

المحتويات

الصفحة	الموضوع
١	- آداب مهنة التحاليل
٤	- إدارة الجودة
٩	- نظام الجودة بالمعمل
٢٣	- خرائط الجودة
٢٦	- تقييم الجودة الخارجى
٢٨	- إستخدام الكمبيوتر فى المعامل الطبية
	- إحتياطات الأمان
٣٣	- المبادئ العامة لمكافحة عدوى المستشفيات
٥١	- ملحق النتائج الحرجة -
٥٣	- المراجع

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أولاً : تخطيط الجودة

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ثانياً : مراقبة الجودة

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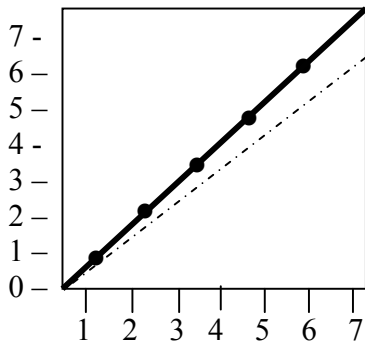


Quality control system

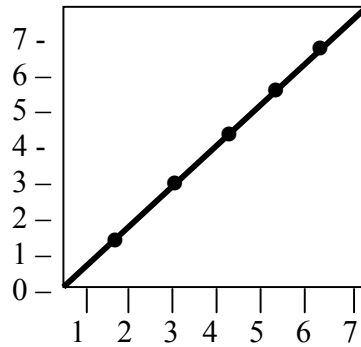
(Quality Assurance system)

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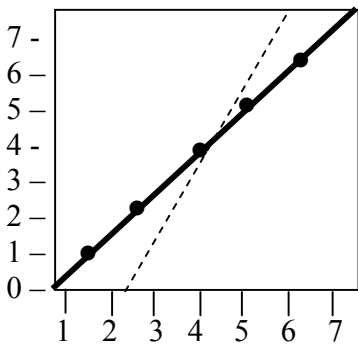
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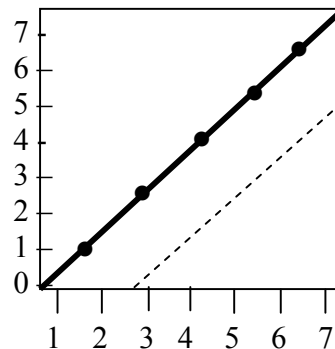
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الناتج المثالية المتوقعة (●—●)

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Clinical Laboratory Improvement Amendments (CLIA)

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CLIA	
Calcium , total	Target \pm 1.0 mg/dl
Chloride	Target \pm 5%
Cholesterol , total	Target \pm 10%
Cholesterol , HDL	Target \pm 30%
Glucose	Greater of target \pm 6mg /dl or \pm 10%
Potassium	Target \pm 0.5mmol/L
Sodium	Target \pm 4mmol/L
Total protein	Target \pm 10%
Triglycerides	Target \pm 25%
Urea nitrogen	Greater of target \pm 2mg /dl or \pm 9 %
Uric acid	Target \pm 17 %

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Good Laboratory practice

TeamSpirit
(GLP)

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Organization

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Preventive and Corrective Measures :

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Internal and External Audit

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Feedback

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calibration

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Interlaboratory Comparisons of Patient Samples

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Validation of Measurements and Observations

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- Sensitivity -
- . Measuring Range - Linearity - Specificity -
- . Accuracy (Trueness and Precision) -
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Transferability (Commutability)

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- . External Quality Assessment
- Quality Assurance :** ■
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(1) - Tourniquet

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(2) " Haemolysis " : ()

ALP	
	LD

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	%	
HDLc		
IgA , IgG, IgM		Triglycerides
		Phospholipids

Carboxyhaemoglobin

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Antinuclear Antibodies

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, ALP		,
, AST		, LD
, CK-		,
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Control Of Laboratory Measurements

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General Measures

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Check Tests

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.Control Charts

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: Patient Data

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Accuracy (Trueness and Precision)

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Laboratory

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- Manual

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Intralabortory And Interlaboratory Comparison

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: Interlaboratory Comparison _____

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Laboratory Testing Procedures And Their Potential Errors

