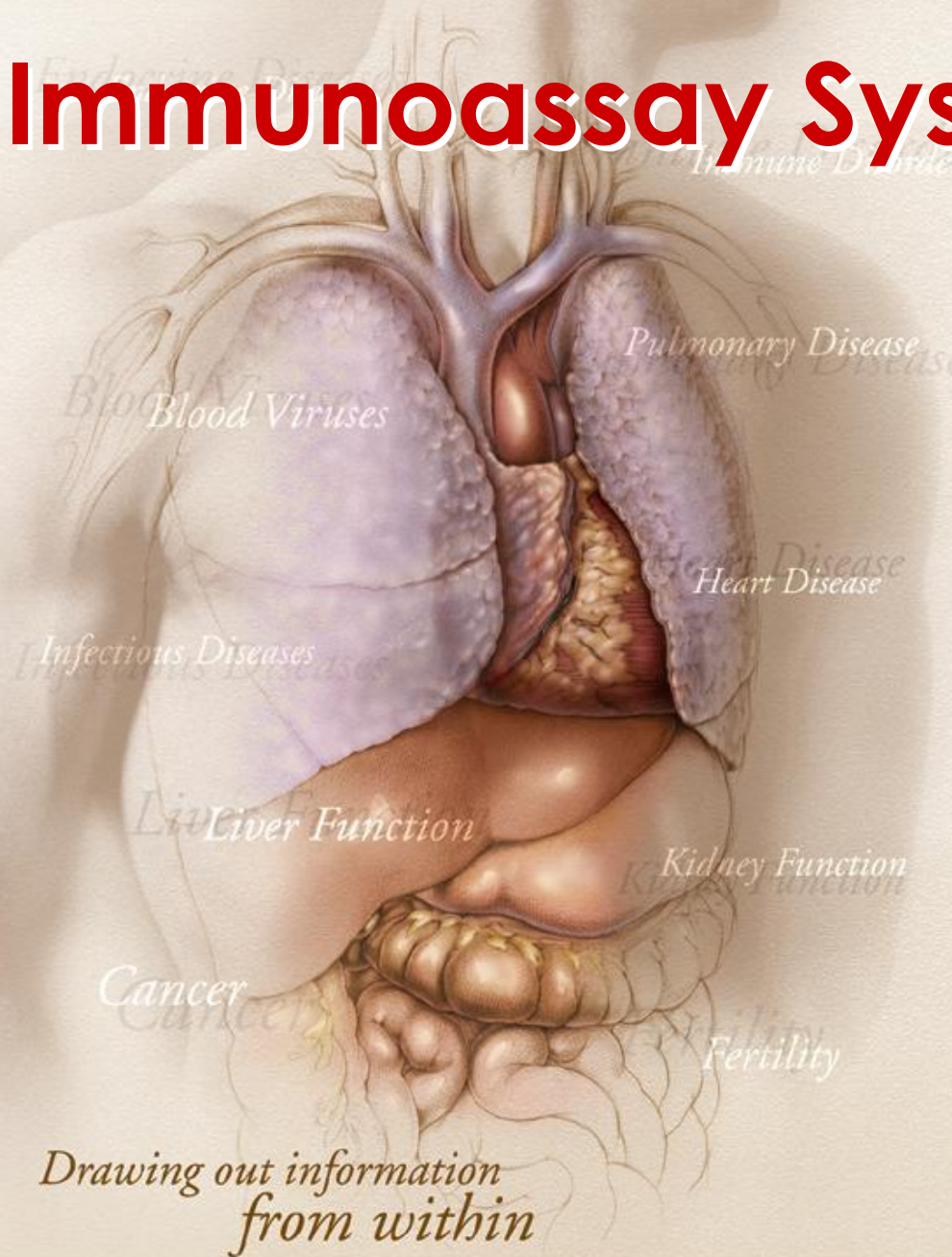


Immunoassay Systems



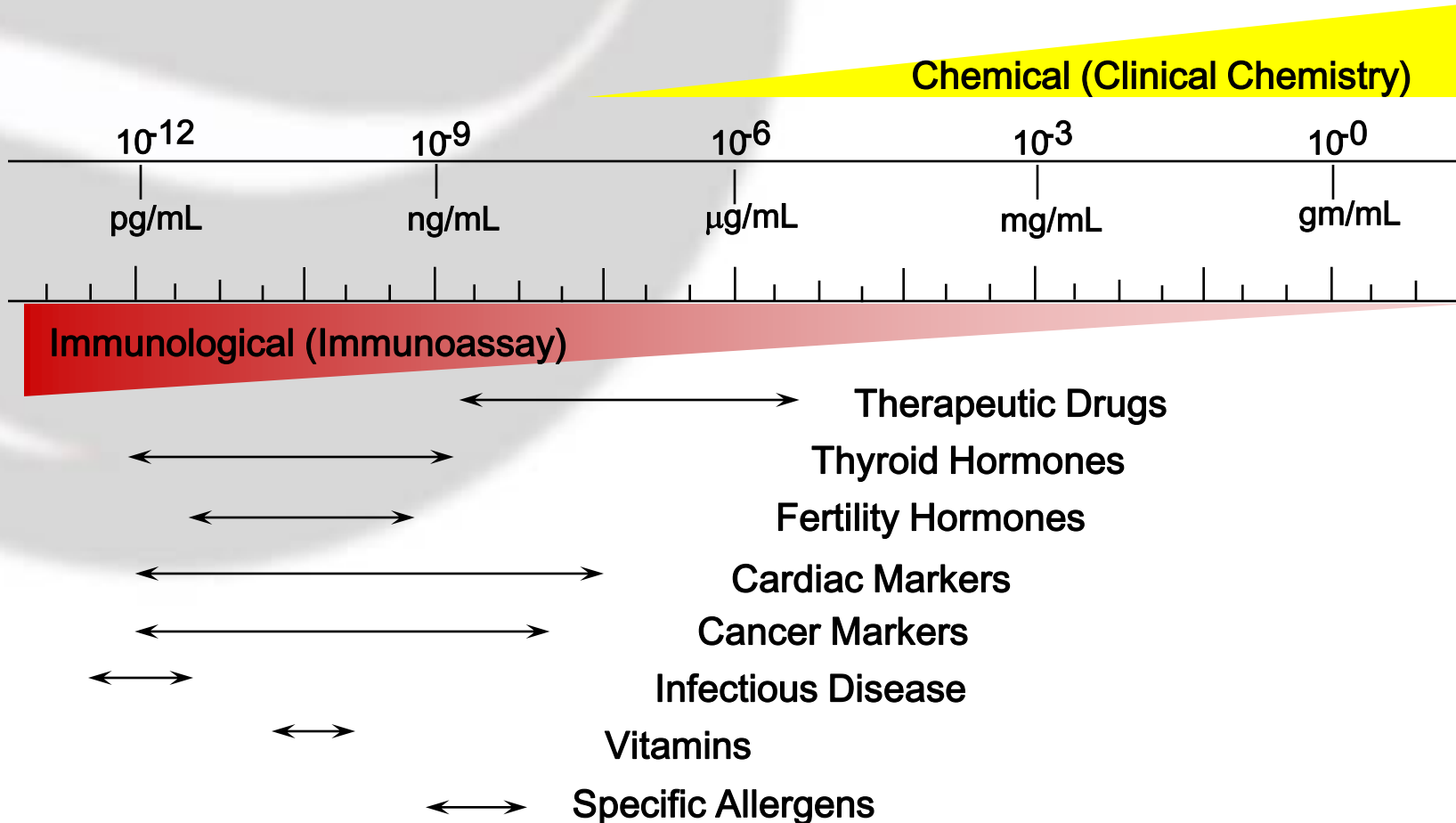
Access-2

*Drawing out information
from within*

History

- **1967 - Kallestad Diagnostics**
 - Focused on high quality immunoassay reagents
 - Entered instrumentation market in 1987
- **1989 - Purchased by Sanofi Diagnostics Pasteur**
 - Acquired Genetic Systems Corp in 1990
- **1997 - Access product line (Chaska site) purchased by Beckman Instruments**

Access is an Immunoassay System



Chemiluminescence

➤ Advantages:

- Low Detection Limits - Greater Sensitivity
- Low Background Interference
- Wide Linear Dynamic Range
- Stable Conjugate
- Relatively Non-toxic
- Electronic Amplification - PMT 10^6
- No need for wavelength selectors

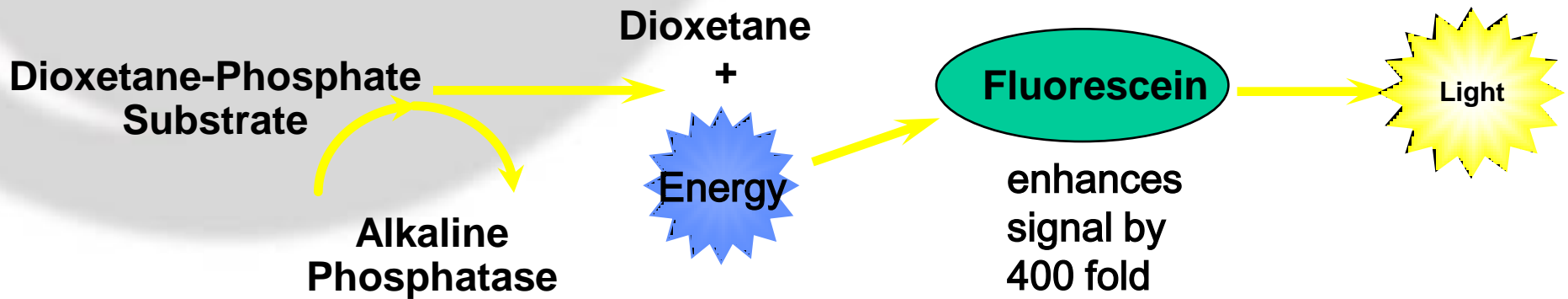
