

	هيئة الطاقة الذرية	
هيئة مخابر التحاليل الطبية اللجنة المركزية		وزارة الصحة مديرية مخابر الصحة العامة

تقرير مرحلي عن نتائج البرنامج الوطني لضبط جودة معايرة الواسمات الورمية

الدورة الرابعة

تشرين أول - 2004

إعداد : هيئة الطاقة الذرية - مكتب ضمان الجودة

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البرنامج الوطني لضبط جودة معايرة الواسمات الورمية

* ** *

()

.BIAS

T.PSA

F.PSA

:

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			-1
		.(Immuno Radio Metric Assay):IRMA	-2
			-1-2
			- 2-2
			-3-2
			-4-2
			-3
			-4
			-5
			-6
		(1)	-1-6
		(2)	-2-6
	.(7-3) ()	(A)	-3-6
	.(9 -8)	(B)	-4-6
	.(13-10)		-5-6
	.(29-14)	(C)	-6-6
	.BIAS (Histogram)	(D)	-7-6
.T.PSA	BIAS		-
.F.PSA	BIAS		-
.CA 15-3	BIAS		-
.CEA	BIAS		-
			-7
			-8
			-9

: -1

ISO/IES-17025:1999

M-10 ISO/IES-17025:1999

:(Immuno Radio Metric Assay) :IRMA -2

I^{125} ()
(- -)

Gamma Counter

: -1-2

PSA - Immuno Radio Metric Assay - IRMA

I^{125})
(-

Standards

Gamma Counter

T.PSA

:

-2-2

..% 22

:

65

:

.(34-20

)

◀

.(45 -40

)

◀

.(Wilm`s Tumor

)

◀

Biochemical Substances

Tumor Markers

humoral tumor

cellular tumor markers

markers

Tracer

Antigenic

¹²⁵I

monoclonal antibodies

:

-3-2

PSA, CEA, CA 15-3 :

.1

:

.2

P53, Cerb B2,

-

UPA, EGFR, Cath D,

-

-4-2

.1

.2

.3

.4

.5

.6

.7

-3

Z-Score

.1

.BIAS

.2

.3

.4

.5

-4

.(2)

-

-1-5

:

()



()



Ht

-70

Ht



50 -45

80

45

15 -10 / 3000

° 85-

10



UK NEQAS

10



:

-2-5



DIXON

BIAS



$$BIAS = \frac{X_{th} - X_{ana}}{X_{th}} \times 100 ;$$

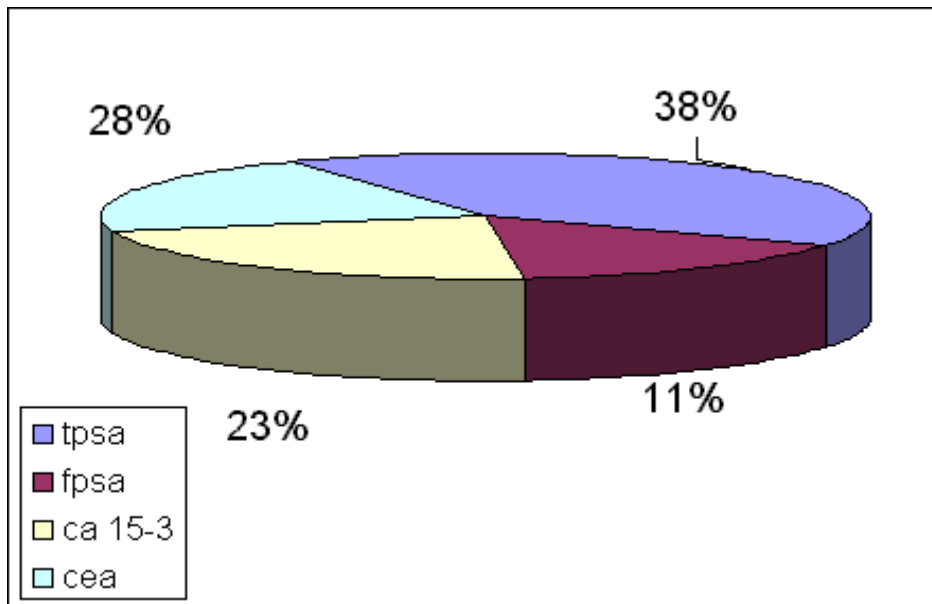
X_{ana}

X_{th} :

