Examination Sets

The sample provides incomplete information, which must be integrated with

- **Biological variability**
- **Patient's clinical history**

Having anamnestic data helps to understand abnormal results better

Causes of biological variability

- Sex
- Etnic group
- Age
- Body mass
- Circadian rhythms
- Change of season
- Menstrual cycle
- Pregnancy

- Diet
- Food consumption
- Posture
- Stress
- State of hydratation
- Physical tiredness
- Altitude

Glycemia

Glycemia is the concentration of glucose in the blood

It is measured using blood from a vein or capillary

It should be measured after 8 hours of no food consumption

Normal result: 70-110 mg/dL

Hypoglycemia

Plasmatic glycemia is under 45 mg/dL

After fasting

Excess of insulin production

Abnormal anti-insulin hormones (Addison's disease, Hypothyroidism)

Medication (anti-diabetics)

Particular situations (pregnancy, malnutrition, haepathic disease)

Hyperglycemia and diabetes clinical classification

- Diabetes mellitus type 1
- Immunomediate
- Young onset with acute symptoms
- LADA or Diabetes 1.5 (Latent Autoimmune Diabetes of Adults) over 35 years

- Diabetes mellitus type 2
- Is the most common form, representing 90-95% of all forms
- Insulin resistence
- Medication induced
- Infection induced
- Pregnancy
- Pancreatic disorders

Criteria for the diagnosis of diabetes mellitus

- **Symptoms of diabetes (poliuria, polidipsia, loss of weight) associated to incidental finding of blood sugar ≥200 mg/dL**
- **Fasting glucose (at least 8 hours) ≥126 mg/dL**
- **Post charge of glucose (WHO), glycemia ≥ 200 mg/dL after charge of 75 g of glucose**

1)To make a diagnosis of diabetes is necessary to have at least one of three criteria

2)One of three criteria should be confirmed in a subsequent day

Category of patients with abnormal glucose homeostasis

- **Fasting glucose ≥ 110 mg/dL=abnormal**
- **Fasting glucose ≥126 mg/dL=diagnosis of diabetes**

Laboratory parameters according to American Diabetes Association

- **Pre diabetes**

-fasting glycemia 100 - 125 mg/dl

-glycemia after OGTT(oral glucose tolerance test) 140 - 199 mg/dl.

-level of haemoglobin glicata 5.7 – 6.4%

- **Diabetes**

-fasting glycemia over 126 mg/dl

-glycemia after OGTT over 200 mg/dl

-level of haemoglobin glicata over 6.5%

THE JOURNAL OF CLINICAL AND APPLIED RESEARCH AND EDUCATION

VOLUME 40 | SUPPLEMENT 1

Diabetes Care®

WWW.DIABETES.ORG/DIABETESCARE

JANUARY 2017

Diabetes and laboratory analysis

- Glycemia***
- Glycosuria(unreliable)
- Glycosylated Haemoglobin (HbA1c) ***
- Microalbuminuria***
- Ketons***

Other criteria of ADA

- **Screening for the diagnosis of diabetes and pre-diabetes should be accomplished in all adult subjects, even if they have no symptoms**
  - **Families of first-degree diabetics**
- **Women who have given birth to macrosomic fetuses or who have been diagnosed in the past with gestational diabetes**
- **Arterial hypertension with values equal to or greater than 140/90 mmHg or in hypertensive treatment**
- **Hdl cholesterol values below 35 mg / dl or triglycerides greater than 250 mg / dL**
- **Early detection of high glycemic values even though sporadic**
- **A history of cardiovascular disease**
- **Women With polycystic ovary syndrome**

Lipidic profile

Risk factors

Major cardiovascular risk factors *

- Cigarette smoke
- Hypertension
- High plasma cholesterol levels and LDL cholesterol
- Reduction of plasma HDL cholesterol levels
- Diabetes mellitus
- Old age

Other Risk Factors

- Obesity (abdominal)
- Physical inactivity
- Family history
- Ethnicity
- Psychosociological factors
- High triglycerides
- Fibrinogen and high PCR
- High Omocysteine
- Lipoprotein (a)

***Framingham Heart Study, American Heart Association, American College of Cardiology**

Adult Treatment Panel III*

Suggests determination of a complete lipid profile at fasting for at least 12 hours including:

Total cholesterol

LDL-cholesterol

HDL-cholesterol

Triglycerides

At least once every 5 years in all adults over the age of 20

*Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults

Table II.2–4. ATP III Classification of Total Cholesterol and LDL Cholesterol

Total Cholesterol (mg/dL)		LDL Cholesterol (mg/dL)	
		<100	Optimal
<200	Desirable	100–129	Near optimal/ above optimal
200–239	Borderline High	130–159	Borderline High
≥240	High	160–189	High
		≥190	Very High

Table II.3–2. ATP III Classification of HDL Cholesterol

Serum HDL Cholesterol (mg/dL)	
<40 mg/dL	Low HDL cholesterol
≥60 mg/dL	High HDL cholesterol

Table II.3–1. Classification of Serum Triglycerides

Triglyceride Category	ATP II Levels	ATP III Levels
Normal triglycerides	<200 mg/dL	<150 mg/dL
Borderline-high triglycerides	200–399 mg/dL	150–199 mg/dL
High triglycerides	400–1000 mg/dL	200–499 mg/dL
Very high triglycerides	>1000 mg/dL	≥500 mg/dL

