

APPENDIX A, Distributions of laboratories in Khartoum State

Table A.1. Distributions of laboratories in Khartoum State

NO	Departments	NUMBER OF LABS
1	federal hospitals	22
2	State Hospitals	24
3	Military Hospitals	17
4	Primary Health care centers	156
5	NGOs laboratories	540
6	private hospitals	94
7	Laboratories and private clinics	610
8	Coefficient of camps	20
Total		1483

APPENDIX B. Data collection questionnaire template for calibration flame photometer.

Questionnaire for ISO Standards of Flame Photometer

Hospital Lab. Name:

- 1- Manufacturing Country
Manufacturer's name
Instrument Model
Serial Number:

2- The instrument's details is fully logged book. **Yes** **No**

3- Who installed it? **Company** **Technician** **Other**

4- The user operate the instrument:

After training **Without training**

5- Environment stability achieved: **Yes** **No**

6- The Status of the device upon receipt

New **Reconditioned**

Used **I don't know**

7- Did you verify manufacture criteria: **Yes** **No**

8- Calibration process is performed:

i. **Prior to use unless it comes with a calibration certificate**

ii. **After repair**

iii. **Periodic calibration**

iv. **Whenever accuracy is in doubt**

v. **Never**

9- Maintenance process is usually done:

Regularly **Due to malfunction**

10- The current situation of the instrument is :

Good **Bad** **Damaged**

11- Based on the performance of the instrument, do you prefer to:

Still use it **Replace it as soon as possible**

APPENDIX C. Reading collection tables

Table C.1. Flame photometer readings pre and post calibration

Hospital name Instrument No

Flame Photometer Company Serial No. :

No.	Item and its reading										Comment		
1.	Compressor												
	Standard range (kPa)					DPI reading							
	Compressor pressure					96.53 – 206.85							
2.	Pressure gauge												
	The Pressure gauge pre calibration adjusted at												
	Pressure gauge (kPa)			DPI reading (kPa)			The mean						
	50						The mean of readings $\Sigma X / 3 =$						
	100												
	150											% error average =	
	Pressure gauge diversion												
	Pre adjust reading					Post adjust reading							
	Pressure gauge adjusted at (P =14 psi)			DPI reading			Pressure gauge indicator			DPI reading (P = 96.53 kPa)			
	96.53 kPa												
3.	Atomizer												
	The pre-adjusted sucking rate of nebulizer												
	Sucking rate per minute			The residual volume of 6 ml			The pressure at nebulizer						
	The sucking rate of nebulizer after calibrating												
	Sucking rate per minute			The residual volume of 6 ml			The pressure at nebulizer						
4.	Normal control and pathological control readings												
			Normal control Lot (062A)					pathological control Lot (061A)					
Sample No.	Filter	Actual value	Range		Reading value	Final value	Actual value	Range		Reading value	Final value		
Sample 1 Not diluted	Na	114	103-126	1×			160	144-176	1×				
	K	4.06	3.65-4.46	1×			7.00	6.30-7.69	1×				
Sample 2 Diluted A	Na	57		2×			80		2×				
	K	2.03		2×			3.5		2×				
Sample 3 Diluted B	Na	28.5		4×			40		4×				
	K	1.015		4×			1.75		4×				
5.	Pre and post calibration reading for Normal and pathological control												
			Normal control Lot (062A)					pathological control Lot (061A)					
	Filter	Actual value	Range	pre	post		Actual value	Range	pre	post			
	Na	114	103-126				160	144-176					
	K	4.06	3.65-4.46				7.00	6.30-7.69					

Table C.2. Ion Selective Electrode readings

Hospital name Instrument No

Ion Selective Electrode Company **Serial No. :**

No.	Transducer	Normal control Lot (062A)		pathological control Lot (061A)		Comment
		Actual value	reading	Actual value	reading	
1.	Na	114		160		
2.	K	4.06		7.00		

APPENDIX D. The certified tools and used materials

Table D.1. DPI calibration certificate



CALIBRATION CERTIFICATE

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UNIT UNDER TEST (UUT)

Manufacturer : Druck
 Type Number : DPI104
 Serial Number : 3448247
 Pressure Range : 0 to 7 bar g
 Pressure Connector : ¼ BSP Male
 Calibration Date : 19 August 2011

