



# Immunoassay Instrument

## What is Immunoassay?

A method for detecting and quantifying specific compounds in bodily fluids

## How is this accomplished?

By inducing reactions; color changes, changes in resistance, emission of light or radioactivity

## Everyday Examples:

At home covid tests, pregnancy tests, insulin tests

## What can be tested for?

Vitamins, minerals, drugs, hormones, markers for various diseases and conditions

## Immunoassay Instruments:



Siemens Healthineers. (2025). *Dimension EXL 200 and Atellica IM 1600 Product Photos*.  
<https://www.siemens-healthineers.com/en-us/laboratory-diagnostics/clinical-chemistry-and-immunoassay-systems/dimension-exl-200-integrated-chem-sys>

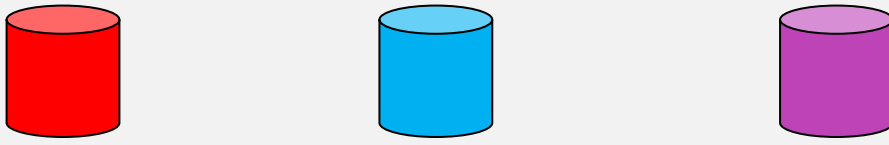
Biobase. (2025). *BK12200 Product Photo*.  
<https://www.biobase.com/product/automatic-chemiluminescence-immunoassay-system-bki2200>

Lansionbio. (2025). *LS-1100 Product Photo*.  
<https://www.lansionbiotech.com/shop/ls-1100-dry-fluorescence-immunoassay-analyzer-1>

## Anatomy of a Reaction:

If you can formulate a chemical that will react or bind to a substance when it is in the prescience of it, you can test for it

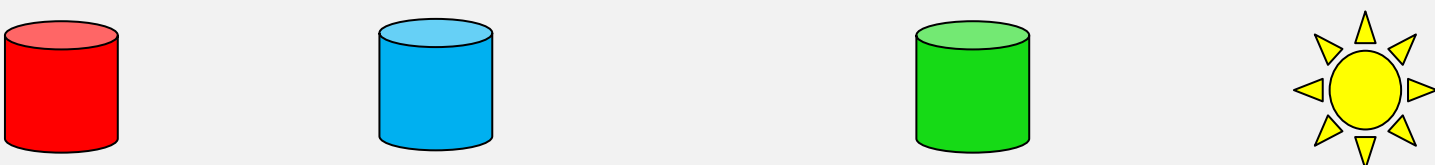
### Enzyme Immunoassay:



Sample + Reaction Chemical = Color Change

*Change in color indicates positive or negative result*

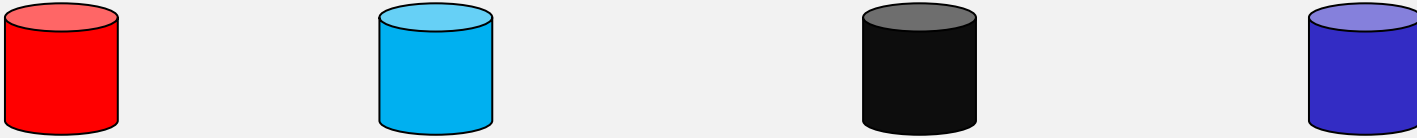
### Chemiluminescence Immunoassay:



Sample + Reaction Chemical + Light Emitting Chemical = Light

*Amount of light produced directly proportional to amount of substance present in sample*

### Counting Immunoassay:



Sample + Reaction Chemical and or Ion Probe = Change in resistance

*Change in resistance directly proportional to amount of substance present in sample*

## Problem Statement:

The measurement of various compounds in the blood are a key component of any yearly checkup. Most instruments capable of doing this are expensive, require extensively trained operators and significant maintenance. Many small clinics do not have the infrastructure or personnel to support these instruments, but need the results to serve their patients.