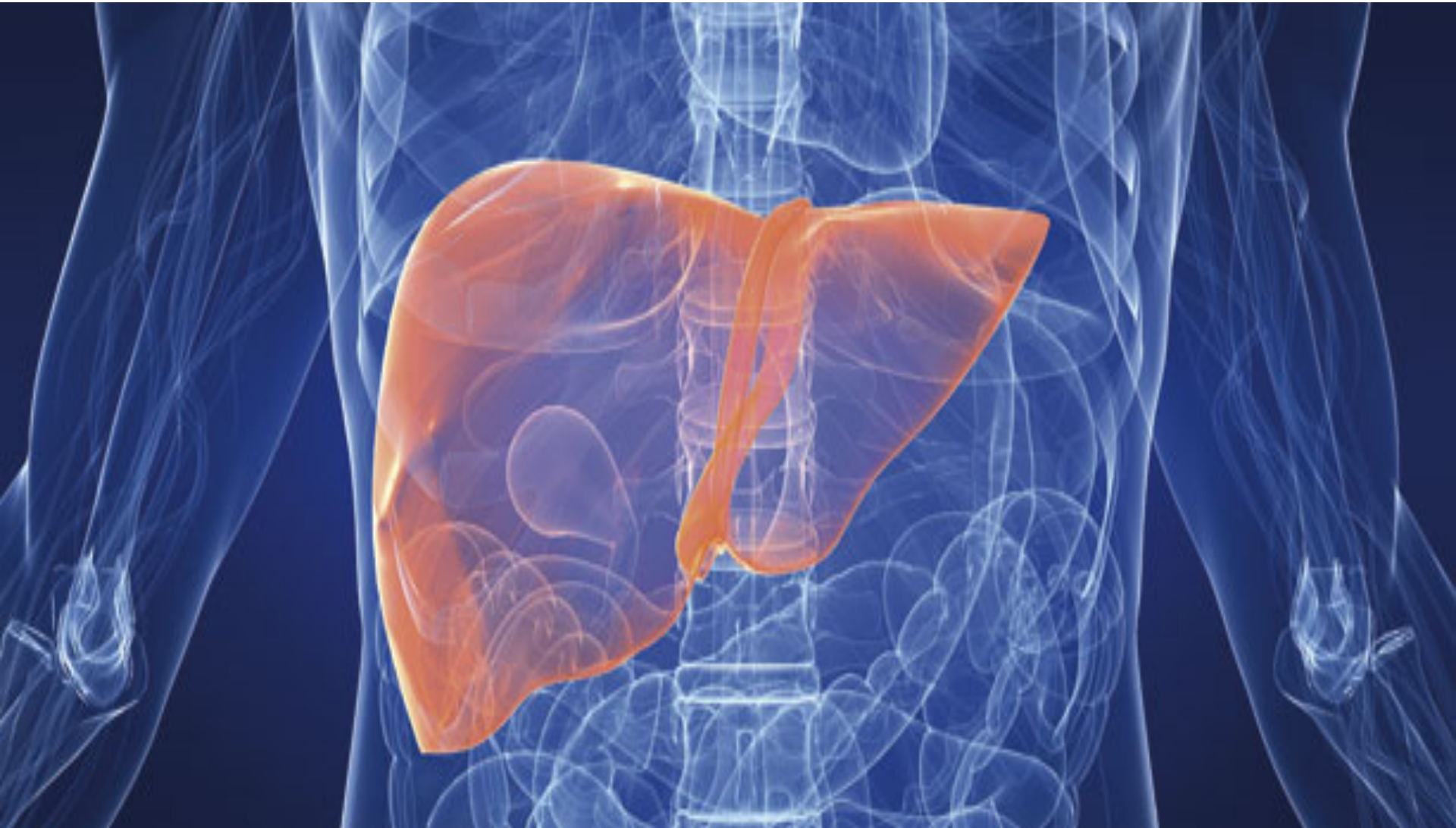
Parameters	Reference values
Total cholesterol	<200 mg/dl (desirable) 200-239 md/dl (borderline) >240 mg/dl (high)
HDL	>35 mg/dl
LDL	<130 mg/dl*
VLDL	≤30 mg/dl
Triglycerides	<150 mg/dl

* <100 mg / dl in patients with high cardiovascular risk,
<70 mg / dl in patients with very high cardiovascular risk.

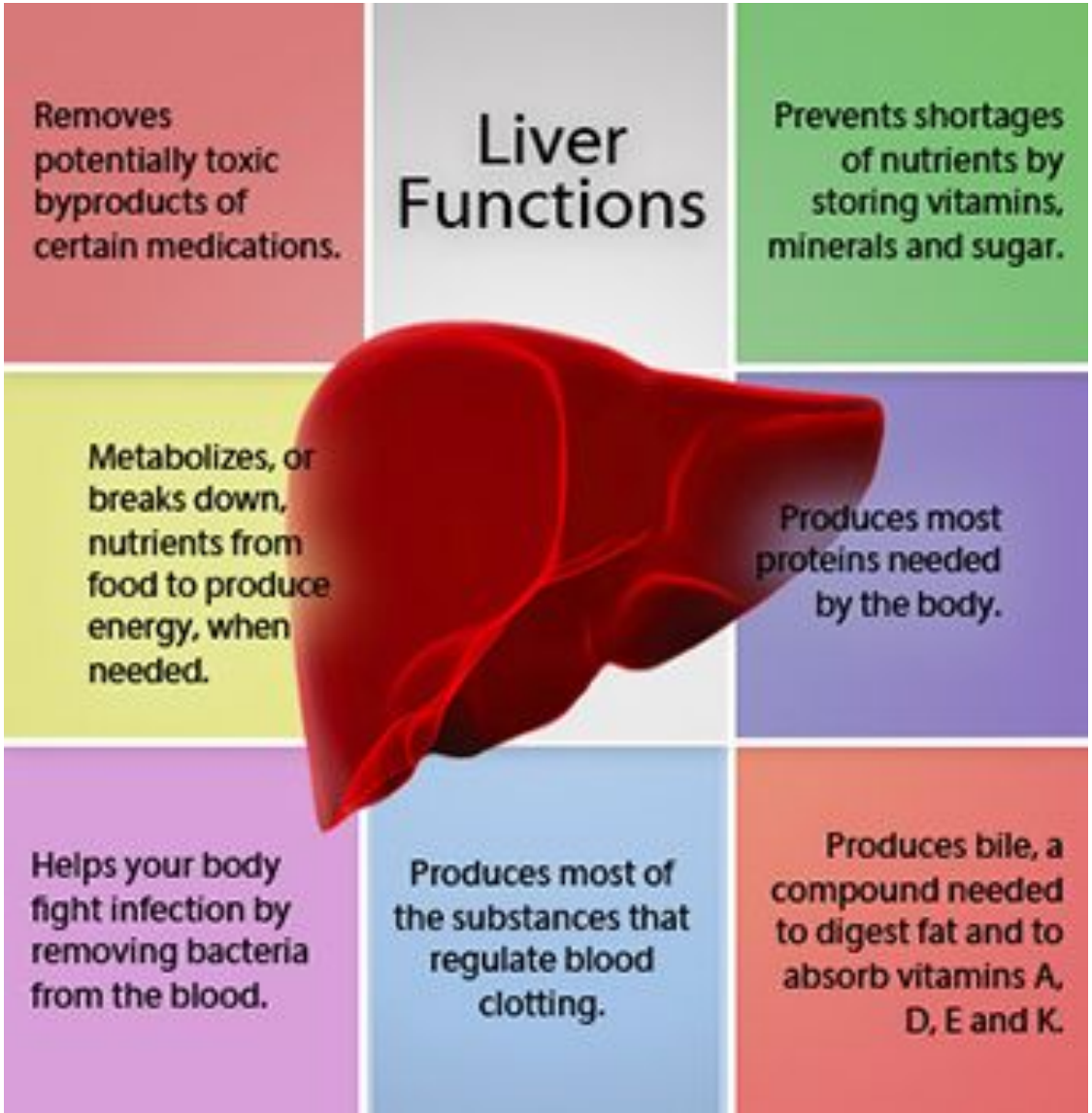
American College of Cardiology (ACC) e dell'American Heart Association (AHA)