CALIBRATOR INFORMATION

Calibration Instrument : DPI515
 Serial Number : 51501920
 (*1) Calibrated Against : UKAS Lab.0221
 Calibration Instrument : 34401A
 Serial Number : MY45022435
 (*1) Calibrated Against : UKAS Lab.0221

PRESSURE PERFORMANCE 20°C (*1)

Actual Applied Value bar	Unit Under Test Reading bar (*2)	Unit Under Test Deviation (*3)	Permissible Deviation (*4)
-0.0001	-0.0001	0.000 %fs	±0.035 %fs
1.3997	1.3997	0.000 %fs	±0.035 %fs
2.7998	2.7997	-0.001 %fs	±0.035 %fs
4.1996	4.1997	0.001 %fs	±0.035 %fs
5.5994	5.5994	0.000 %fs	±0.035 %fs
6.9996	6.9997	0.001 %fs	±0.035 %fs
3.5000	3.4997	-0.004 %fs	±0.035 %fs
0.0004	0.0003	-0.001 %fs	±0.035 %fs

ANALOGUE PERFORMANCE 20°C (*1)

Voltage Setpoint %	Analogue Output Reading V (*2)	Unit Under Test Deviation (*3)	Permissible Deviation (*4)
2	0.100	-0.006 %fs	±0.095 %fs
20	1.000	-0.010 %fs	±0.095 %fs
40	2.000	0.003 %fs	±0.095 %fs
60	2.999	-0.015 %fs	±0.095 %fs
80	3.999	-0.022 %fs	±0.095 %fs
100	5.000	-0.003 %fs	±0.095 %fs

Certified by:



Date:

20 AUG 2011

NOTES

- (*1) Traceable to relevant International Standards (including N.I.S.T.).
- (*2) Actual recorded values. For specification, see Permissible Deviation column.
- (*3) Deviation calculated from UUT Reading minus Actual Applied Value.
- (*4) Non linearity, hysteresis, temperature effects and repeatability.

PS1074 V1.02

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Table D.2. Biochemistry Calibrator

BIOCHEMISTRY CALIBRATOR						
						LOT 047A
COMPONENT	METHOD	VALUE	UNITS	VALUE	UNITS	TRACEABILITY
ACID PHOSPHATASE	Naphthyl phosphate/pentanedicl	18,1	U/L	0,300	µkat/L	BMC
ALBUMIN	Bromocresol green	30,5	g/L	30,5	g/L	SRM 927 c (NIST)
ALKALINE PHOSPHATASE	2-Amino-2-methyl-1-propanol buffer Dithanolmercur	492	U/L	5,45	µkat/L	BMC
ALT/GPT	IFCC without pyridoxal phosphate IFCC with pyridoxal phosphate	99,0 103	U/L U/L	1,64 1,72	µkat/L µkat/L	BMC C-RSE/IFCC
α-AMYLASE	IFCC Direct substrate	270 287	U/L U/L	4,49 4,76	µkat/L µkat/L	C-RSE/IFCC BMC
AST/GOT	IFCC without pyridoxal phosphate IFCC with pyridoxal phosphate	118 134	U/L U/L	1,96 2,23	µkat/L µkat/L	BMC C-RSE/IFCC
BILIRUBIN, DIRECT	Diazoted sulfanilic	1,12	mg/dL	19,2	µmol/L	BMC
BILIRUBIN, TOTAL	Diazoted sulfanilic	3,82	mg/dL	65,3	µmol/L	SRM 909 b (NIST)
CALCIUM	Methylthymol blue Arsenazo III	12,1 10,7	mg/dL mg/dL	3,04 2,66	mmol/L mmol/L	SRM 909 b (NIST) SRM 909 b (NIST)
CHLORIDE	Selective electrode	104	mmol/L	104	mmol/L	SRM 909 b (NIST)
CHOLESTEROL	Cholesterol oxidase/peroxidase	186	mg/dL	4,82	mmol/L	SRM 909 b (NIST)
CK	IFCC	320	U/L	5,32	µkat/L	C-RSE/IFCC
CREATININE	Alkaline picrate	3,10	mg/dL	274	µmol/L	SRM 909 b (NIST)
GLUCOSE	Glucose oxidase/peroxidase	173	mg/dL	9,63	mmol/L	BMC
γ-GT	IFCC	144	U/L	2,39	µkat/L	C-RSE/IFCC
IRON	Ferrozine Chromazurol B	173 62,6	µg/dL µg/dL	31,0 11,2	µmol/L µmol/L	BMC BMC
LD/LDH	Pyruvate IFCC	599 280	U/L U/L	9,94 4,64	µkat/L µkat/L	BMC C-RSE/IFCC
MAGNESIUM	Xylydyl Blue / Calmagite	1,87	mg/dL	0,768	mmol/L	SRM 909 b (NIST)
PHOSPHORUS	Phosphomolybdate/UV	6,73	mg/dL	2,17	mmol/L	BMC
POTASSIUM	Selective electrode	4,95	mmol/L	4,95	mmol/L	SRM 909 b (NIST)
PROTEIN, TOTAL	Biuret	60,2	g/L	60,2	g/L	SRM 927 c (NIST)
SODIUM	Selective electrode	134	mmol/L	134	mmol/L	SRM 909 b (NIST)
TRIGLYCERIDES	Glycerol phosphate oxydase/peroxydase	136	mg/dL	1,54	mmol/L	SRM 909 b (NIST)
UREA	Urease (Color / UV)	84,7	mg/dL	14,1	mmol/L	SRM 909 b (NIST)
URIC ACID	Uricase/peroxidase	7,93	mg/dL	472	µmol/L	SRM 909 b (NIST)