Chemiluminescence

<u>Type of Label</u>	<u>Examples of Labels</u>	<u>Detection limits</u>
➤ Radio isotopes	^3H ^{125}I	5×10^{-15} mole 5×10^{-17} mole
➤ Enzymes	Beta-galactosidase Horseradish peroxidase Alkaline phosphatase	1.5×10^{-16} mole 3×10^{-16} mole 5×10^{-17} mole
➤ Bioluminescence	Firefly luciferin/luciferase Enzyme enhanced Firefly luciferin/luciferase	5.6×10^{-16} photons/min/mg 10^{-19} mole 10^{-19} mole
➤ Fluorescence	Europium(III) ion Fluorescein	2×10^{-17} mole 10^{-13} mole
➤ Chemiluminescence	Peroxidase/luminol/enhancer Glucose-6-phosphate dehydrogenase peroxydase/ isoluminol Dioxetanes	$< 10^{-15}$ mole 10^{-18} mole 10^{-21} mole

Chemiluminescence Dioxetane

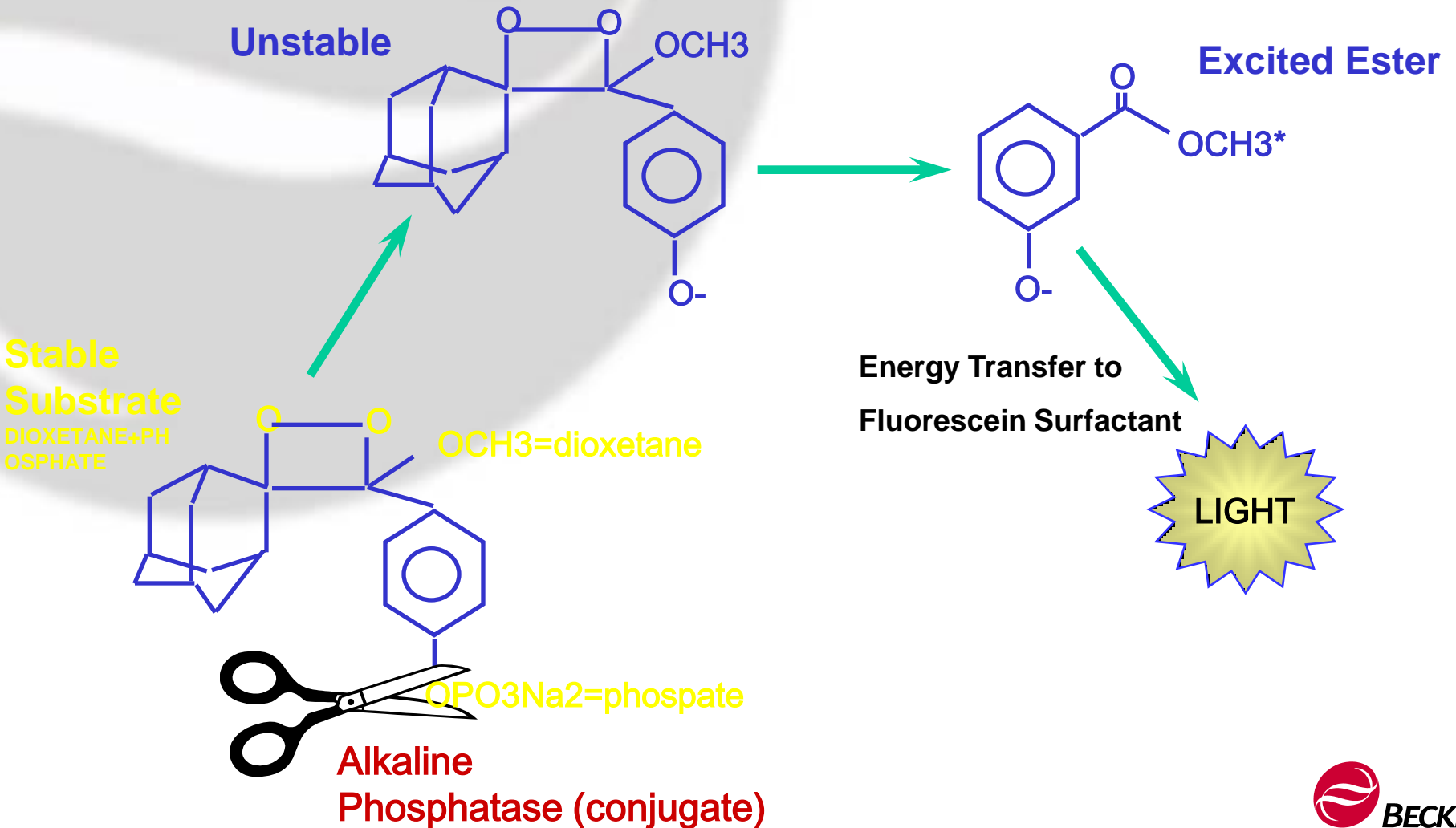
➤ Enzymatic reaction :