Parameters	Reference values
Lipoprotein(a)	<30 mg/dL
Homocysteine	16-30µmol/L* 31-100µmol/L** >100µmol/L***
Fibrinogen	150-400 mg/dL
Protein C reactive (hsPCR)	<1 mg/L* 1-3 mg/L** >3 mg/L***

Hepatic profile



Liver function



Intoxication of the Liver

Induced by

Virus Infection
A, B, C, Delta Hepatitis
(acute & chronic states)

Toxic Metabolic Disorders
Hyperalimentation
(fat, carbohydrate, proteins & vitamins)
Diabetes Mellitus
Dyslipoproteinemias
Hyperthyroidism
Malnutrition
(Kwashiorkor, protein deficiency, metatrophy)

Chemical Noxae
Longterm Industrial Contact
Accidental Intake
Poisoning by Inhalation

Alcohol
Chronic Alcohol Abuse
Acute Intoxification

Drugs
Chronic Intake
Acute Intoxification

Decreased Enzyme Activity

Insufficient Hepatic Metabolism

Reduced Detoxification

Cell Necrosis/Fatty Degeneration/Fibrogenesis

Functional tests

Cytolysis tests

- AST or GOT: 0-37 U / l (oxalacetic glutamic transaminase)
- ALT or GPT: 0-41 U / l (pyruvic glutamate transaminase)
- LDH: 0-480 U / l
- LDH-1: heart, red blood cells, kidneys, germ cells
- LDH-2: heart, red blood cells, kidneys (less than LDH-1)
- LDH-3: lungs and other tissues
- LDH-4: white blood cells, lymph nodes, muscles, liver
- LDH-5: liver, skeletal muscle

Excretion tests

Alkaline phosphatase: 30-130 U / L

- Hepatitis
- Chronic cholestasis
- Tumors

Gamma-glutamyltransferase (GGT): 0-50 U / l

- Pancreatic Diseases
- Hepatobiliary diseases
- Hepatic tumors
- Hepatic impairment
- Alcohol
- Myocardial infarction

Total bilirubin 0.3 and 1.0 mg / dL
It Is the catabolic product of EME

Indirect or Non-conjugated Form (Glycuronic Acid)

It is normally found in plasma and increases in hemolytic diseases

-Fasting

-S. Gilbert

-Increased emolysis

Direct or conjugated form (Glycuronic acid)

It is normally found in bile and increases in obstructive pathologies

-Colostatic epatopathy

-Pancreas Tumors

-Calculous bile duct

Renal analysis

- **Azotemia (VN: 10-50 mg / dL): measure the final product of protein metabolism. Excreted by the urinary tract. It is an index of renal function**
- **Causes of hyperazotemia: pre-renal, renal and post renal disease**
- **Creatinine (VN: 0.9-1.3 mg / dL): creatinine clearance corresponds to the volume of kidney filtration in the time unit. Renal Function Indicator. Increased creatinine always involves a defect of renal function**
- **Causes of creatinine increase: renal parenchyma, vascular, obstructive, degenerative and loss of functioning nephropathies**

Emergency

- Blood Gases, Ionized Calcium, Whole Blood glucose, Whole Blood Na, K, Whole Blood Hemoglobin, Prothrombin Time, PT (INR)
- Hematology, coagulation, chemistry tests
- All urine chemistries, lithium, kidney function

