
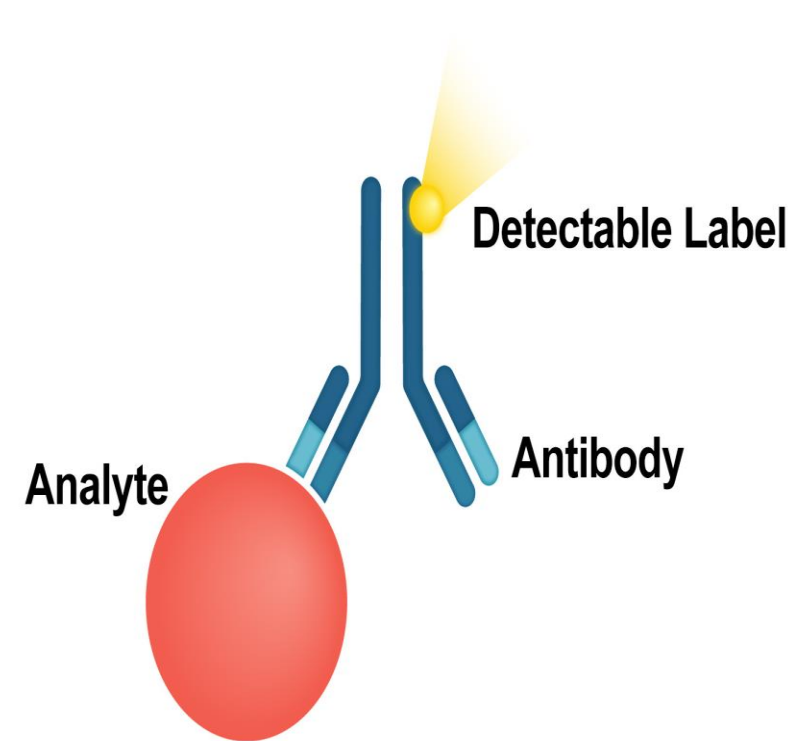


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# Introduction

- Immuno refers to an immune response that cause the body to generate antibodies.
- Assay refers to a test.
- An immunoassay is a test that utilize immunocomplexing when antibodies and antigen are brought together.



# Types of immunoassays

## Enzyme-Linked Immunosorbent Assay (ELISA)-


- ELISA is a widely used immunoassay that utilizes enzymes and antibodies to detect and quantify specific antigen in a sample.



# Application of ELISA

- Enzyme-linked immunosorbent assays are applied in many diagnostic tests.


## **Detect and Measure the Presence of Antibodies in the Blood**

- Autoantibodies (anti-dsDNA, anti-dsg1, ANA, etc.)
  - Antibodies against infectious disease (antibacterial, antiviral, antifungal)
  - Hepatitis A, B, C, HIV, etc.
- 

## **Detect and Estimate the Levels of Tumor Markers**

- Prostate-specific antigen (PSA)
- Carcinoembryonic Antigen (CEA)


## **Detect and Estimate Hormone Levels**

- Luteinizing hormone(LH)
  - Follicular stimulating hormone
  - Prolactin
  - Testosterone
  - Human chorionic gonadotropin (hCG)
- 