- **Enzyme** : Alkaline Phosphatase (Conjugate)
- **Substrate** : Dioxetane-Phosphate



(Lumi-Phos 530™) = Substrate + Fluorescein

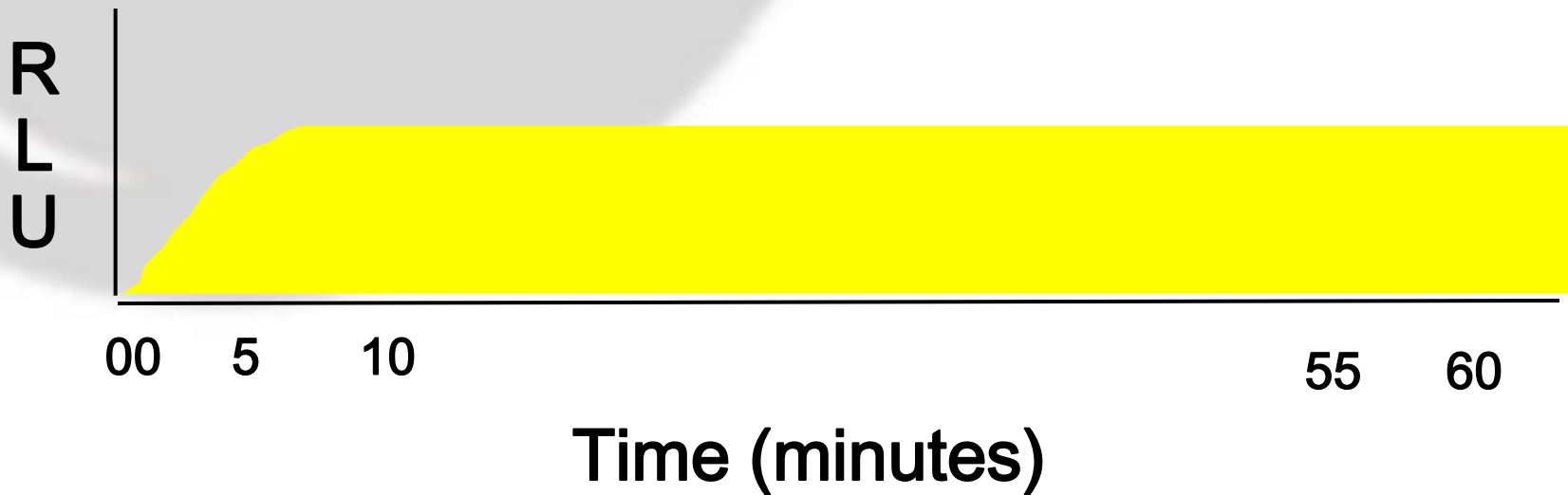
Chemiluminescence Dioxetane



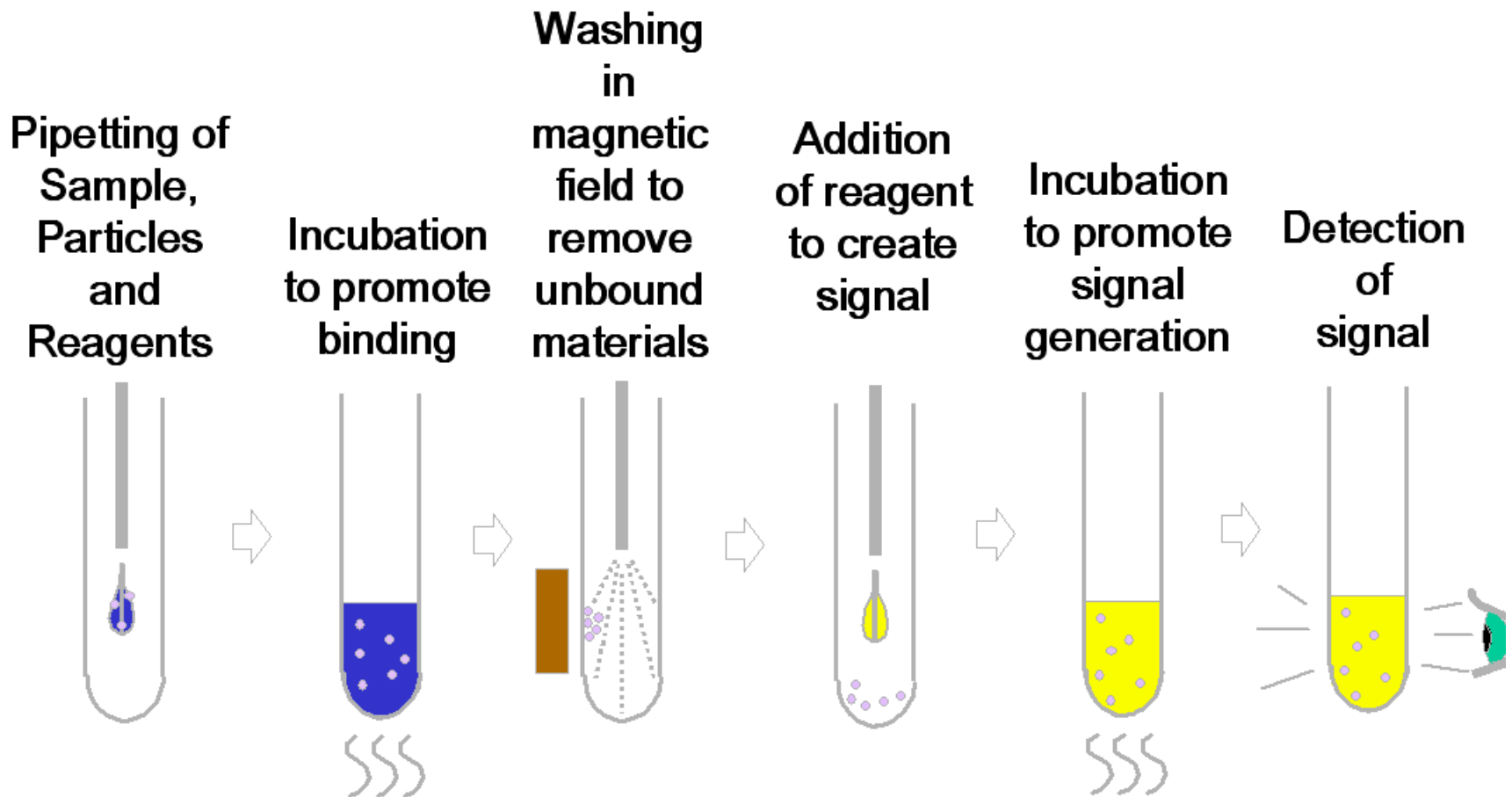
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Chemiluminescence Dioxetane

