

المواصفات الفنية للأجهزة

CODE NO:

DEVICE NAME: ESR Analyzer

Applications	used for determined Erythrocyte Sedimentation Rate(ESR) in the blood
design	Heavy duty and compatible
Measuring method	Infrared ray beam
Number of reading channels	≥ 10
Through put	≥ 20 tests per hours
Sample Volume (ml)	≤ 1.6 ml
Reading time (selectable)	≤ 30 minutes
Loading pattern	random access
display	Yes
Bar code reader	Yes
Printer	Yes
Stored patient results	Yes , ≥ 200 test
Interface	RS232 for printer , host and bar code scanner
Analysis result	In westergren millimeter per hour
Temperature correction	Automatic compensation to 18 °C
Power requirements	220-240VAC,50-6-Hz
Environmental conditions	the equipment suitable for working in the climate conditions of Iraq in terms of temperature & humidity

CODE NO:

Device name: (ELISA analyzers)

Application : ELISAs assay , Protein Quantitation , Nucleic acid analysis , Cell Viability, Proliferation, and Cytotoxicity, Kinetic assay , Enzyme assay , evaluate the quantity of antigen or antibodies associated with infectious viral diseases (e.g., HIV, measles, herpes, rubella) , other nonviral applications (e.g., mycoplasma pneumoniae) , other to be specified .

A - Photometric micro plate readers

- **PHOTOMETRIC METHOD:** yes , dependent on manufacturer
- **OPTICAL SYSTEM :** measurement and reference channels required , multiple channel preferred
- **photometric accuracy :** < 2 %
- **measurement range, ABS :** between 0 - 4.0
- **wavelength range, nm :** between 200 – 1000
- **precision:** $\pm 1\%$
- **resolution, od :** ≤ 0.01
- **light source :** Tungsten halogen or xenon flash
- **photodetector :** photomultiplier tube(PMT) preferred and other to be specified
- **FILTER TYPE :** according to manufacturer
- **compatible micro plates :** flat or round or bottom , 96 -well plates
- **Isothermal reading chamber :** optional
- **programmable assays :** preferred
- **data management :**
 - **Analysis: Reading speed, sec/plate :** $\leq 15/96$ -well
 - **Display :** yes
 - **Computer interface :** yes
 - **Printer :** yes (external or built-in)
 - **Bar-code reader:** Optional
- **Robotics compatible :** yes
- **Self-calibration :** yes
- **Quality control :** yes

B- Microplate Washers:

- **Configuration:** full plate washer or other to be specified
- **automated/manual :** automated

CODE NO:

Device name: (ELISA analyzers)

- washing parameters : wash volume/time, soak time and other
- user programmable: yes
- programs:
 - user definable: yes
 - number of cycles : ≥ 9
 - maximum soak time, sec : ≤ 3.600
- compatible plates : well plates other to be specified
- capacity, number of plates : ≥ 1
- wash head : multiple interchangeable wash heads of varying configurations
- fluid reservoir :
 - capacity, l
 - wash : ≤ 4
 - rinse : < 4
 - waste : ≤ 4
 - liquid-level sensing : yes
- precision, % cv : ≤ 3
- minimum residual volume μl / well : ≤ 5
- maximum dispense volume ml /well : ≤ 3
- power requirement(for system): 220/240 VAC, 50/60 HZ
- Environmental requirements: The equipment suitable for working in the climate conditions of Iraq in terms of temperature & humidity

CODE NO:

DEVICE NAME: FULLY AUTOMATED CLINICAL
CHEMISTRY ANALYZER WITH ISE MODULE (floor type)

Application	Determine the concentration of certain metabolites, electrolytes, proteins, and/or drugs in samples of serum, plasma, urine, cerebrospinal fluid, and/or other body fluids.
FDA CLEARANCE OR CE MARK	YES
CONFIGURATION	Floor type
Processing modes	Random access , Continuous
System capacity	≥ 150
THROUGHPUT, max tests/hr	≥ 800
SAMPLE TYPE	Serum/plasma , Urine , optional : CSF
SAMPLE SIZE, μL	≤ 100
TEST MENU, min	To be specified by user
PROGRAMMED TESTS	Yes
USER-DEFINABLE TESTS	Yes
METHOD USED	End point, kinetic, ISE or other
Optical system	Photometric, Spectrophotometric or other
Light source	Halogen , Tungsten-halogen or other
REAGENTS, TYPE	Liquid or other
Substitution (open or closed system)	Yes