NOTES

The enzymes values (U/L and µkat/L) are for a incubation temperature of 37 °C.

BMC: BioSystems master calibrator.

C-RSE/IFCC: Traceable to the reference system as described by the IFCC Committee on Reference Systems for Enzymes.

Table D.3. Biochemistry control serum – level - I

BIOCHEMISTRY CONTROL SERUM

LEVEL **I** LOT **062A**

COMPONENT	METHOD	VALUE	RANGE	UNITS	TRACEABILITY
ACID PHOSPHATASE	Naphthyl phosphate/pentanediol	7,32	3,66 - 11,0	U/L	BMC
		0,122	0,061 - 0,162	µkat/L	
ALBUMIN	Bromocresol green	25,8	21,1 - 30,4	g/L	SRM 927 c (NIST)
ALKALINE PHOSPHATASE	2-Amino-2-methyl-1-propanol buffer	155	127 - 183	U/L	BMC
		2,58	2,11 - 3,04	µkat/L	
	Diethanolamine buffer	223	183 - 263	U/L	BMC
		3,70	3,04 - 4,37	µkat/L	
ALT/GPT	IFCC without pyridoxal phosphate	33,4	27,3 - 39,4	U/L	BMC
		0,554	0,454 - 0,653	µkat/L	
	IFCC with pyridoxal phosphate	37,8	31,0 - 44,6	U/L	C-RSE/IFCC
		0,627	0,514 - 0,740	µkat/L	
α-AMYLASE	IFCC	122	99,9 - 144	U/L	C-RSE/IFCC
		2,02	1,66 - 2,39	µkat/L	
	Direct substrate	141	116 - 166	U/L	BMC
		2,34	1,92 - 2,76	µkat/L	
AST/GOT	IFCC without pyridoxal phosphate	44,1	36,2 - 52,1	U/L	BMC
		0,732	0,600 - 0,864	µkat/L	
	IFCC with pyridoxal phosphate	52,7	43,2 - 62,2	U/L	C-RSE/IFCC
		0,875	0,717 - 1,03	µkat/L	
BILIRUBIN, DIRECT	Diazotized sulfanilic	0,636	0,445 - 0,827	mg/dL	BMC
		10,9	7,61 - 14,1	µmol/L	
BILIRUBIN, TOTAL	Diazotized sulfanilic	2,17	1,78 - 2,56	mg/dL	SRM 909 b (NIST)
		37,0	30,4 - 43,7	µmol/L	
CALCIUM	Methylthymol blue	9,76	8,59 - 10,9	mg/dL	SRM 909 b (NIST)
		2,44	2,15 - 2,73	mmol/L	
	Arsenazo III	8,56	7,54 - 9,59	mg/dL	SRM 909 b (NIST)
		2,14	1,88 - 2,40	mmol/L	
CHLORIDE	Selective electrode	83,9	75,5 - 92,2	mmol/L	SRM 909 b (NIST)