- **Stable glow produced**
 - Temperature and pH dependent

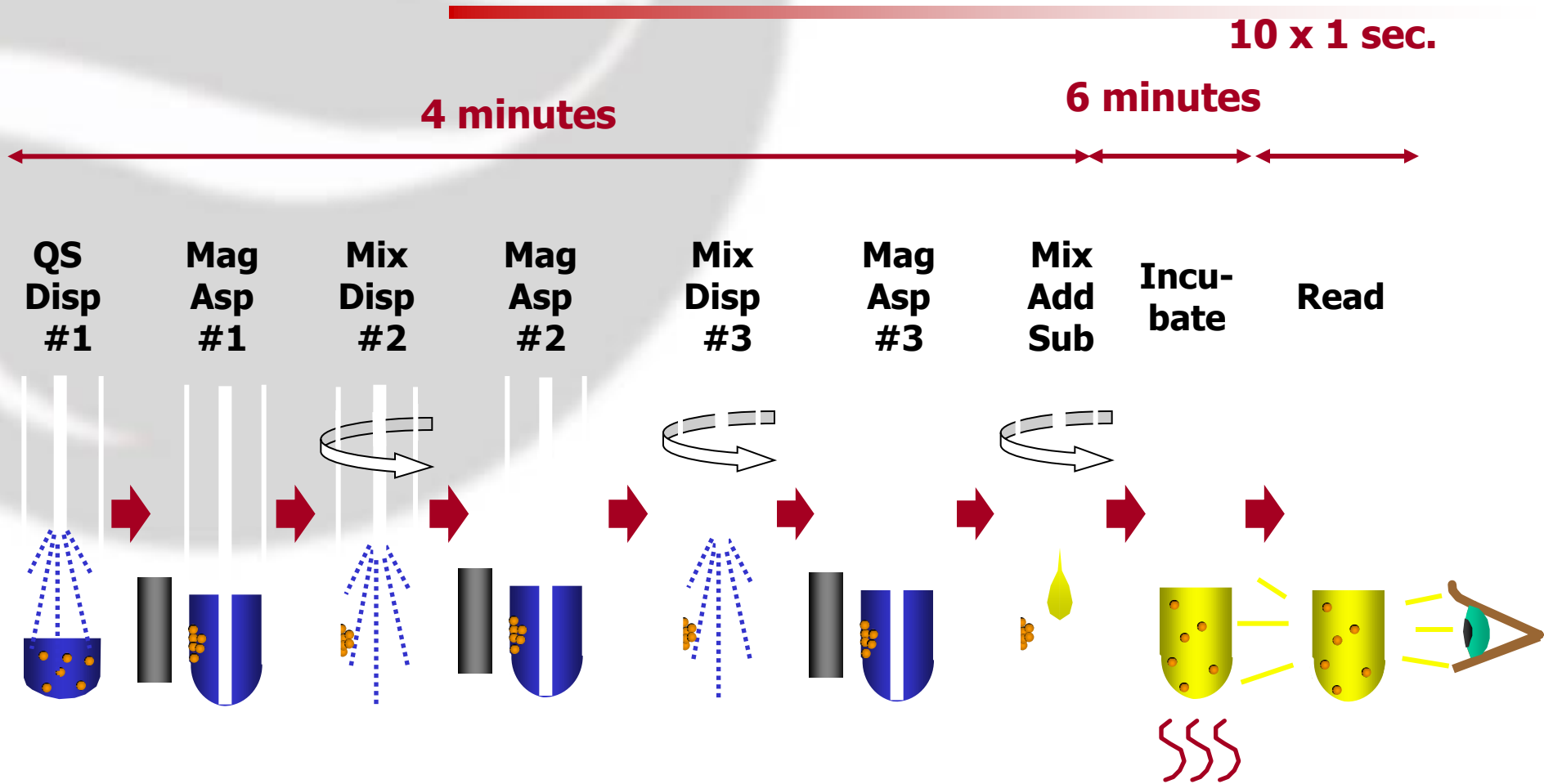


Access-2 Test Process



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Access-2 Wash Process



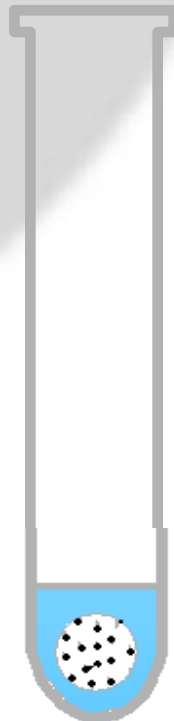
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Evolution of Techniques

Coated
Tube



Coated
Bead



Coated
Microwell



Coated
Particles



Paramagnetic Particles (PMP)

- **Antibody coated**
 - Suspended evenly throughout reaction mixture
 - Analyte is captured on surface of particle
 - Particles are washed in a magnetic field
 - Particles are resuspended easily
- **Advantages**
 - Rapid reaction kinetics
 - Low sample volumes required
 - Pipetable, thus easily automatable