-	Test Ordering
-	Sample
-	Analytical Process
-	Report

Guidelines For Staff

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General and Administrative procedures

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Laboratory Handbook for Users

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ESR - Hb - ALP -BUN Abbreviations

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Instruments and Measuring System

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Internal audit

Quality control charts

Levey –)

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(Jenning

(Standard Deviation)

27 MARCH 1986

GLUCOSE

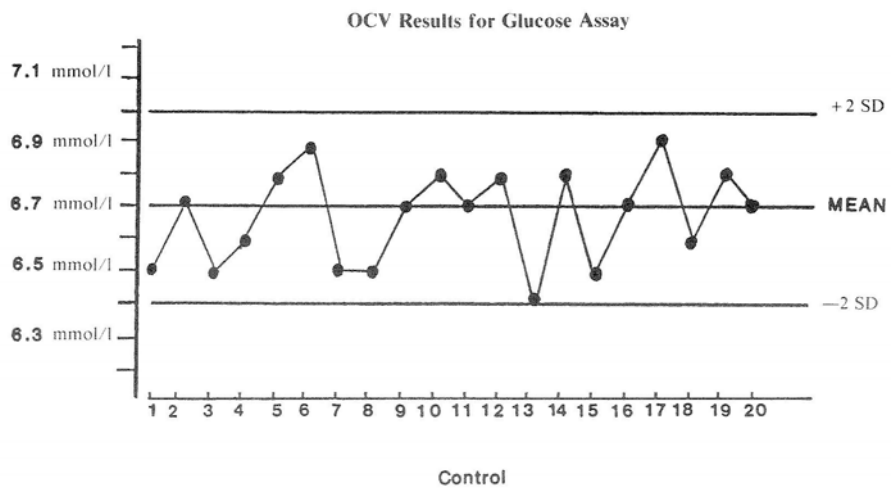
ANALYST

Test No.	Test Results in mmol/l	Differences from mean	Squared differences	Calculations
1	6.5	-0.2	0.04	SD = $\frac{0.44}{20-1}$ = $\sqrt{0.023}$ = 0.15 mmol/l
2	6.7	0.0	0.00	
3	6.5	-0.2	0.04	
4	6.6	-0.1	0.01	
5	6.8	+0.1	0.01	
6	6.9	+0.2	0.04	
7	6.5	-0.2	0.04	
8	6.5	-0.2	0.04	
9	6.7	0.0	0.00	
10	6.8	+0.1	0.01	
11	6.7	0.0	0.00	
12	6.8	+0.1	0.01	
13	6.4	-0.3	0.09	
14	6.8	+0.1	0.01	
15	6.5	-0.2	0.04	
16	6.7	0.0	0.00	
17	6.9	+0.2	0.04	
18	6.6	-0.1	0.01	
19	6.8	+0.1	0.01	
20	6.7	0.0	0.00	
Total = 133.4		Total = 0.44		
Mean = $133.4 \div 20$ = 6.7 mmol/l				

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 (Mean) ()
 (2SD) (+) (3SD)
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 (2SD)
 (3SD)



Quality Assessment External

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Mean, % Of Deviation , SD And CV
($2 \text{ SD} \pm \text{Mean}$)

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(Control Samples)		
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Staphylococci

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Coagulase+ ve

staph aureus
(MRSA)

Coagulose-ve

: Enterococci *

(VRE)

Streptococci *

Strept. Pneumoniae

Gram –ve Bacilli *

E-Coli, Klebsiella, Serratia

Coliform

Proteus, Enterobacter and Citrobacter

Pseudomonas -

G + ve Bacilli

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Candida albicans

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Blood – Borne Viruses

(HBV , HCV)

. (HIV)

Respiratory Syncytial Virus

Rotavirus

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() Acid Fast Bacilli

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Transport medium

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10 u IU / ml
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10 u IU / ml
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Prevention of Infection in Clinical Laboratories

Laboratory-acquired Infections

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Blood-Borne Viruses- Mycobacterium tuberculosis, Brucella spp., Shigella. and Salmonella spp.

