PD233: Design of Biomedical Devices and Systems

(Lecture-11 In-vitro Diagnostics)

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Course Website:
http://cpdm.iisc.ac.in/utsaah/courses/

In-vitro diagnostics

Test that can detect disease, condition, or infections form analysis of sample (blood, urine or tissue taken from human body)

Examples:

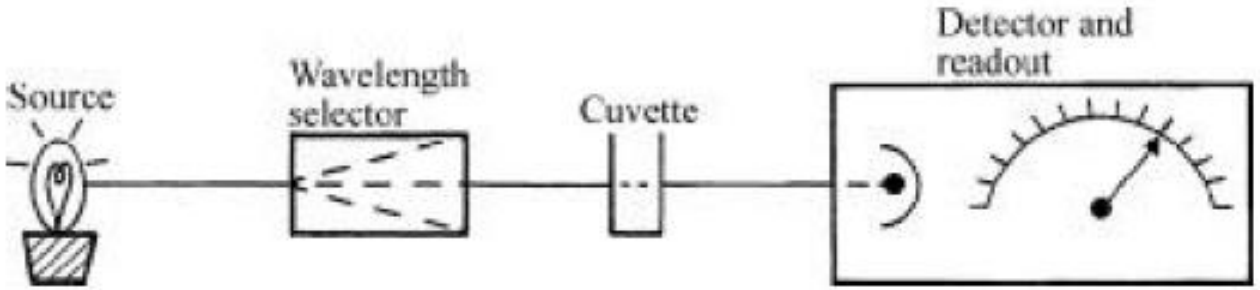
- Urine test strips
- Pregnancy tests
- Blood sugar monitoring systems
- Hepatitis or HIV tests
- Clinical Chemistry

Devices and accessories used are also regulated as medical device (all be it as a category of their own)

Devices for Self-use form a special category where they are intended by manufacturer to be used by a lay persons in home environment.

Spectrophotometer

Basic from of instrumentation in clinical laboratory



Block diagram of spectrophotometer (Webster Chap 11)

Substance of clinical interest has selective absorption or transmission of electromagnetic energy at different wavelength.

Types: UV (200 to 400nm), Visible (400 to 700) and near infrared (700 to 800)

Colorimeter which use single wavelength are members of spectrophotometer class.

Methods for wavelength selection

- Glass filters
- Prisms
- Diffraction gratings

Sample chamber (cuvette)

- Need to be transparent for wavelength of interest
- Should be able to manufacture reproducibly
- Absorption depends on the length of optical path

Beer-Lambert's Law

$$P = P_o \, 10^{-aLC}$$

P_o= Input power

P = Output power

a = absorptivity (extinction coefficient)

L = length of optical path

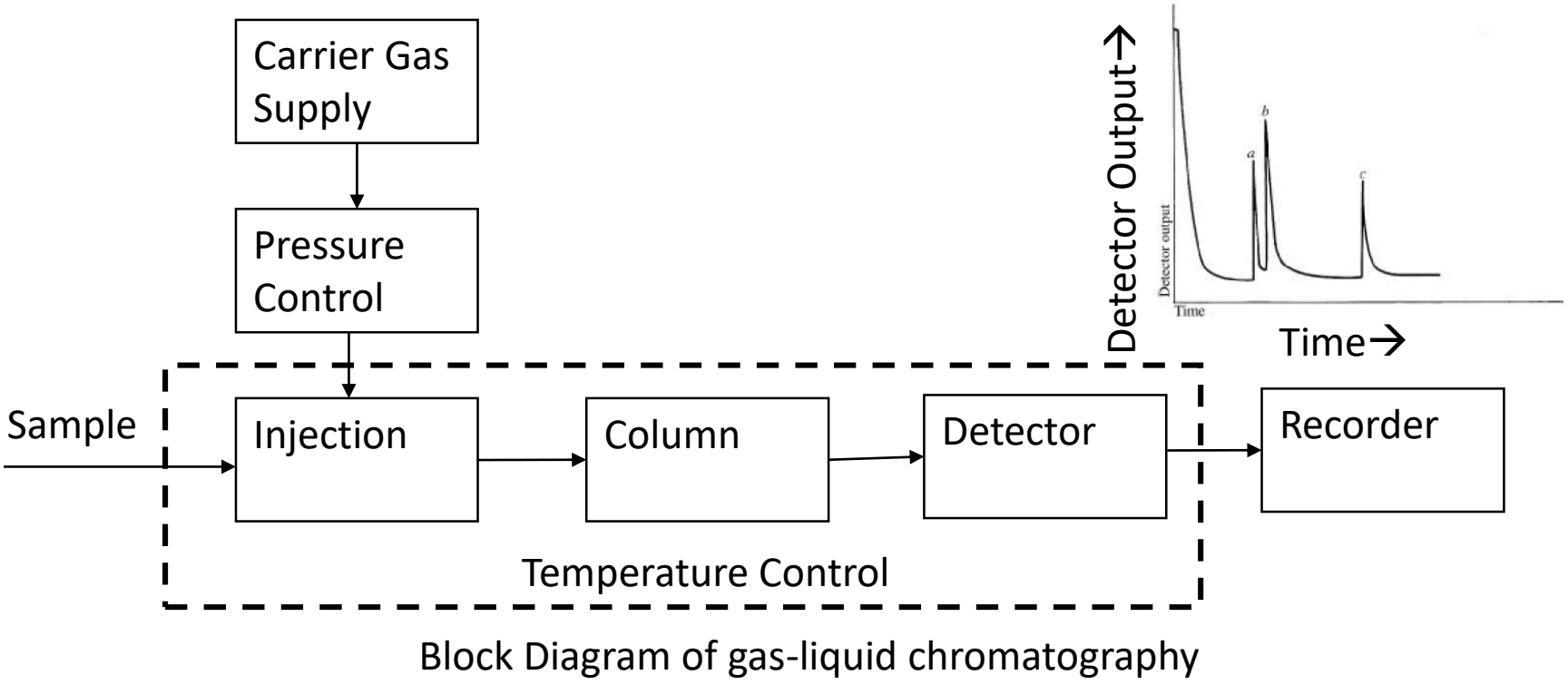
C = concentration of absorbing substance