# Screening Donated Blood for Possible Viral Contaminants

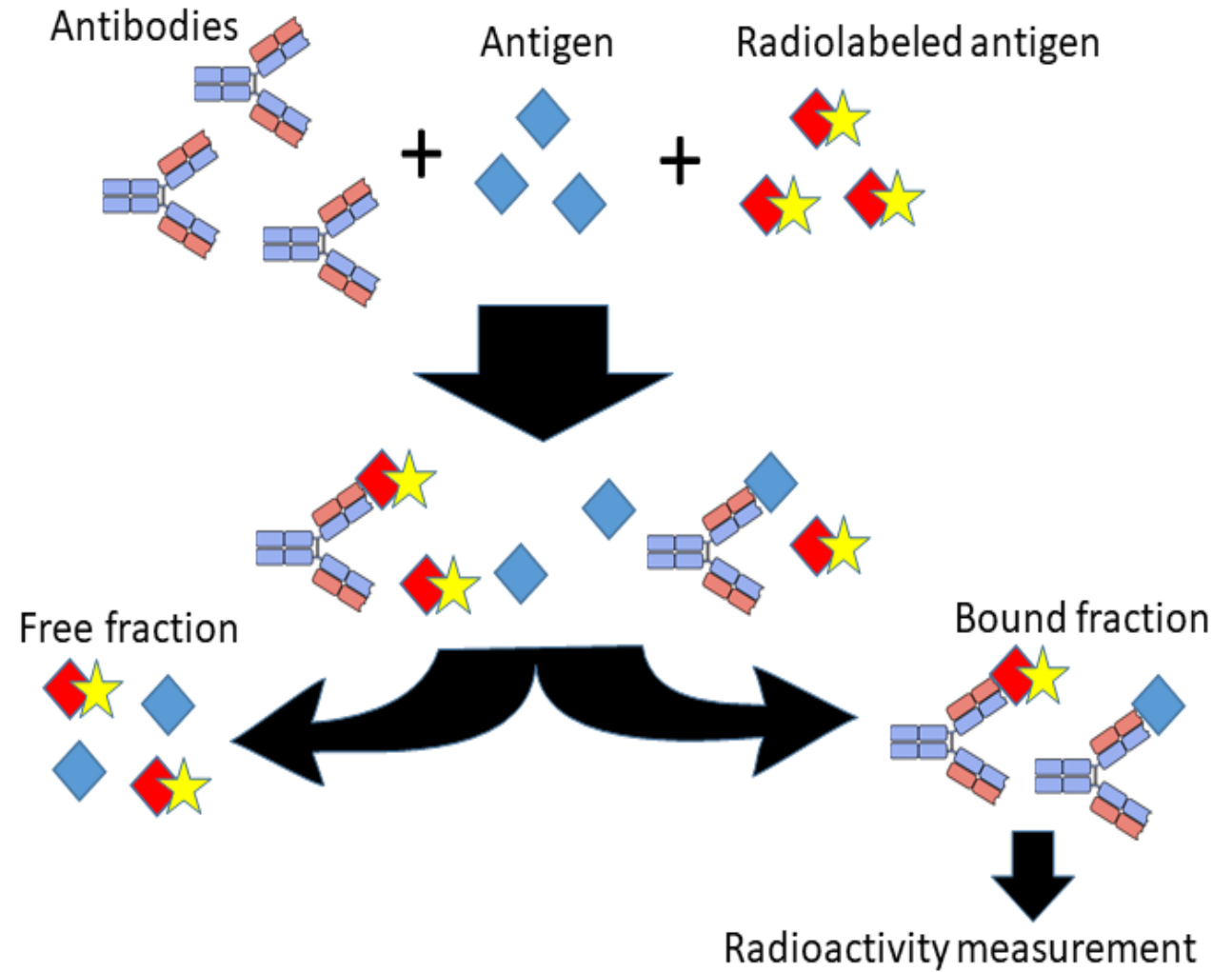
- Anti-HIV-1/2
- Anti-HCV
- HBsAg

## Detecting Drug Abuse

- Amphetamine
  - Methamphetamine
  - 3,4-methylenedioxymethamphetamine
  - Cocaine
  - Benzoyllecgonine
- 

# Radioimmunoassay(RIA)

- RIA is an older technique that uses radioactive isotopes to measure the binding of antigen and antibodies.
- Radioimmunoassay can be used to detect substances like Hormones, Vitamins, Serum Proteins, Infective agents and drugs.