Pre operation and Post Operation Set

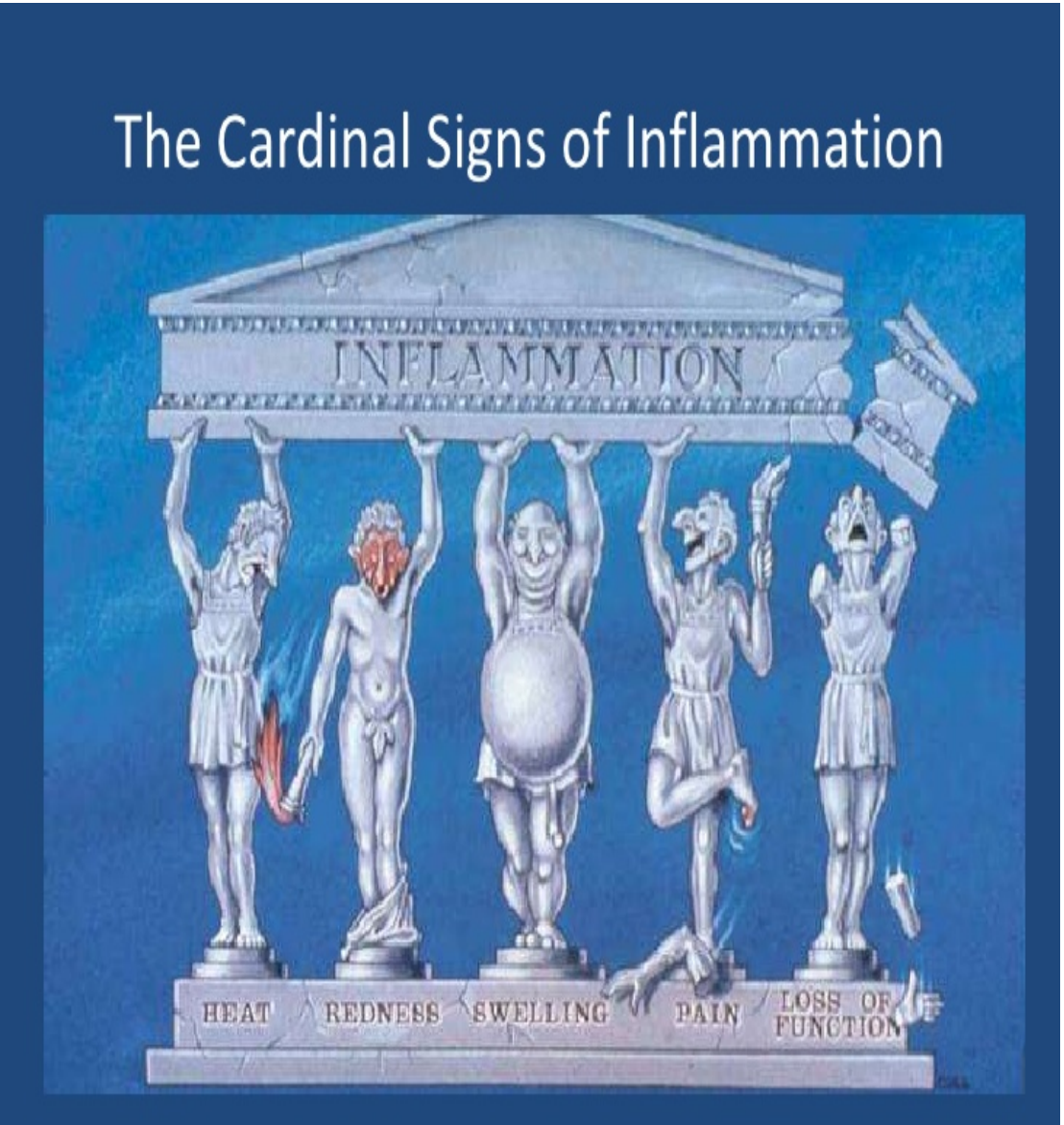
Basic

- Hb, HCT, WBC, RBC, PLT, blood group, PTT, thrombin time, fibrinogen, HBsAg, glucose, proteins, creatinine, bilirubin, cholesterol, Na, K, Cl, Ca
- Urine: protein, blood, glucose, nitrites, urobilinogen
- Endoscopy: coagulation factors

Enhanced

- ALT, amylase, creatine kinase, C-reactive protein, cholinesterase, urea, ionized calcium, albumin, pH, pCO2, pO2, HCO3sat
- Urine: creatinine, urea, Na, K, sediment
- Diabetic patient: glycemic profile

Inflammatory process activity determination set



Basic

- Erytrocyte sedimentation rate(ESR-VES), mucoproteins, fibrinogen, C-reactive protein

Enhanced

- Alpha-2-macroglobulin, alpha1 antitrypsin, haptoglobin, ceruloplasmin, C3 C4 complements, Immunoglobulins

Liver set

Basic

- Blood: ALT AST, GMT(GGT) gamma-glutamyltransferase, alkaline phosphatase, bilirubin, prothrombin
- Urine: urobilin, bilirubin

Enhanced

- IgA,IgM, IgG, protein profile, LD, GMT(GGT) gamma-glutamyltransferase, HBsAg, anti-HBc, anti-HAV