$$\text{Absorbance } A = \log_{10}(P_0/P) = aCL$$

Chromatography

Method of separating substance into components parts.

Difference in rate of movement of components of ***mobile phase***, caused by interactions with the ***stationary phase***.

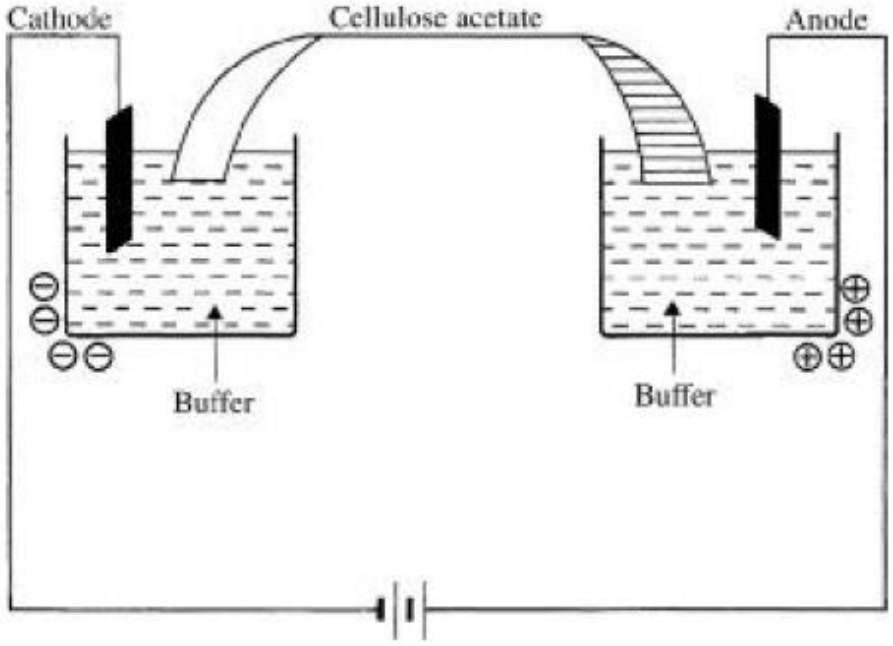


Block Diagram of gas-liquid chromatography

Electrophoresis

Migration of charged species under influence of electric field/potential difference