Paramagnetic Particles (PMP)

Advantages

- Variety of sizes and functional groups
- Shelf life > 1 year at 2 - 8°C
- Suspended in solution easier for coating
- Exceptional Assay performance:
 - Large surface to volume ratio
 - Ability to suspend them with target analyte
 - Liquid phase kinetics
 - Fast assay equilibrium
 - Small sample volumes

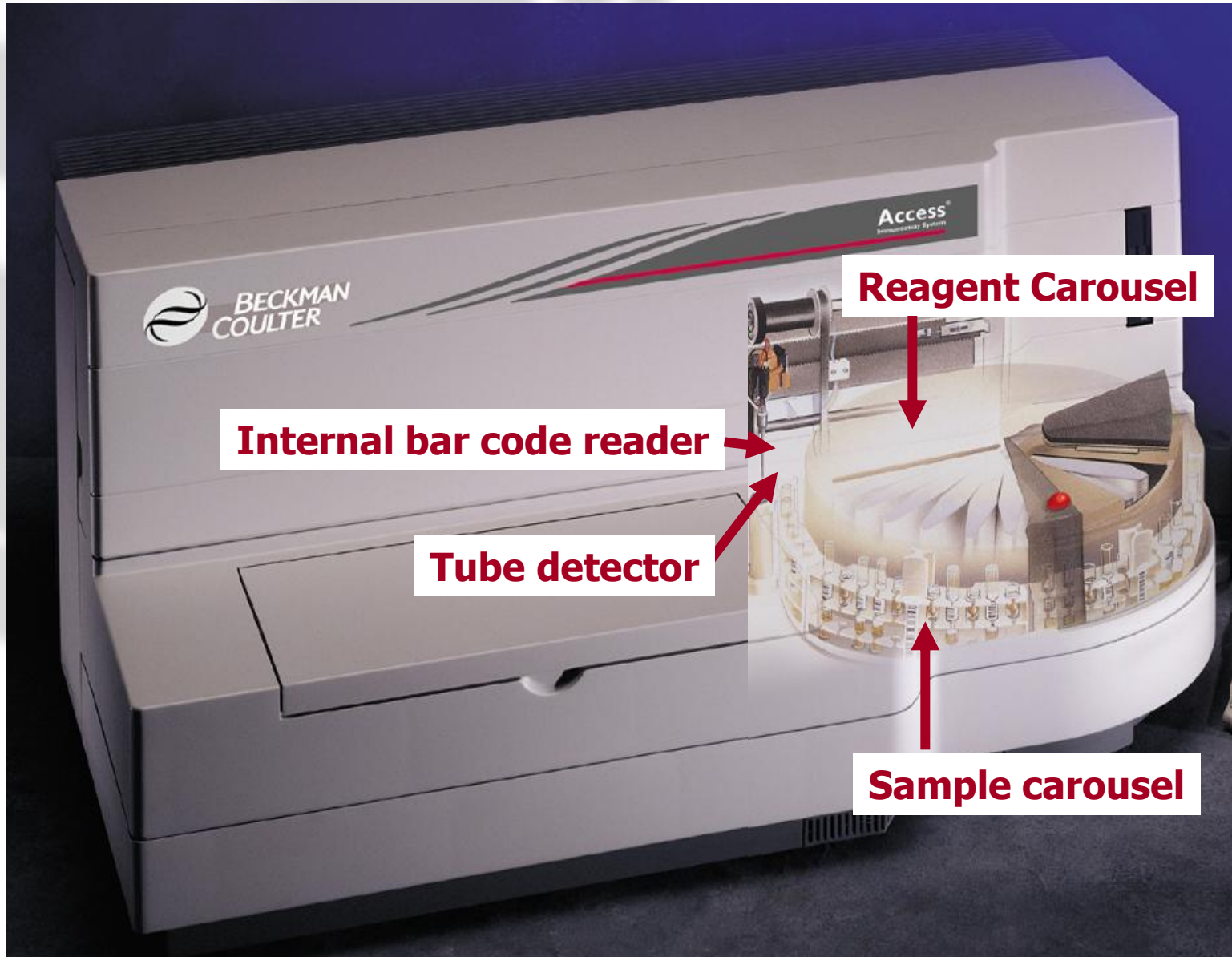
Modular Components



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Carousel Module



Internal bar code reader

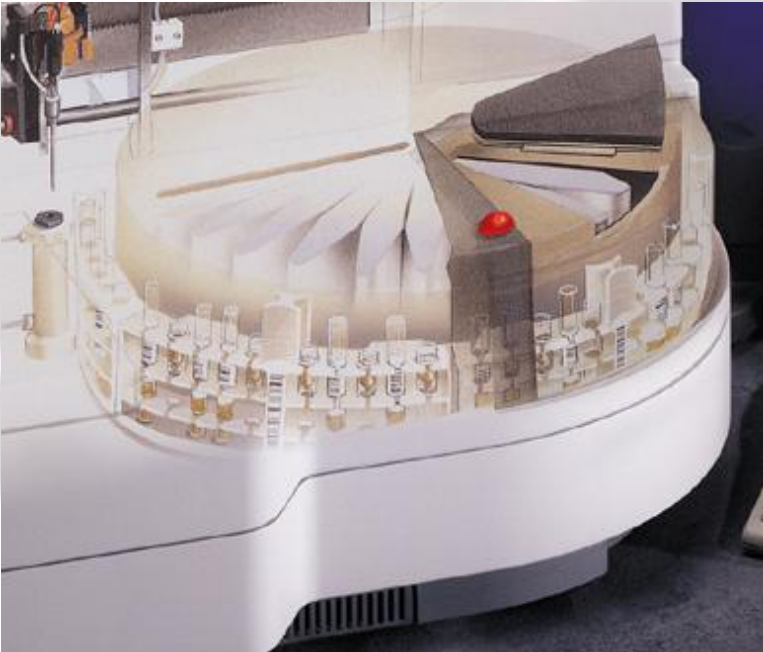
Tube detector

Reagent Carousel

Sample carousel

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Carousel Module



- On Board capacity of **24 Reagent Packs**
- Reagent packs are in refrigerated compartment.
- **60 Samples** capacity with continuous load and continuous STAT load

Carousel Module:

The Reagent Pack

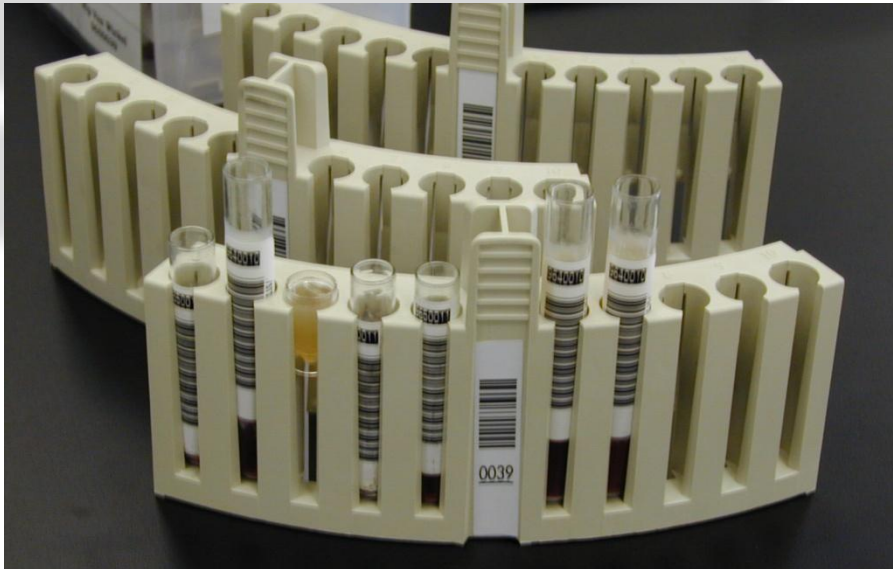


- The Access Reagent Pack is a 5 compartment pack with an elastomeric seal
- Average on board stability of **28 days**
- Reagent usage tracked by software:
 - Pre-run warning for supply depletion or expiration
- Superior **Calibration Curve stability**

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Carousel Module:

The Sample Rack/Tray



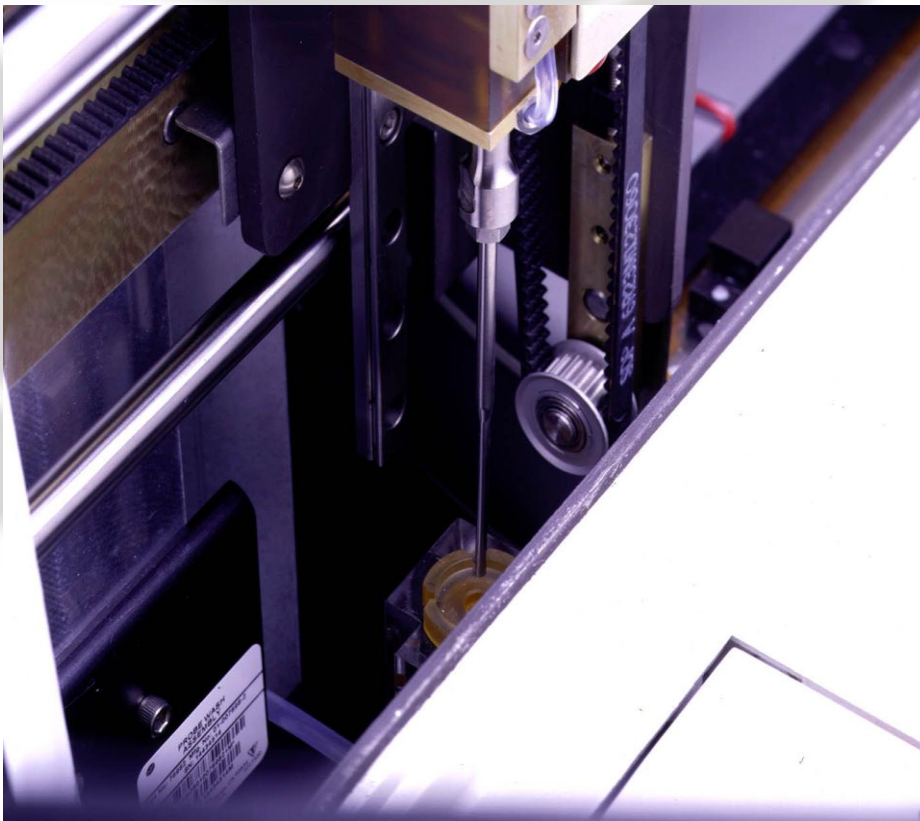
- **60 Samples** capacity with continuous load and continuous STAT load
- **Primary bar coded tubes** loaded through host query or broadcast download
- **Continuous STAT** access

Main Pipettor Module



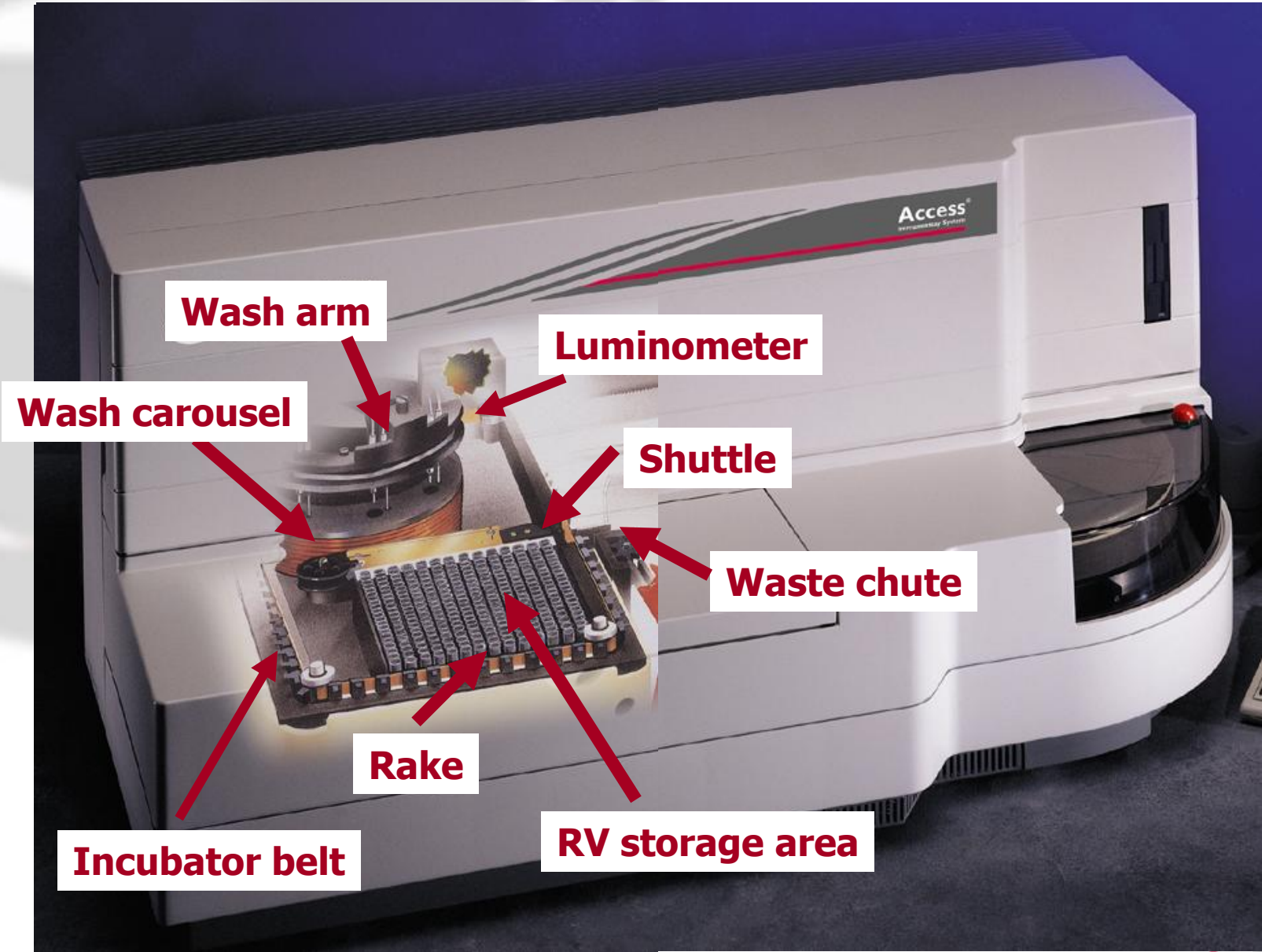
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Main Pipettor Module