CHOLESTEROL	Cholesterol oxidase/peroxidase	149	127 - 172	mg/dL	SRM 909 b (NIST)
		3,87	3,29 - 4,45	mmol/L	
CK	IFCC	180	144 - 215	U/L	C-RSE/IFCC
		2,98	2,38 - 3,58	µkat/L	
CREATININE	Alkaline picrate	1,54	1,26 - 1,81	mg/dL	SRM 909 b (NIST)
		136	112 - 160	µmol/L	
GLUCOSE	Glucose oxidase/peroxidase	84,2	71,6 - 96,9	mg/dL	BMC
		4,68	3,98 - 5,38	mmol/L	
γ-GT	IFCC	39,1	32,1 - 46,1	U/L	C-RSE/IFCC
		0,649	0,532 - 0,766	µkat/L	
IRON	Ferrozine	105	86,2 - 123	µg/dL	BMC
		18,7	15,4 - 22,0	µmol/L	
	Chromazurol B	38,0	31,4 - 44,7	µg/dL	BMC
		6,81	5,62 - 8,00	µmol/L	
LIPASE	Color	68,2	51,1 - 85,2	U/L	BMC
		1,13	0,849 - 1,42	µkat/L	
LDH	Pyruvate	398	326 - 470	U/L	BMC
		6,61	5,42 - 7,79	µkat/L	
	IFCC	175	144 - 207	U/L	C-RSE/IFCC
		2,91	2,39 - 3,44	µkat/L	
MAGNESIUM	Xylidyl Blue / Calmagite	1,20	0,960 - 1,44	mg/dL	SRM 909 b (NIST)
		0,492	0,393 - 0,590	mmol/L	
PHOSPHORUS	Phosphomolybdate/UV	4,17	3,42 - 4,92	mg/dL	BMC
		1,34	1,10 - 1,58	mmol/L	
POTASSIUM	Selective electrode	4,06	3,65 - 4,46	mmol/L	SRM 909 b (NIST)
PROTEIN, TOTAL	Biuret	50,0	44,0 - 56,0	g/L	SRM 927 c (NIST)
SODIUM	Selective electrode	114	103 - 126	mmol/L	SRM 909 b (NIST)
TRIGLYCERIDES	Glycerol phosphate oxydase/peroxydase	51,9	44,1 - 59,7	mg/dL	SRM 909 b (NIST)
		0,586	0,499 - 0,674	mmol/L	
UREA/BUN	Urease (Color / UV)	27,1	23,0 - 31,1	mg/dL	SRM 909 b (NIST)
		4,49	3,82 - 5,17	mmol/L	
URIC ACID	Uricase/peroxidase	5,57	4,73 - 6,40	mg/dL	SRM 909 b (NIST)
		331	282 - 381	µmol/L	

NOTES

The enzymes values (U/L and µkat/L) are for a incubation temperature of 37 °C.

BMC: BioSystems master calibrator.

C-RSE/IFCC: Traceable to the reference system as described by the IFCC Committee on Reference Systems for Enzymes.