CODE NO:

DEVICE NAME: FULLY AUTOMATED CLINICAL
CHEMISTRY ANALYZER WITH ISE MODULE (floor type)

Refrigerated onboard	Yes
SYSTEM FEATURES	
Closed-tube sampling	No
Direct sampling	Yes
Liquid-level sensing	Yes
Clot detection	Yes
Auto dilution	Yes
Abnormal values flag	Yes
Auto verification	According to manufacture
Auto quality control	Yes
Auto calibration	Yes
DATA MANAGEMENT	
Display	Yes , touch screen
Results stored	Yes
Computer interface	Yes
Current LIS vendor interfaces	Yes
Printer	Yes
Bar-code reader	Yes
LINE POWER, VAC, Hz	220-240, 50/60 HZ
Backup or UPS	Yes , ≥ 30 min

CODE NO:

DEVICE NAME: FULLY AUTOMATED CLINICAL
CHEMISTRY ANALYZER WITH ISE MODULE (floor type)

water deionizer for supply	Yes
Onboard supply	Yes
Environmental requirements	The equipment suitable for working in the climate conditions of Iraq in terms of temperature & humidity

CODE NO:

DEVICE NAME : Automated Coagulation
analyzers

Application	Coagulation analyzers perform a variety of tests to detect abnormalities in the components required to complete normal blood clotting.
CONFIGURATION	Bench top
system capacity	≥ 40
THROUGHPUT, samples/hr	
Pt	≥ 150
APTT	≥ 70
Number of assays onboard simultaneously	≥ 16
Sample type	plasma
SAMPLE SIZE, mL	≤ 3 mL, variable
TEST MENU:	APTT, D-dimer, FIB, PT, TT, other to be specified
METHOD USED	Photo-optical, Photo metric , other to be specified
APTT INCUBATION	
• Time, min	Programmable(preferred) or ≤ 5 min.
• Sample time flag	yes
SYSTEM FEATURES	
• Direct sampling	YES
• Closed-tube sampling	preferred
• Autosampler	YES
• Assay continues while loading reagents/consumables	Yes
• Stat capability	Yes
• REAGENTS REFRIGERATED ONBOARD	Yes

CODE NO:

DEVICE NAME : Automated Coagulation
analyzers

DATA MANAGEMENT <ul style="list-style-type: none">• Display• Computer interface• LIS interface• Printer• CALIBRATION• Bar-code reader<ul style="list-style-type: none">-Sample-reagent	Color touchscreen or LCD touchscreen Yes Yes LaserJet, or other Automatic Yes Yes
POWER CONSUMPTION, VAC <ul style="list-style-type: none">• Environmental requirements	220 -240, 50/60 Hz The equipment suitable for working in the climate conditions of Iraq in terms of temperature & humidity

CODE NO:

DEVICE NAME: fluorescence immunoassay

Application	It used in hospital and clinical laboratories to analyze the drugs and endogenous substances in biological fluids (body fluid).
FDA or CE CLEARANCE	YES , (FDA) preferred
CONFIGURATION	Bench top or floor type
Processing modes	At least two modes of the following modes
THROUGHPUT, max tests/hr	≥ 70
SAMPLE CAPACITY	≥ 60
SAMPLE TYPE	Serum, plasma , other to be specified
SAMPLE SIZE, μL	< 220 Smallest is preferred
METHOD USED	fluorescence immunoassay(FIA) , other to be specified
TEST MENU	Endocrine function ,Thyroid markers ,Viruses, or , other should to be specified.
REAGENTS, TYPE • Refrigerated on board	Liquid, ready-to-use or other type According to manufacturer
SYSTEM FEATURES	
Liquid-level sensing	Yes
Clot detection	Yes
Auto dilution	Yes
Auto calibration	Yes

CODE NO: DEVICE NAME: fluorescence immunoassay

Auto wash	Yes
DATA MANAGEMENT	
Display	LCD touchscreen , $\geq 15''$
Quality control management	Yes
Results stored	Yes
Computer interface	Yes
Printer	Yes
Bar-code reader	Yes
LINE POWER, VAC, Hz • Backup	220~240 VAC, 50/60 Hz Preferred (Battery or UPS)
Environmental requirements	The equipment suitable for working in the climate conditions of Iraq in terms of temperature & humidity