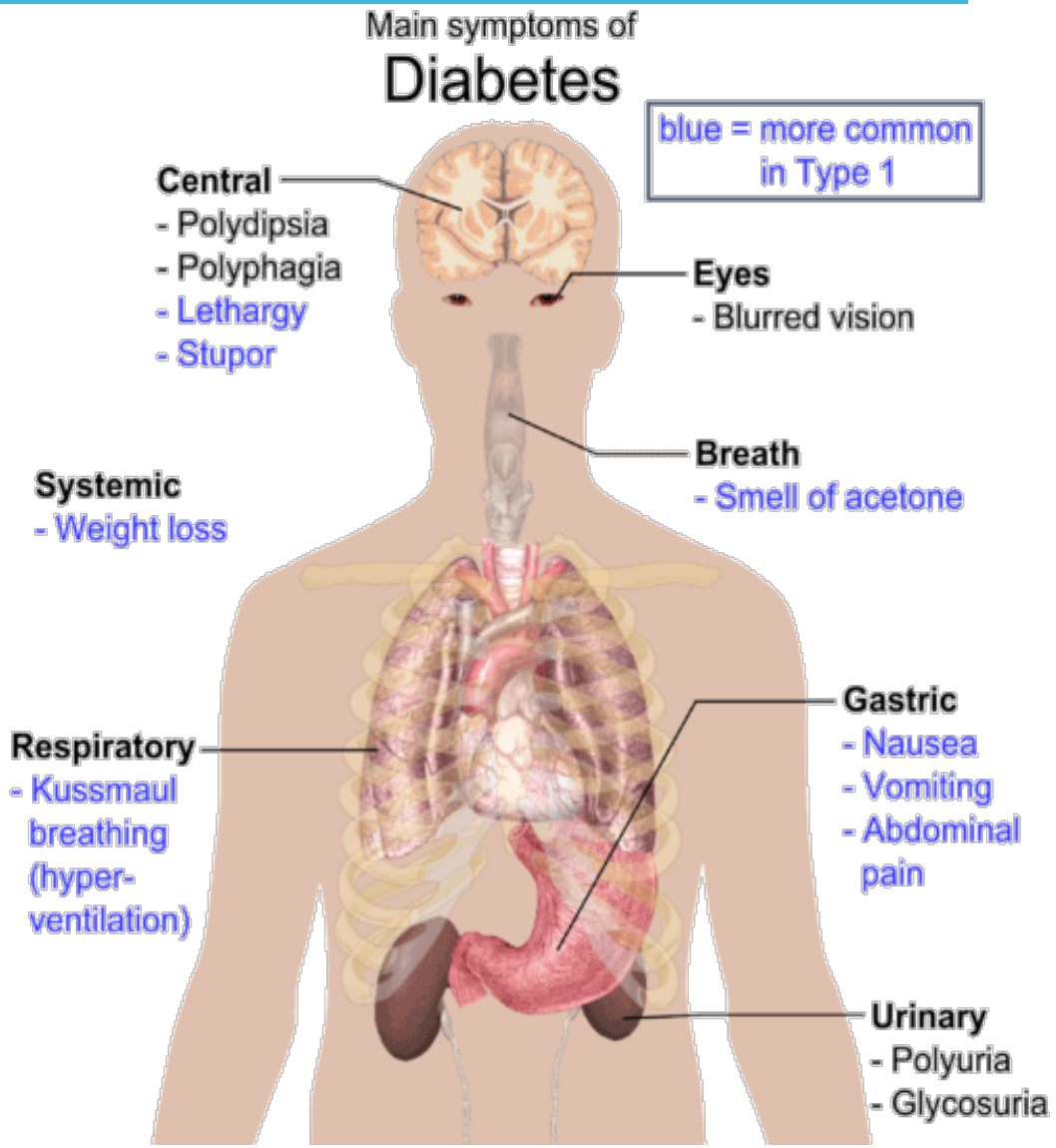
Diabetic Set

Basic

- Glucose fasting and 1-2 hrs after meal
- Urine: glucose, ketobody

Enhanced

- Glycemic profile, LDL-C, cholesterol, glycated hemoglobin, HDL



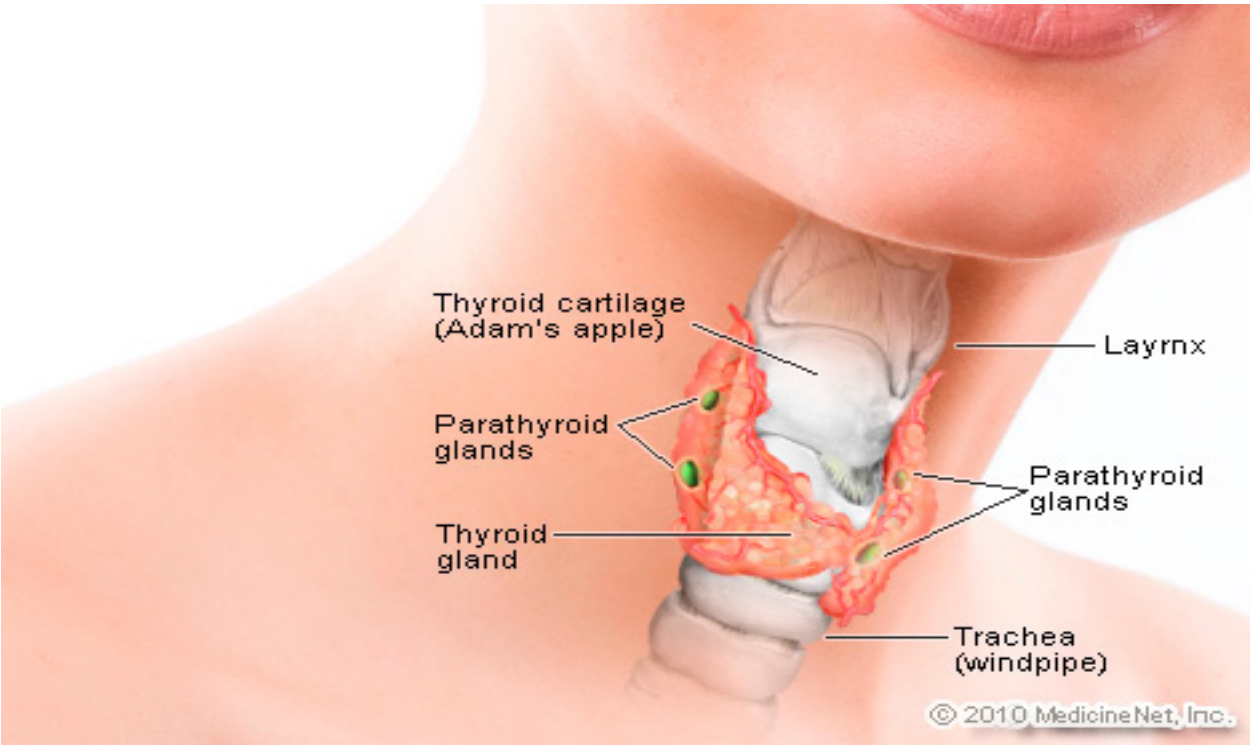
Thyroid set

Basic

- TSH(thyroid-stimulating hormone), fT4

Enhanced

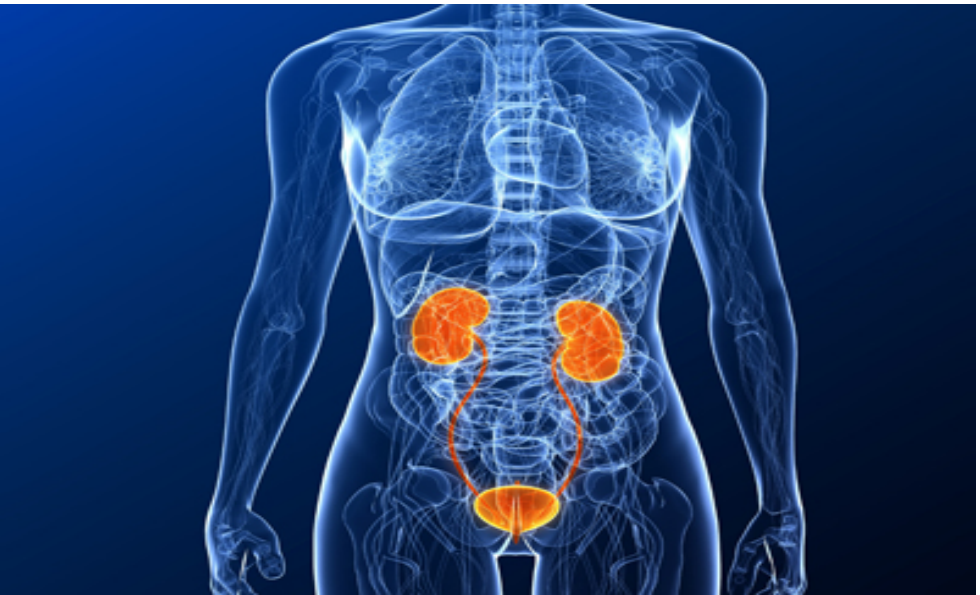
- FT3, T3, T4, cortisol, antithyroglobulin AB, anti-TPO, anti-TSH receptor