Table D.4. Biochemistry control serum – level - II

BIOCHEMISTRY CONTROL SERUM

LEVEL **II** LOT **061A**

COMPONENT	METHOD	VALUE	RANGE	UNITS	TRACEABILITY
ACID PHOSPHATASE	Naphthyl phosphate/pentanediol	24,6	12,3 - 37,0	U/L	BMC
		0,409	0,205 - 0,614	µkat/L	
ALBUMIN	Bromocresol green	40,0	32,8 - 47,3	g/L	SRM 927 c (NIST)
ALKALINE PHOSPHATASE	2-Amino-2-methyl-1-propanol buffer	351	287 - 414	U/L	BMC
		5,82	4,77 - 6,87	µkat/L	
	Diethanolamine buffer	524	429 - 618	U/L	BMC
ALT/GPT	IFCC without pyridoxal phosphate	8,69	7,13 - 10,3	µkat/L	BMC
		190	156 - 224	U/L	
	IFCC with pyridoxal phosphate	3,16	2,59 - 3,73	µkat/L	BMC
		194	159 - 229	U/L	
α-AMYLASE	IFCC	234	194 - 274	U/L	C-RSE/IFCC
		3,22	2,64 - 3,80	µkat/L	
	Direct substrate	744	610 - 878	U/L	BMC
AST/GOT	IFCC without pyridoxal phosphate	12,4	10,1 - 14,6	µkat/L	BMC
		770	631 - 909	U/L	
	IFCC with pyridoxal phosphate	12,8	10,5 - 15,1	µkat/L	C-RSE/IFCC
BILIRUBIN, DIRECT	Diazotized sulfanilic	184	151 - 217	U/L	BMC
		3,05	2,50 - 3,60	µkat/L	
BILIRUBIN, TOTAL	Diazotized sulfanilic	207	170 - 244	U/L	BMC
		3,43	2,82 - 4,05	µkat/L	
CALCIUM	Methylthymol blue	1,72	1,20 - 2,23	mg/dL	SRM 909 b (NIST)
		29,3	20,5 - 38,1	µmol/L	
CHLORIDE	Selective electrode	6,20	5,08 - 7,31	mg/dL	SRM 909 b (NIST)
		106	86,9 - 125	µmol/L	
		13,5	11,8 - 15,1	mmol/L	
CHOLESTEROL	Cholesterol oxidase/peroxidase	3,36	2,96 - 3,77	mg/dL	SRM 909 b (NIST)
		11,8	10,4 - 13,2	mmol/L	
CK	IFCC	2,95	2,60 - 3,30	mmol/L	SRM 909 b (NIST)
		503	403 - 604	U/L	
CREATININE	Alkaline picrate	8,36	6,69 - 10,0	µkat/L	SRM 909 b (NIST)
		4,67	3,83 - 5,51	mg/dL	
GLUCOSE	Glucose oxidase/peroxidase	413	339 - 488	µmol/L	BMC
		264	224 - 304	mg/dL	
γ-GT	IFCC	14,7	12,5 - 16,9	mmol/L	BMC
		223	183 - 263	U/L	
IRON	Ferrozine	3,71	3,04 - 4,37	µkat/L	C-RSE/IFCC
		214	177 - 252	µg/dL	
	Chromazurol B	38,3	31,6 - 45,0	µmol/L	BMC
LIPASE	Color	77,9	64,3 - 91,6	µg/dL	BMC
		13,9	11,5 - 16,4	µmol/L	
LDH	Pyruvate	118	88,2 - 147	U/L	BMC
		1,95	1,46 - 2,44	µkat/L	
	IFCC	733	601 - 865	U/L	C-RSE/IFCC
MAGNESIUM	Xylydyl Blue / Calmagite	348	286 - 411	U/L	SRM 909 b (NIST)
		5,78	4,74 - 6,82	µkat/L	
PHOSPHORUS	Phosphomolybdate/UV	2,94	2,35 - 3,53	mg/dL	BMC
		1,21	0,964 - 1,45	mmol/L	
POTASSIUM	Selective electrode	8,93	7,32 - 10,5	mg/dL	SRM 909 b (NIST)
PROTEIN, TOTAL	Biuret	2,88	2,36 - 3,39	mmol/L	SRM 909 b (NIST)
SODIUM	Selective electrode	7,00	6,30 - 7,69	mmol/L	SRM 909 b (NIST)
		160	144 - 176	mmol/L	
TRIGLYCERIDES	Glycerol phosphate oxydase/peroxydase	211	180 - 243	mg/dL	SRM 909 b (NIST)
		2,39	2,03 - 2,75	mmol/L	
UREA/BUN	Urease (Color / UV)	146	124 - 168	mg/dL	SRM 909 b (NIST)
		24,2	20,6 - 27,9	mmol/L	
URIC ACID	Uricase/peroxidase	9,53	8,10 - 11,0	mg/dL	SRM 909 b (NIST)
		568	482 - 653	µmol/L	

NOTES

The enzymes values (U/L and µkat/L) are for a incubation temperature of 37 °C.

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