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Needle Incinerator

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Bacteriological Loop

Biological Safety Cabinet (BSC)

Tuberculin test

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النتائج الحرجة

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Hematology

	Low	High
Hct (packed cell volume)	<20 vol%	>60 vol%
Hb	<7 gm/dL	>20 gm/dL
Platelet count (adult)	<40,000/cu mm	>1,000,000/cu mm
Platelet count (pediatric)	<20,000/cu mm	>1,000,000/cu mm
aPTT	None	>78 secs
PT	None	>30 secs or >3× control level
Positive test for fibrin split products, protamine sulfate, high heparin level		
Fibrinogen	<100 mg/dL	>700 mg/dL
WBC	<2000/cu mm	>30,000/cu mm
Presence of blast cells, sickle cells		
New diagnosis of leukemia, sickle cell anemia, aplastic crisis		

Blood Chemistry

	Low	High
Ammonia	None	>40 μmol/L
Amylase	None	>200 U/L
Arterial pCO ₂	<20 mm Hg	>70 mm Hg
Arterial pH	<7.2 U	>7.6 U
Arterial pO ₂ (adults)	<40 mm Hg	None
Arterial pO ₂ (newborns)	<37 mm Hg (standard deviation [SD] = 7)	92 mm Hg (SD = 12)
Bicarbonate	<10 mEq/L	>40 mEq/L
Bilirubin, total (newborns)	None	>15 mg/dL
Calcium	<6 mg/dL	>13 mg/dL
Carbon dioxide	<10 mEq/L	>40 mEq/L
Cardiac troponin (cTn)		
Cardiac troponin T (cTnT)	None	>0.1 μg/L
Cardiac troponin I (cTnI)	None	>1.6 μg/L
Chloride	<80 mEq/L	>115 mEq/L
CK	None	>3-5× upper limit of normal (ULN)

CK-MB	None	>5% or ≥ 10 µg/L
Creatinine (except dialysis patients)	None	>5.0 mg/dL
Glucose	<40 mg/dL	>450 mg/dL
Glucose (newborns)	<30 mg/dL	>300 mg/dL
Magnesium	<1.0 mg/dL	>4.7 mg/dL
Phosphorus	<1 mg/dL	None
Potassium	<2.8 mEq/L	>6.2 mEq/L
Potassium (newborns)	<2.5 mEq/L	>8.0 mEq/L
Sodium	<120 mEq/L	>160 mEq/L
BUN (except dialysis patients)	2 mg/dL	>80 mg/dL

Cerebrospinal Fluid

	Low	High
Glucose	<80% of blood level	
Protein, total	None	>45 mg/dL
Positive bacterial stain (e.g., Gram, acid-fast), antigen detection, culture, or India ink preparation		
WBC in CSF	None	>10/cu mm
Presence of malignant cells or blasts or any other body fluid		

Microbiology

Positive blood culture
 Positive Gram stain or culture from any body fluid (e.g., pleural, peritoneal, joint)
 Positive acid-fast stain or culture from any site
 Positive culture or isolate for *Corynebacterium diphtheriae*, *Cryptococcus neoformans*, *Bordetella pertussis*, *Neisseria gonorrhoeae* (only nongenital sites), dimorphic fungi (*Histoplasma*, *Coccidioides*, *Blastomyces*, *Paracoccidioides*)
 Presence of blood parasites (e.g., malaria organisms, *Babesia*, microfilaria)
 Positive antigen detection (e.g., *Cryptococcus*, group B streptococci, *Haemophilus influenzae* type B, *Neisseria meningitidis*, *Streptococcus pneumoniae*)
 Stool culture positive for *Salmonella*, *Shigella*, *Campylobacter*, *Vibrio*, or *Yersinia*

Urinalysis

Strongly positive test for glucose and ketone
 Presence of reducing sugars in infants
 Presence of pathological crystals (urate, cysteine, leucine, tyrosine)

Serology

Incompatible cross match
 Positive direct and indirect antiglobulin (Coombs') test on routine specimens
 Positive direct antiglobulin (Coombs') test on cord blood
 Titers of significant RBC alloantibodies during pregnancy
 Transfusion reaction workup showing incompatible unit of transfused blood
 Failure to call within 72 hrs for Rh Ig after possible or known exposure to Rh-positive RBCs
 Positive confirmed test for hepatitis, syphilis, acquired immunodeficiency syndrome (AIDS)
 Increased blood antibody levels for infectious agents (see pp. 23–24)

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