Renal set

Basic

- Creatinine, urea
- Urine: pH, protein, blood, leukocytes, nitrites, sediment, quantitative proteinuria



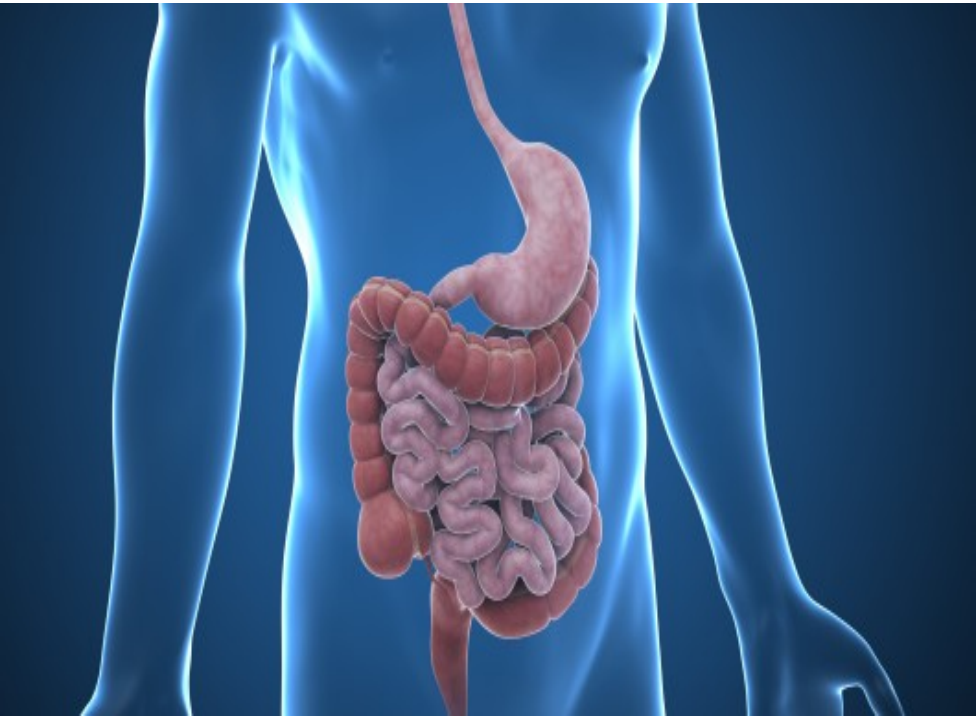
Enhanced

- Na, K, Cl, protein fraction, cholesterol, uric acid, Ca
- Urine: Na, K, Cl, Ca, creatinine, urea, creatinine clearance, protein fraction, C3 complement, C4 complement

Gastroenterologic set

Basic

- Stool: occult bleeding



Enhanced

- Blood: Helicobacter pylori, C-peptide
- Gastric juice
- Duodenal fluid
- Stool

Hematologic Set

Basic

- Erytrocyte sedimentation rate
- Hemoglobin
- Hematocrit
- RBC
- PLT
- WBC
- Blood group
- Coagulation tests
- Fe(iron)
- Tranferrin

Enhanced

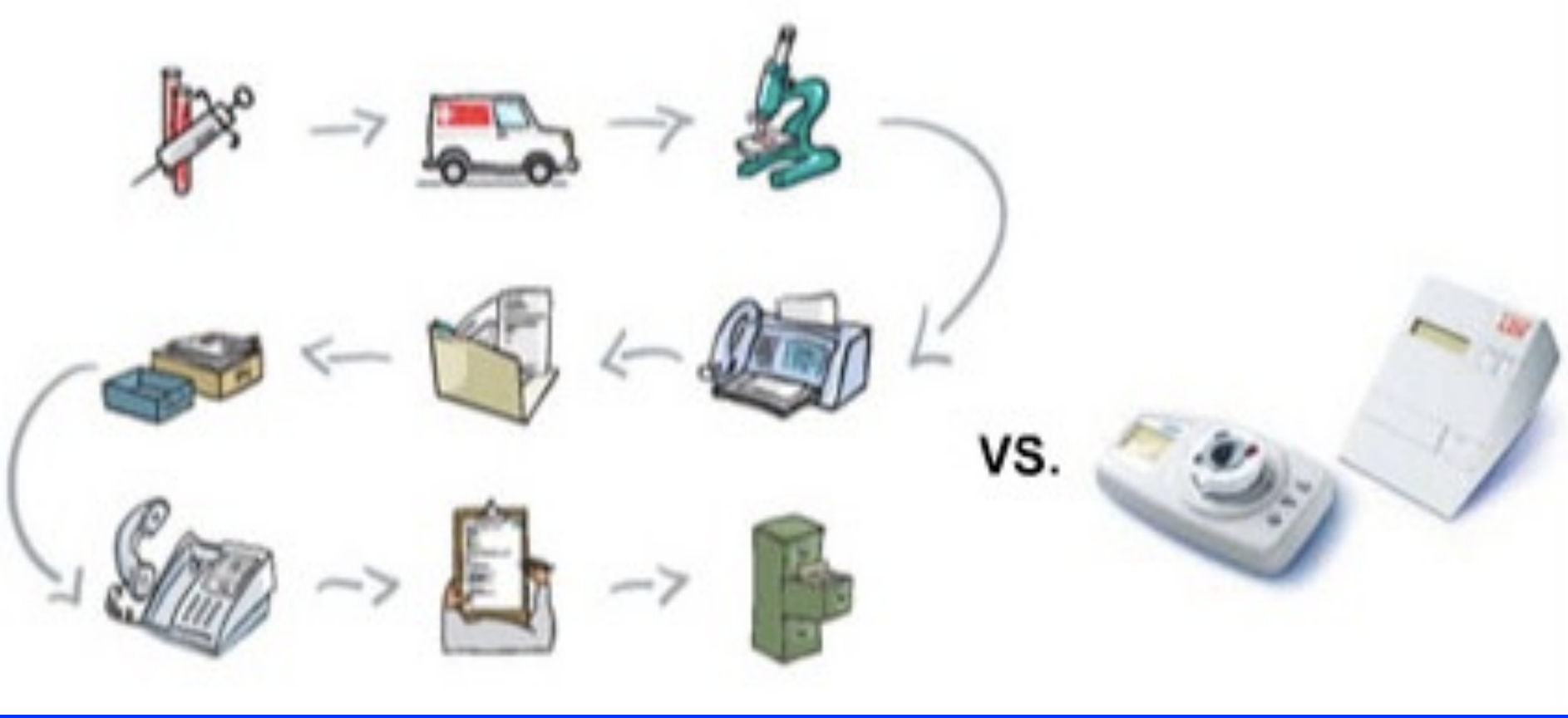
- AST and ALT
- Bilirubin
- Creatinine and urea
- LDH
- Ferritin
- HIV test

