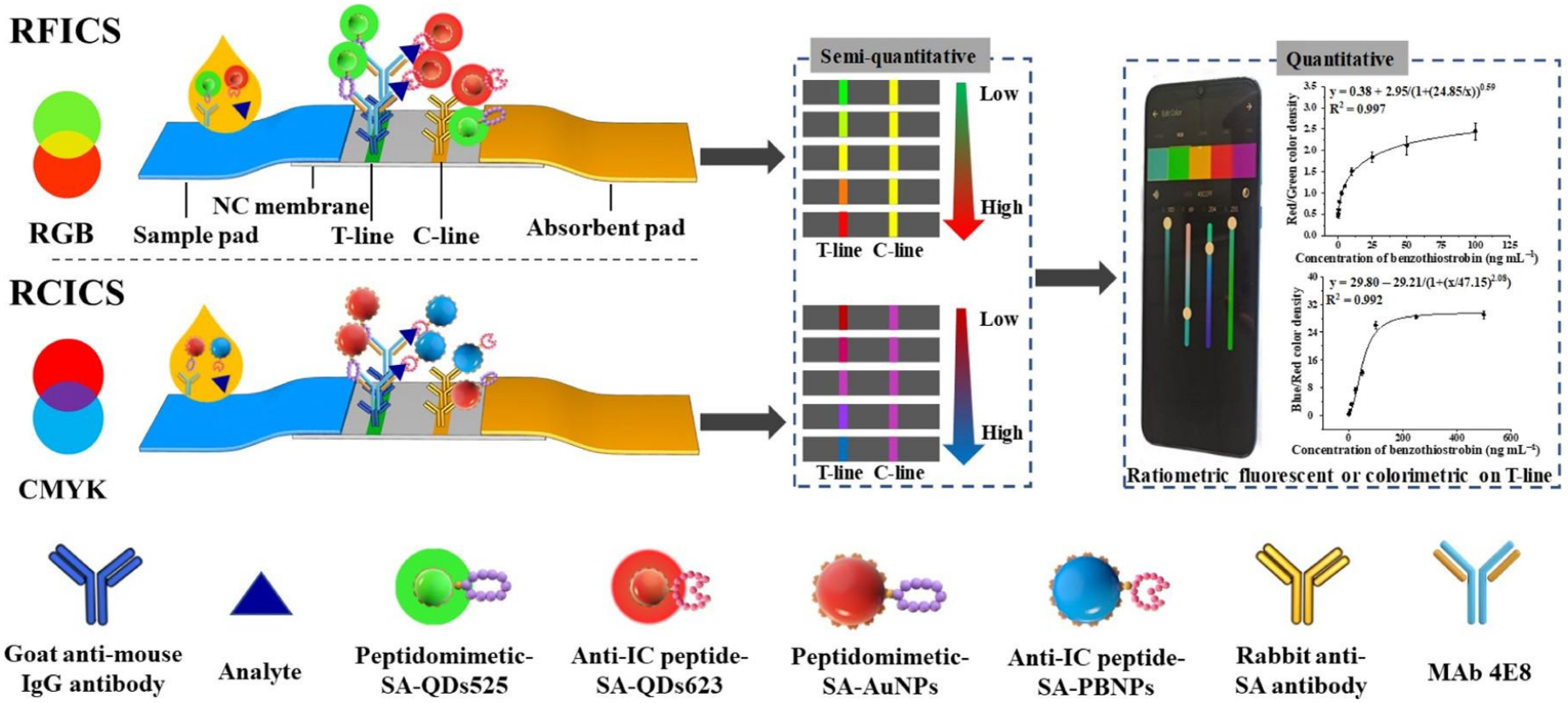


Anal. Chem. **2023**, 95, 1359–1365



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Literature Study

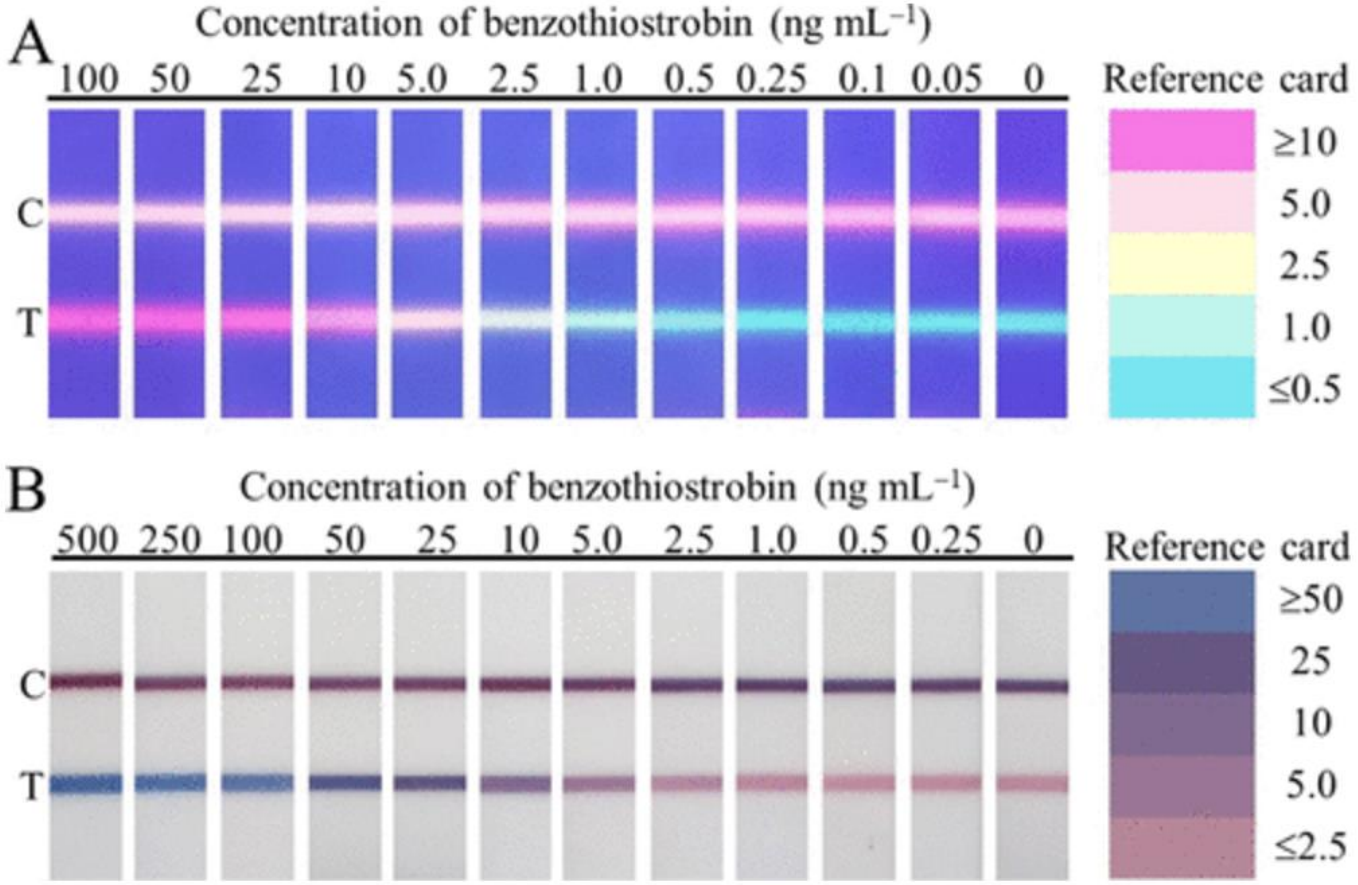


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Anal. Chem. **2022**, 94, 7358–7367



Literature Study



Anal. Chem. **2022**, 94, 7358–7367



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Classroom Work

1. Which assay format (e.g., sandwich assay, competitive assay) does the lateral flow assay method established in this study adopt for bacterial detection? Briefly describe its detection mechanism (including key recognition elements and the signal generation method).

2. What is the detection sensitivity (limit of detection and linear range) of the developed test strip for *Pseudomonas aeruginosa*? How does the strip perform in terms of selectivity against non-target bacteria (e.g., other Gram-positive or Gram-negative bacteria)?

3. In which types of real samples did the authors validate the detection capability of the test strip? What do the results (e.g., spike recovery rates, agreement with standard methods) indicate about its potential application in fields such as medical diagnosis and food safety?



4. What limitations or shortcomings do you perceive in this method?

Clinical Laboratory Diagnostics

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Thank you!



College of Life Science and Laboratory Medicine

Marissa December 18, 2026