CODE NO:

DEVICE NAME: hematology analyzer
 (3 part differential)

application	Used to perform complete blood counts ,include WBC ,RBC ,Red blood cell and platelet count ,hemoglobin concentration ,mean cell hemoglobin (MCH), mean cell hemoglobin concentration (MCHC),mean cell volume (MCV)
CONFIGURATION	Bench top
Intended area of use	Laboratory
Automated/semiautomated	Fully automated
METHOD USED	Volumetric impedance
TEST MENU	
• Basic hematology	RBC, WBC, Hgb, Hct, MCV, MCH, MCHC); Plt
• WBC differentials	3-part differential: L# and %, M# and %, G# and %
• OTHER	RDW ,PDW, PCT & others tests can be performed by the device should be specified
SAMPLE TYPE	EDTA Whole blood required; Capillary or venous blood
SAMPLE VOLUME, μL	≤ 120
THROUGHPUT, samples/hr	≥ 60
Analysis time, sec	≤ 60
Start-up time, min	≤ 5

CODE NO:

DEVICE NAME: hematology analyzer
 (3 part differential)

SYSTEM FEATURES	
Auto dilution	YES
Autosampler	Yes
Closed-tube sampling	Yes
Coincidence correct	YES
Adjustable threshold	YES
Histogram display	YES
Robotics capability	NO
APERTURE	(if the device don't have aperture)
Number	>1
SIZE (S), μm	≤ 100
REAGENT TYPE	Should be specified by manufacture
Preparation	No
ALERT INDICATORS	Yes (should be specified in details)
DATA MANAGEMENT	
Display, type	LCD monitor , touch screen (preferred) or other (should be specified)
Data displayed	Yes (results& other)
HIS/LIS interface	Yes
Data entry	Manual and Bar code
Data storage	$\geq 10,000$ patient results
Printer	Yes

CODE NO:

DEVICE NAME: hematology analyzer
(3 part differential)

CALIBRATION	Automatic
QUALITY CONTROL	≥ 3 files ,levey – Jennings charts , others should be specified
Line power, VAC	220-240, 50/60 HZ
Environmental requirements:	The equipment suitable for working in the climate conditions of Iraq in terms of temperature & humidity.

CODE NO:

DEVICE NAME: hematology analyzer
(5 part differential)

application	Used to perform complete blood counts ,include WBC ,RBC ,Red blood cell and platelet count ,hemoglobin concentration ,mean cell hemoglobin (MCH), mean cell hemoglobin concentration (MCHC),mean cell volume (MCV)
CONFIGURATION	Bench top
Intended area of use	Laboratory
Automated/semiautomated	Fully automated
METHOD USED	Volumetric impedance ,light scattered
TEST MENU	
• Basic hematology	RBC, WBC, Hgb, Hct, MCV, MCH, MCHC); Plt
• WBC differentials	5-part differential: L# and %, M# and %, B# and %, E# and %, N# and %
• OTHER	MPV ,RDW ,Retic # and %& others tests can be performed by the device should be specified
SAMPLE TYPE	Whole blood required; CSF and other body fluids optional

CODE NO:

DEVICE NAME: hematology analyzer
(5 part differential)

SAMPLE VOLUME, μL	≤ 100
THROUGHPUT, samples/hr	≥ 80
Analysis time, sec	≤ 60
Start-up time, min	≤ 5
SYSTEM FEATURES	
Auto dilution	YES
Auto sampler	YES
Closed-tube sampling	YES
Coincidence correct	YES
Adjustable threshold	Yes
Histogram display	YES
Robotics capability	Yes

CODE NO:

DEVICE NAME: hematology analyzer
(5 part differential)

APERTURE	(if the device don't have aperture)
Number	>1
REAGENT TYPE	Should be specified by manufacture
ALERT INDICATORS	Yes
DATA MANAGEMENT	
Display, type	LCD monitor , touch screen (preferred) or other (should be specified)
Data displayed	Yes (results& other)
HIS/LIS interface	Yes
Data entry	Manual and Bar code
Data storage	$\geq 10,000$ patient results
Printer	Yes
CALIBRATION	Automatic
QUALITY CONTROL	≥ 6 files ,levey - Jennings charts , others should be specified
Line power, VAC	220-240, 50/60 HZ
Environmental requirements:	The equipment suitable for working in the climate conditions of Iraq in terms of temperature & humidity.