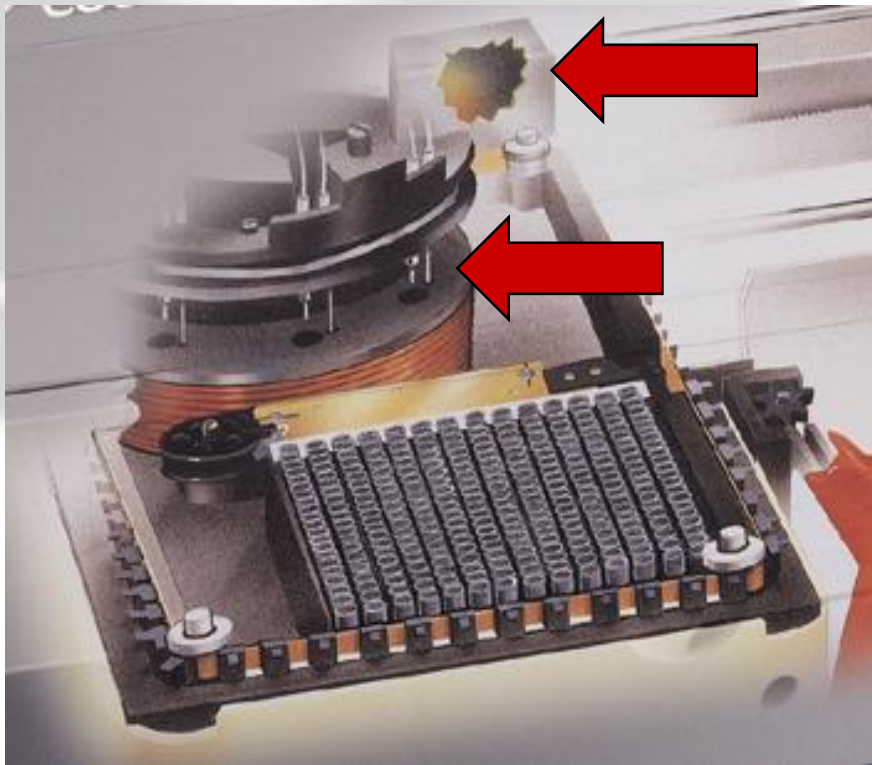
- Titanium Primary Pipettor with multi-tasking capabilities
- Aspirate, Dispense, Level Sense, and Mix
- **Ultrasonic mixing** of Paramagnetic Particles and Reactants

Analytical Module



Analytical Module:

Wash/Read



- Paramagnetic Particle Separation
- 3 Washes prior to substrate addition
- **Continuous Glow Chemiluminescence**