POCT

Reading and understanding blood tests from

Point of care testing

Near-patient testing


VS.

Point-of-care testing definition

The College of American Pathologists (CAP) defines point-of-care testing (POCT) as **testing that does not require dedicated, permanent equipment space**. That is, tests are performed with devices brought to the bedside or other patient locations such as the operating room (OR).

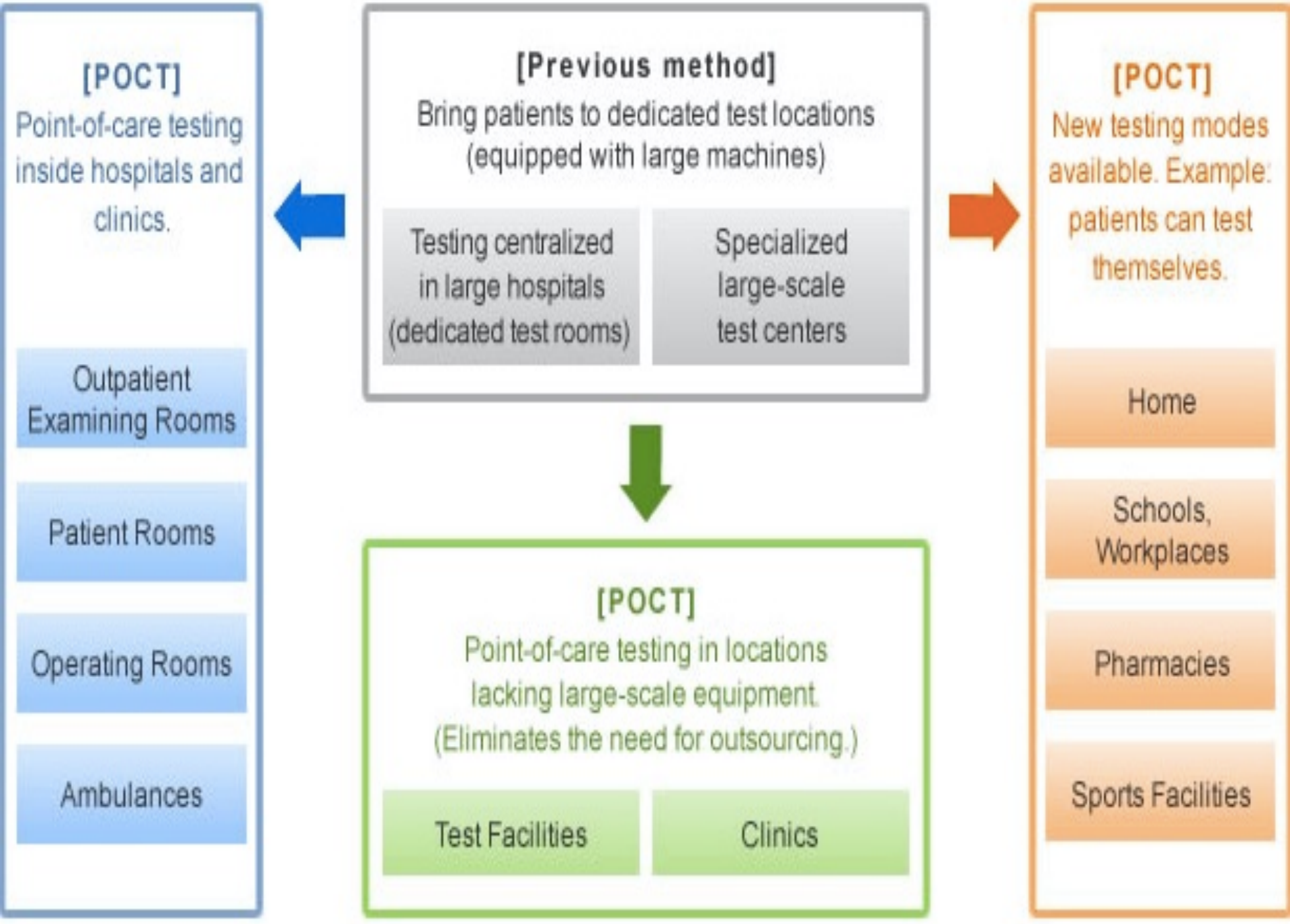
The Clinical Laboratory Improvement Amendment (CLIA) mirrors the CAP definition but further limits the tests and devices to **those where the results are used for clinical decision-making**.
(Dondelinger, R. – 2009)

POCT is also defined as "**any test taken by or on behalf of the treating doctor on-site at the time of consultation, which allows the test result to be used to make immediate decisions about patient treatment**"
(Laurence, C. et al. 2010)

POCT

- **Also named Near Patient Testing is used in wards or in pharmacies and is totally automatized. It can be performed by non-medical laboratory staff**
- **<u>the “farmacia dei servizi e le autoanalisi di prima istanza”, according to the health ministry’s new definition</u>**

<u>Decreto 16 dicembre 2010 GU n. 57</u>


[POCT]
Point-of-care testing inside hospitals and clinics.
Outpatient Examining Rooms
Patient Rooms
Operating Rooms
Ambulances
[Previous method]
Bring patients to dedicated test locations (equipped with large machines)
Testing centralized in large hospitals (dedicated test rooms)
Specialized large-scale test centers
[POCT]
Point-of-care testing in locations lacking large-scale equipment. (Eliminates the need for outsourcing.)
Test Facilities
Clinics
[POCT]
New testing modes available. Example: patients can test themselves.
Home
Schools, Workplaces
Pharmacies
Sports Facilities