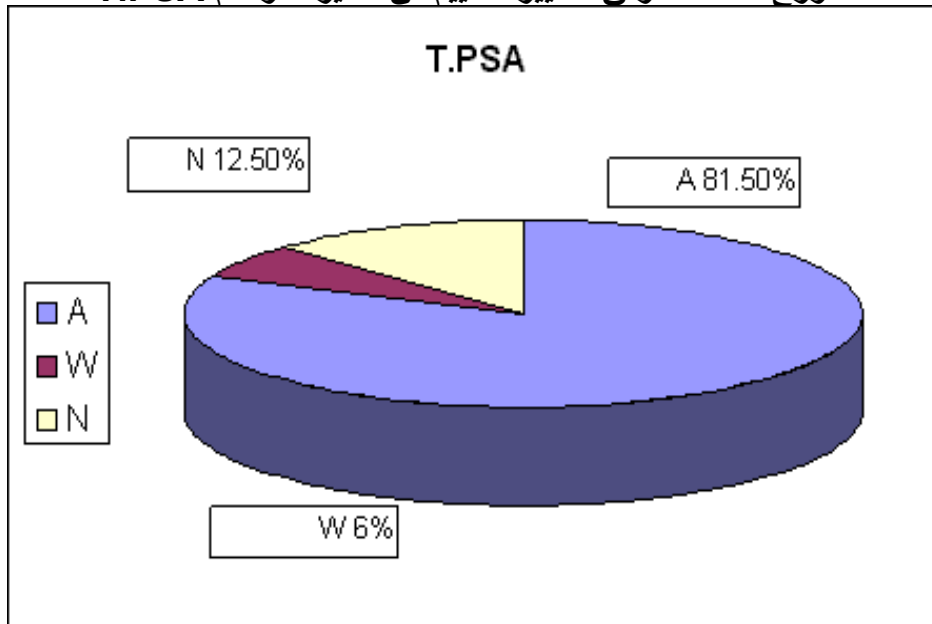
A :
%20 BIAS (A)ceptable)
%20 %30 BIAS
(A)ceptable with W(arning) W
%30 BIAS
(N)ot acceptable) N

: -3-5

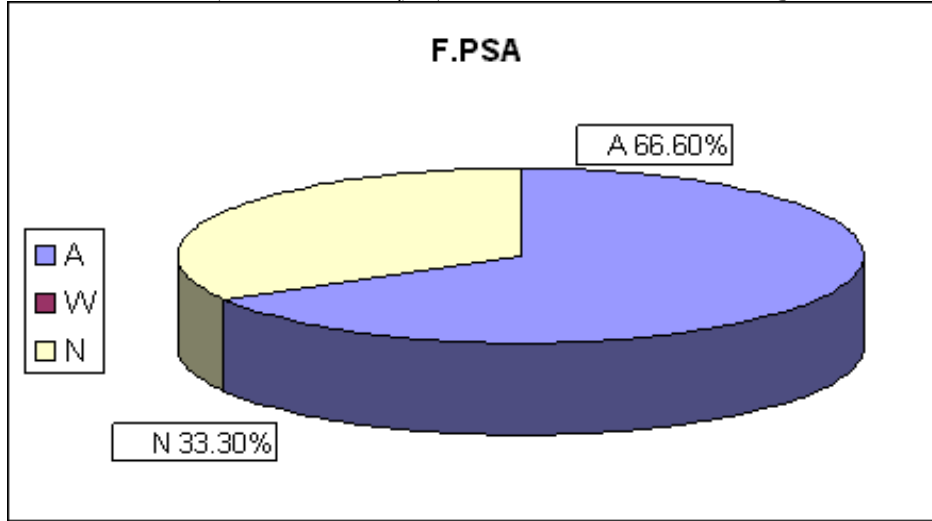
-
-
-
-



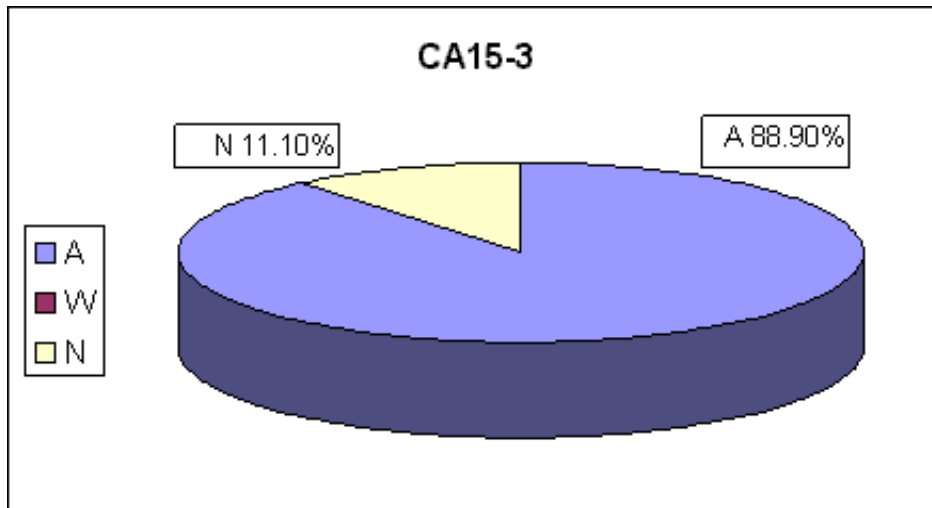
توزع العلامات وفق معايير التقييم في معايرة الواسم T.PSA