Analytical Module

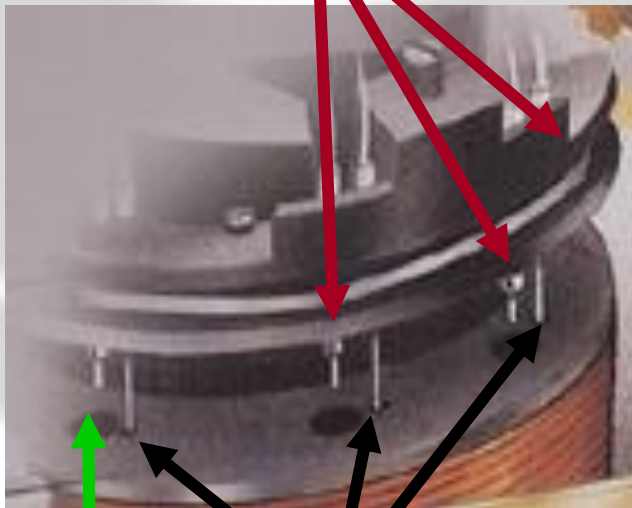
➤ Wash arm

- 3 dispense probes
- 3 aspirate probes
- Substrate probe

➤ Wash carousel

- Moves RVs through wash process, substrate incubation and signal reading

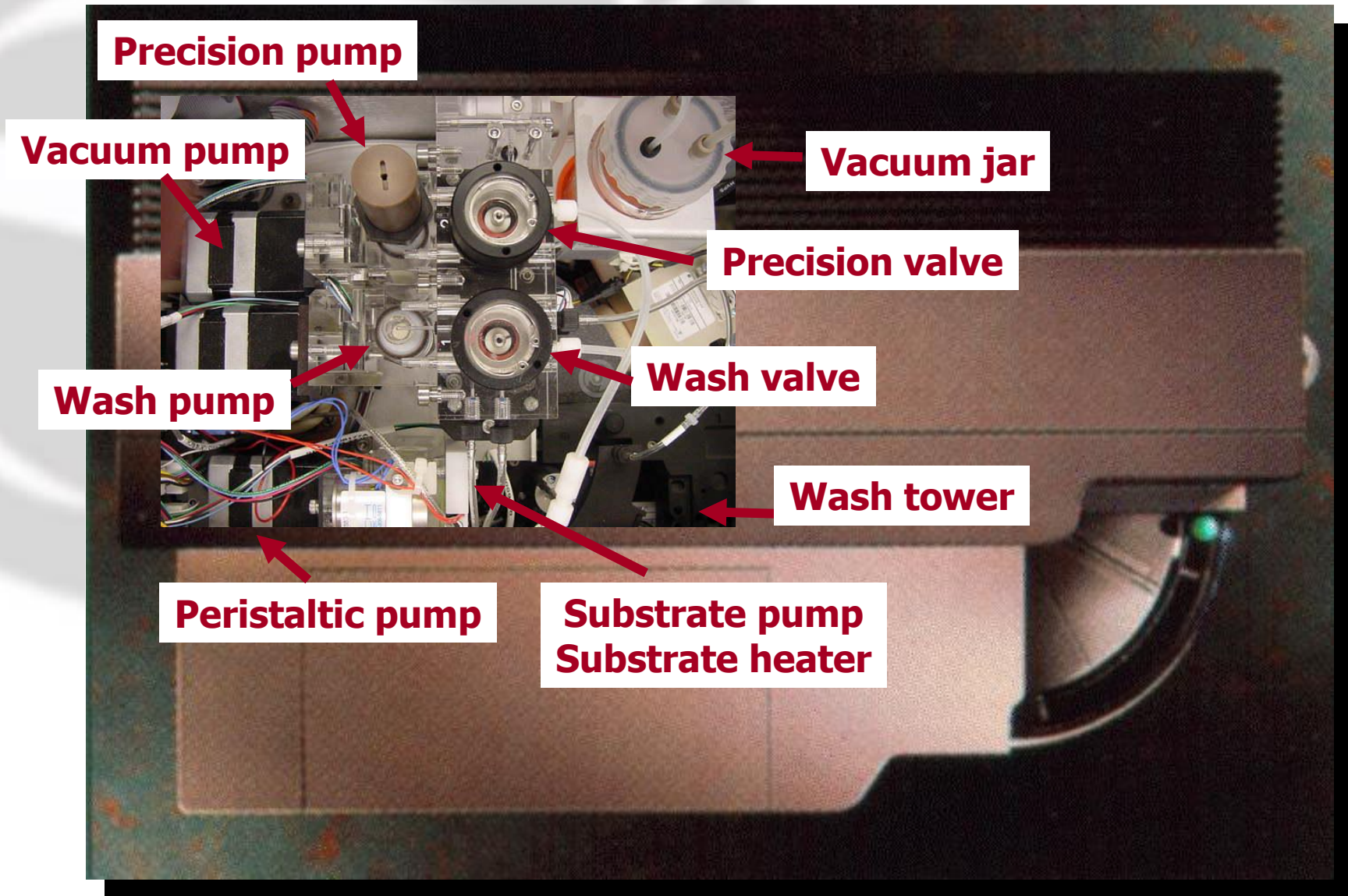
Dispense probes



Aspirate probes

Substrate probe

Fluidics Module



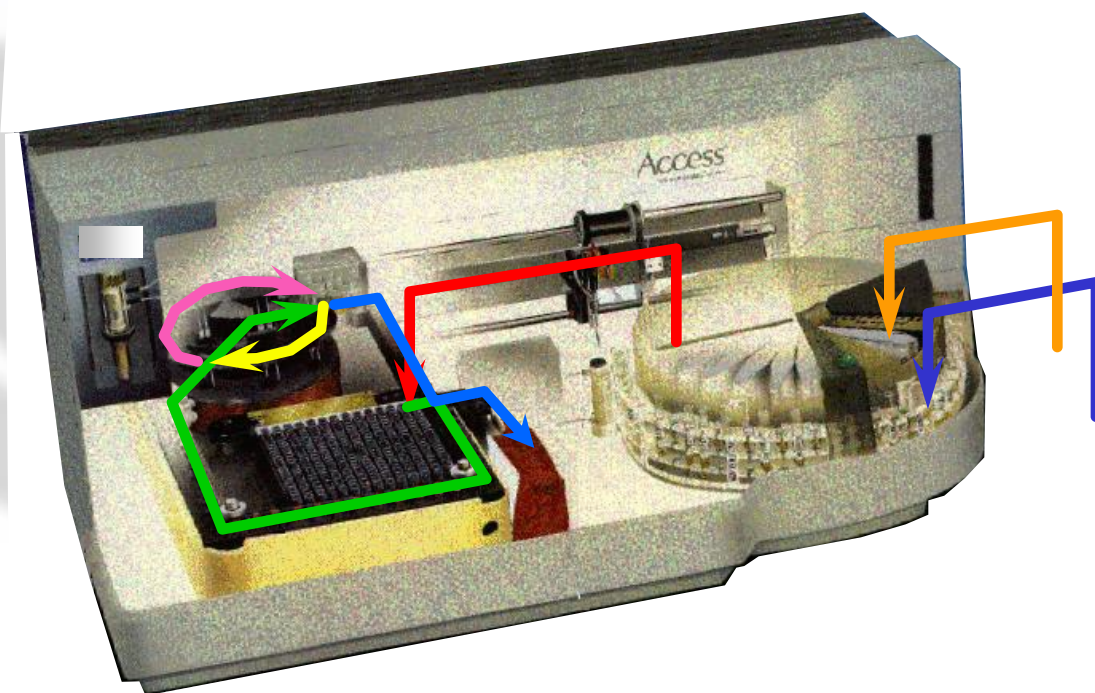
Electronics Module



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BECKMAN
COULTER

Access Process flow



- Samples loaded
- Supplies loaded
- Pipettor transfers fluids to reaction vessel
- Vessel incubates
- Vessel is washed
- Vessel incubates and is read
- Vessel is sent to waste

Peripherals



➤ Access 2

- Flat panel touch screen
 - Monitor arm
- Keyboard
- Printer
- Bar code wand
 - plus
- External computer
- Mouse
- Hub

Summary



- The system performs **100 tests per hour**.
- **True Continuous Random** Access that is any assay or combination of assays can be run on the system at same time.
- ACCESS-2 has continuous loading platform giving the flexibility to **continuously add samples** without disturbing the routine run or putting the system into PAUSE mode.
- **24 Reagents on-board** in a **refrigerated compartment**. No need to remove the reagents from the system.
- The reagent vials caps close automatically, no reagent evaporation issues.
- ACCESS-2 has **ability to be integrated with the Chemistry Analyzer** and Lab Automation Instruments.
- **Primary Tube** sampling, no need to purchase sample cups.
- **Bar Code** Reader for Reagents and Samples.
- **Automatic Rerun** Facility for out of range results.
- Automatic Obstruction Detection (**Clot Detection**) to ensure every sample quality.
- Easy to use, **Touch Screen Operation**, on line step by step operator guidance.
- **Automated Operation**, No manual loading of sample cup holder and test units etc...