Used for analysis of blood plasma, urine, CSF



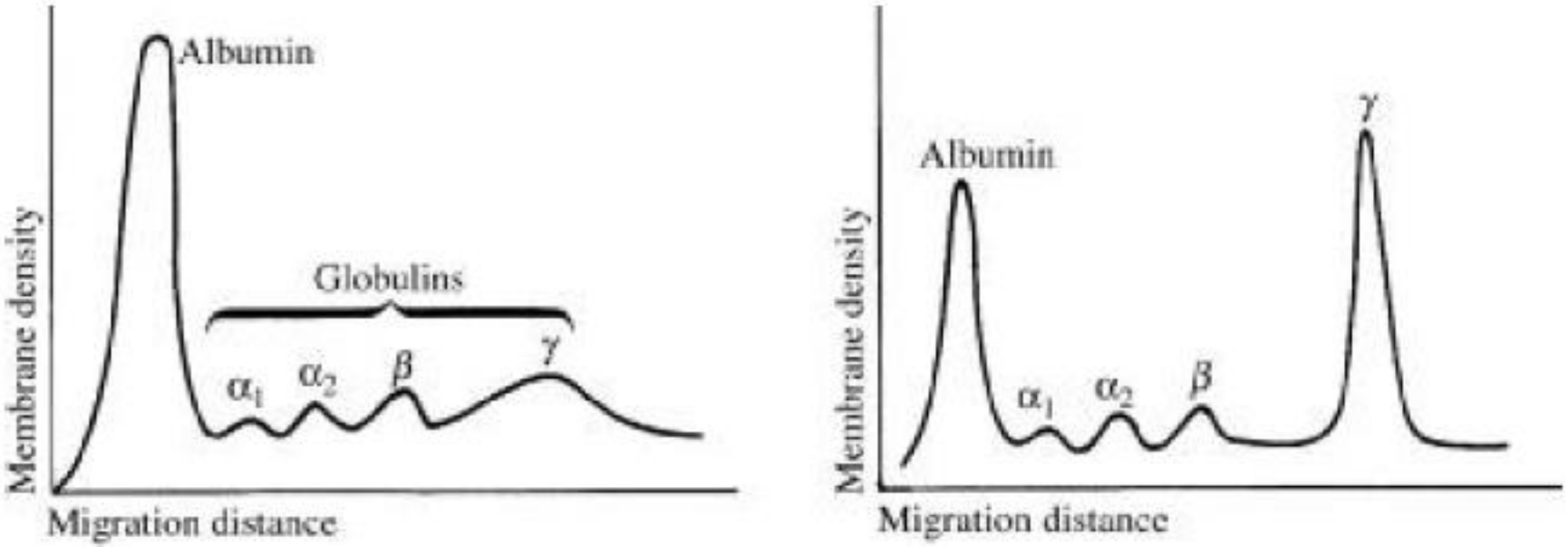
Factors effecting migration

- Magnitude of charge
- Ionic strength of buffer,
- Temperature
- Time
- Type of support media

Detection is based on light transmission after ‘fixing’ the gel

Electrophoresis

Example clinical test



Normal vs over production of gamma globulin
(Figure Webster Chapter 11)

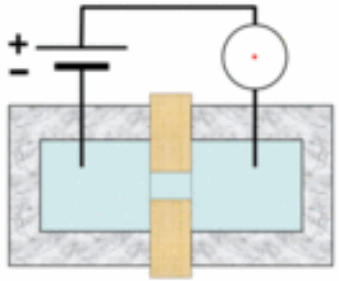
Haematology

Study of Blood

- Red Blood Cells (RBC) (4.6-6.2 x 10^6/µl in adult male, 4.2-5.4x10^6/µl in adult female)
- White Blood Cells (WBC) (4,500- 11,000 /µl)
- Platelets 150,000 -400,000/µl
- Haematocrit (ratio of volume of all of the above to total volume of blood)
- Haemoglobin (O_2 carrying protein) measured in g/dl (13.5- 18 for adult male, 12-16 for adult female)

Total Blood Analysis

- Microscopy (manual or automated)
- Flow cytometer
  - Coulter-counter (based on resistance change)



  - Light based deflection method
  - Fluorescence activated cell sorter (FACS)- also does cell sorting

Blood Glucose Analysis

$$\text{Glucose} + O_2 \xrightarrow{\text{[Glucose Oxidase]}} \text{Gluconic acid} + H_2O_2$$

In portable blood glucose meters Glucose Oxidase is attached to strip and interfaced with electrodes.

When interfaced with the reading machine, reaction induces current in the electrodes.

Device needs to calibrated interpret blood glucose level from the sensed current.

Enzyme-Linked Immunosorbent Assay (ELISA)

Used of measuring concentration of antibodies, based on ***specific enzymatic reaction*** and colorimeter measurement

Still mostly done in wet labs -

- HIV, which causes AIDS
- Lyme disease
- pernicious anemia
- Rocky Mountain spotted fever (RMSF)
- rotavirus
- squamous cell carcinoma
- syphilis
- toxoplasmosis
- varicella-zoster virus, which causes chicken pox and shingles

Pathshodh – IISc Startup

Prof. Navkant Bhat and ex-PhD student from CeNSE

Jana Care

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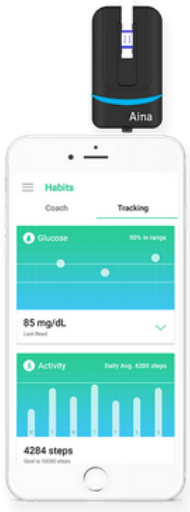
Diabetes Heart Failure Technology Publications About Us



Paper-based tests

First, we develop paper-based test strips for biomarkers that can be useful for screening or home monitoring.

Smartphone-based diagnostics

Next, we turn your smartphone into a diagnostic platform using the Aina device to read paper strips of all kinds, enabling affordable testing anytime, anywhere.

Digital behavioral coaching

Finally, we use biomarker data from Aina to deliver personalized care plans to patients through our digital coaching program called Habits.

Shetty) to build a smartphone app for health workers to screen for Oral Cancer and Cardiovascular Disease in remote rural communities in India. What started off as a side project during graduate school, became one of the largest chronic disease screening programs in the world and eventually led to Jana Care.