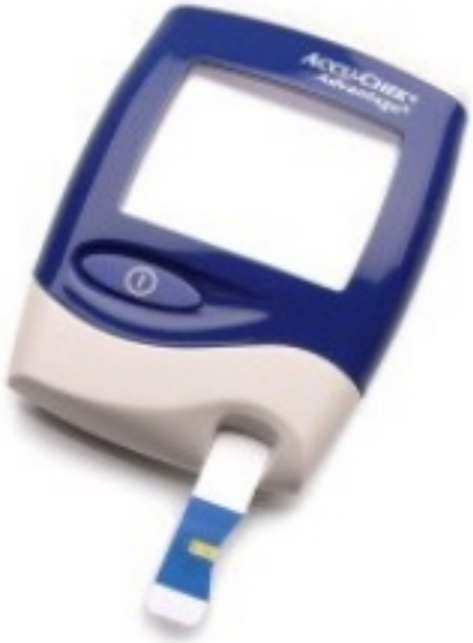
Total POCT-Percent of revenue by segments

- **Infectious disease 21.9%**
- **Cardiac biomarkers 17.6%**
- **Blood gas/electrolites 13.4%**
- **Glucose 13.4%**
- **Coagulation 13.7%**
- **Cholesterol 4.2%**
- **HbA1C 2.6%**
- **Drugs of abuse 2.5%**
- **Hematology 2.3%**
- **Urinalysis 2.3%**
- **Coagulation 2.2%**
- **Pregnancy 2.0%**

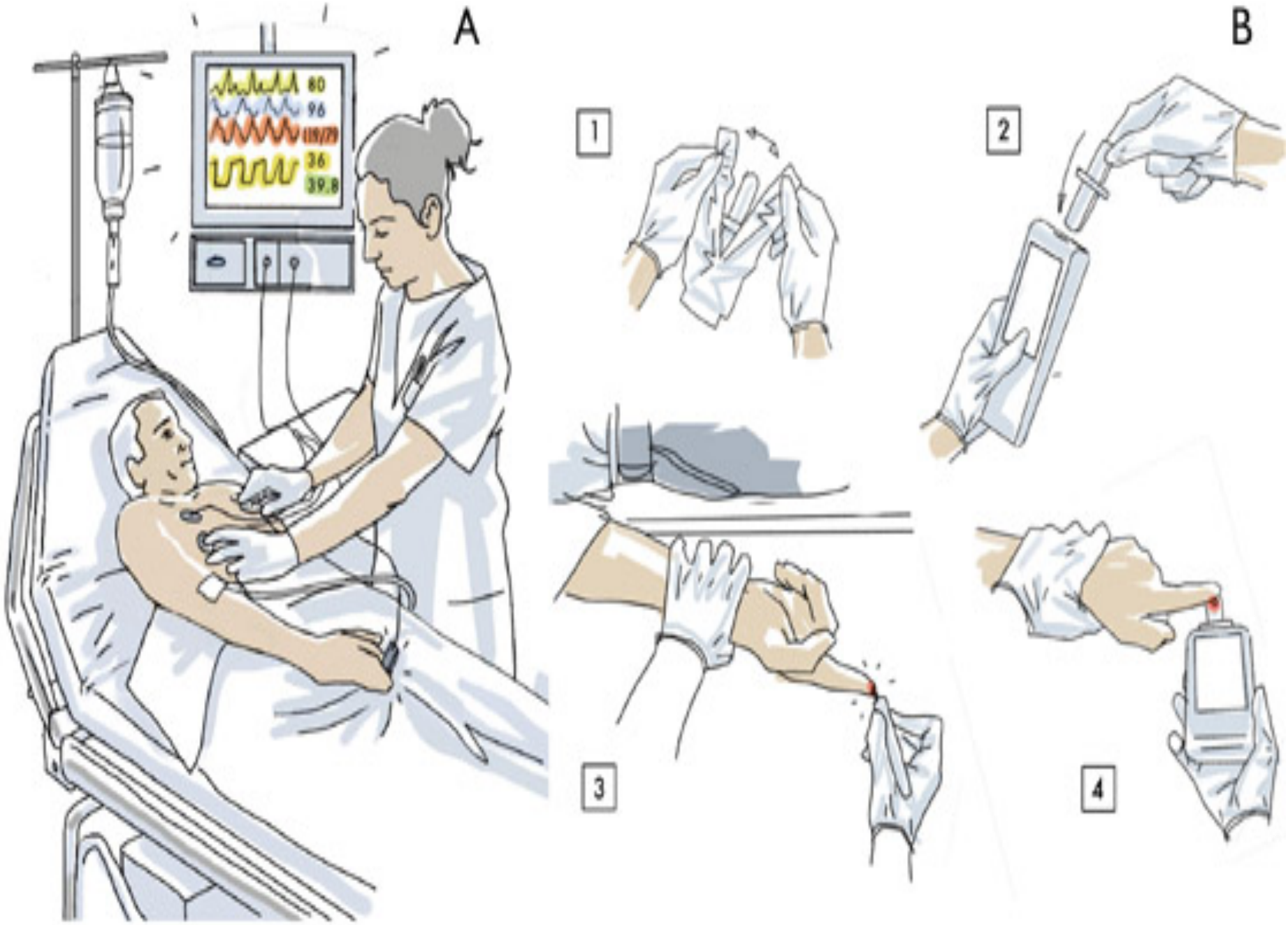
- Glycemia
- Total proteins (blood)
- Triglycerides
- Total cholesterol
- Cholesterol HDL
- Cholesterol LDL
- Total bilirubin
- Transaminase ALT AST
- Gamma-glutamyltransferase (γGT)
- Alkaline phosphatase
- Azotemia
- Creatinine
- Blood panel

Electrochemistry

Strip device



Cassette and bench-top device


A
B
80
96
36
39.8
1
2
3
4

Point of care testing
Near-patient testing

- **Why**: turn around time-TAT and therapeutic TAT
- **When**: need to create new operative procedure
- **How**: through diagnostic systems which provide:

Quality

Easy procedures

Declared clinical objectives