# Fluorescent Immunoassay

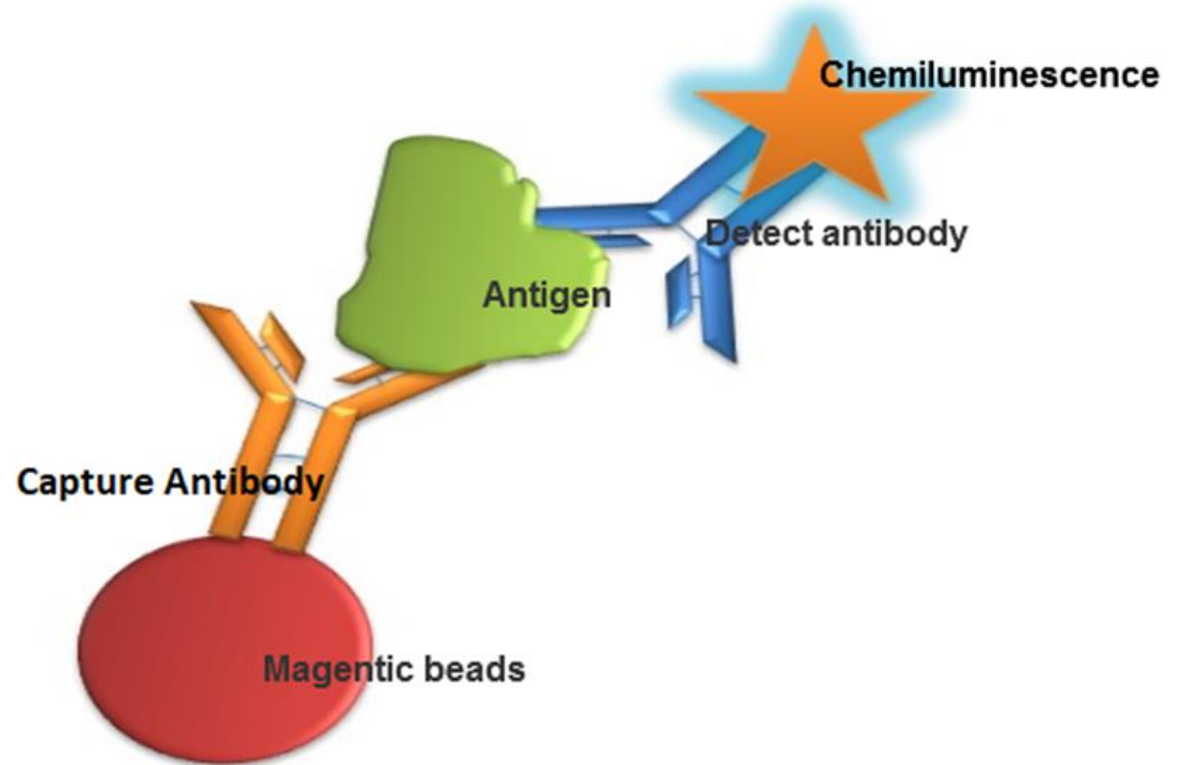
- This method uses fluorescent labels to detect the presence of specific molecules, often seen in application like flow cytometry.
- Fluorescence immunoassay (FIA) is a simple, rapid, and sensitive technique that is used to measure many compounds including drugs, hormones, and proteins. This method has been widely applied in the in vitro diagnostics (IVD) industry.





# Chemiluminescent Immunoassay (CLIA)

- CLIA relies on the emission of light to measure the concentration of target molecules and is commonly used in clinical diagnostics.
- Used for the detection and analysis of various antigens, antibodies, hormones, enzymes, fatty acids, vitamins and drugs.



# Immunoassay Method Evaluation (protocol outline)

Immunoassay critical success factor  
(sensitivity,dynamic,range,reagent,cost,etc.)



Acquire Reagents

(Antibodies analyte,standards sample,control samples,  
labels and substrates)



Instruments Testing  
(calibration, performance testing, linearity)



Assay “Proof of Concept” Experiments  
(Establish preliminary assay parameters, reagent suitability  
data analysis models consult immunoassay expert)



## Assay Optimization

(Select factor to be optimized, determine matrix effects, construct precision profiles, consult a statistician)



## Assay Validation

(Day-to-day effects, scale up, operator effects % recovery analysis)



Method Documentation (SOP) and Implementation