## Approach:

By limiting the design requirements and assay menu for the instrument, the cost can be lowered such that it represents the best value of any instrument on the market. Reliability and utility will be emphasized over costly features that may lower time to results or offer an expansive assay menu. The Honda Civic of immunoassay instruments is the target.

## Prototype:

The form of the prototype is a plan for an immunoassay instrument.

## Design Inputs

The instrument must allow the user to order a test, load a patient sample and automatically produce results.

The instrument cost cannot exceed \$15,000

The instrument must produce results in no more than 10 minutes.

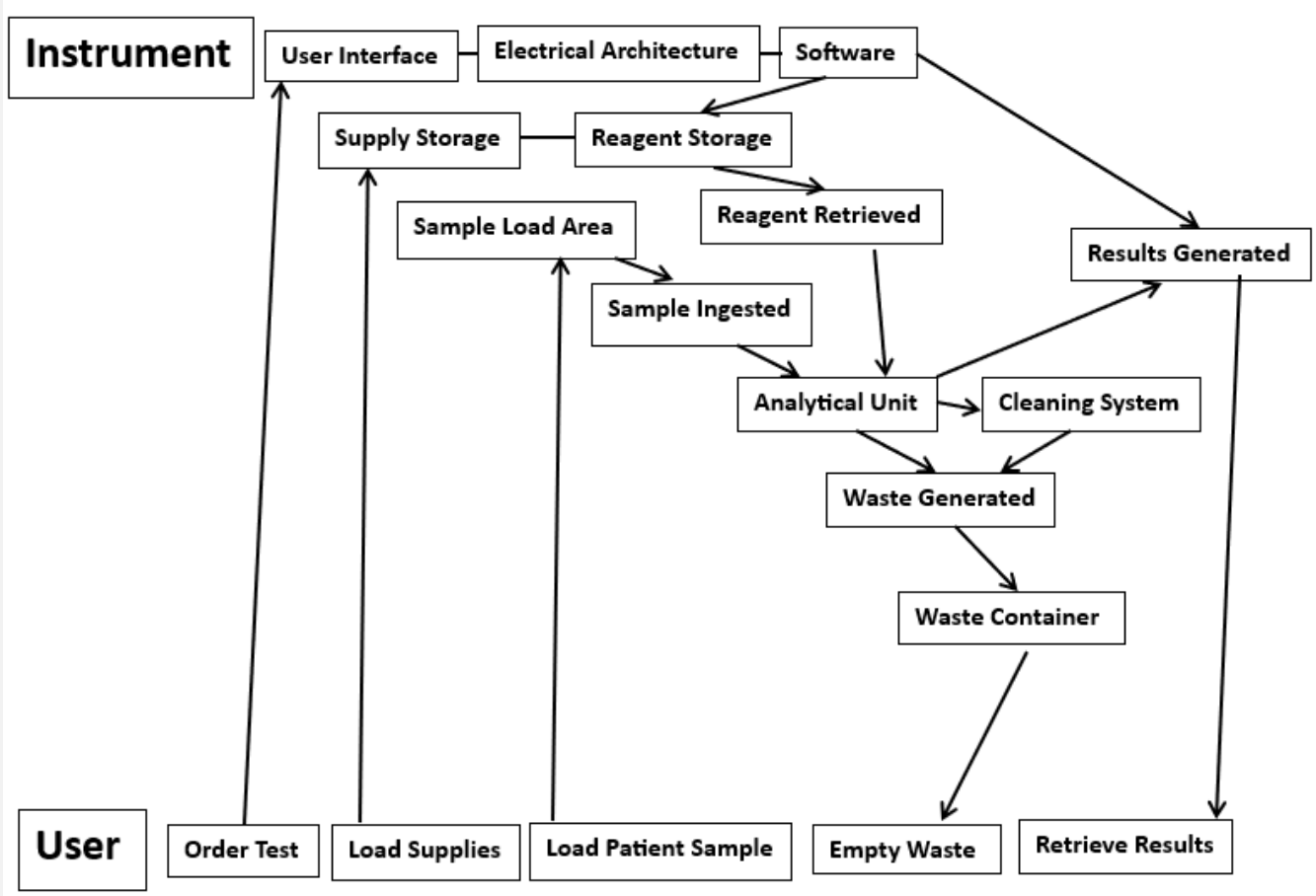
The instrument must have no more than 2 hours a week of maintenance.

The instrument must not require more than 3 field service visits per year for maintenance or emergency repair.

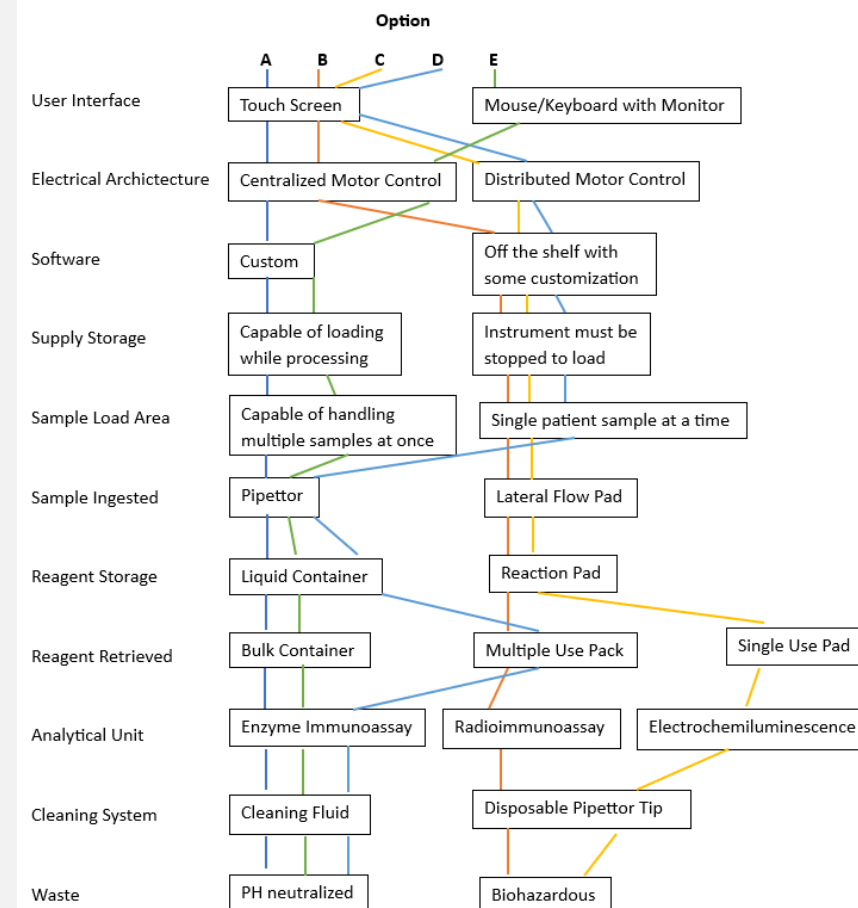
The instrument must have assays for the following tests:

Calcium, Carbon dioxide, Chloride, Creatinine, Glucose, Potassium, Sodium, Blood Urea Nitrogen, HDL, LDL, TSH, PSA, Iron, Ferritin, Folate, Vitamin B12, Vitamin D

## System Diagram



## Design Alternatives



## Health, Safety, Environment and Society

These instruments have the potential to identify health issues as early as possible, allowing people to seek treatment, giving them a better quality and longer life

They also have the potential to generate erroneous patient results. Every immunoassay instrument sold in the US must have FDA approval and meet 120 different standards from ISO and CLSI

While their results are vital to human health, they often produce biohazardous waste and use hazardous chemicals for their assays and cleaning. The supplies are often double packaged for sterility and the use of such instruments generates a large amount of plastic waste

### Students & Faculty Advisors

Nathan Helstrom

### Sponsorships