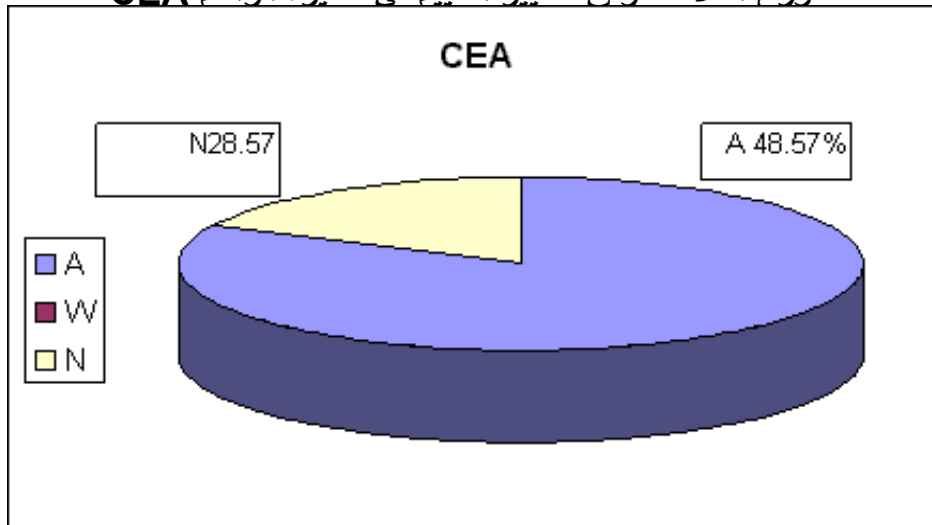
توزيع العلامات وفق معايير التقييم في معايرة الواسم F.PSA



توزيع العلامات وفق معايير التقييم في معايرة الواسم CA 15-3



توزيع العلامات وفق معايير التقييم في معايرة الواسم CEA



(1) - 1-6

				#
shal baba@scs-net.org	6611434			01
-	2238766			02
-	3318696			03
m.t.jabasini@anoth	3317485-fax 3317485			04
farramed@sscs-net.org	4428520- fax 3733880			05
-	2216112			06
-	575001			07
-	2226052			08
-	2241013			09
-	2120501			10
-	235364			11
-	239444			12
-	238713			13
-	315-388			14
nhid-b@scs-net.org	222229- fax 313337			15
-	222252			16
-	476644			17
-	-	-	-	18
-	-	-	-	19
-	-	-	-	20
-	-	-	-	21
-	-	-	-	22

ملاحظة: تم إلغاء أسماء وعناوين المخابر التي لم تشارك في هذه الدورة.

CEA	CA-15-3	P.S.A. free	P.S.A. total	
Elecsys	-	Elecsys	Elecsys	1010
-	-	-	-	1018
Vidas	Immulite	-	Vidas	1054
AXSYM	AXSYM	AXSYM	AXSYM	1060
Vidas	Vidas	Vidas	Vidas	1070
Vidas	Vidas	Vidas	Vidas	1112
Vidas	Vidas	Vidas	Vidas	1113
Vidas	Vidas	Vidas	Vidas	1140
immulite	immulite	immulite	immulite	1141
Vidas	Vidas	Vidas	Vidas	1195
Elecsys	AXSYM	Elecsys	Elecsys	1231
Elecsys	-	-	Elecsys	1252
Elecsys	Elecsys	Elecsys	Elecsys	1268
Elecsys	Elecsys	Elecsys	Elecsys	1283
Vidas	Vidas	Vidas	Vidas	1286
-	-	-	-	1298
AXSYM	AXSYM	AXSYM	AXSYM	1328
-	-	-	Vidas	2021
-	-	-	Vidas	2085
-	-	-	Vidas	2121
Vidas	Vidas	-	Vidas	2146
Vidas	Vidas	Vidas	Vidas	2170
Elecsys	Elecsys	-	Elecsys	2235
Elecsys	Elecsys	AXSYM	AXSYM	2240
-	-	-	Vidas	2516
Vidas	-	-	Vidas	2518
IMX	-	-	IMX	3002
Vidas	Vidas	Vidas	Vidas	3005
Vidas	Vidas	Vidas	Vidas	3058
Elecsys	Elecsys	-	Elecsys	3069
-	-	-	-	3073
immulite	immulite	Immulite	immulite	3105
-	-	-	Vidas	3152
immulite	-	immulite	immulite	3259
-	-	-	Vidas	4138
-	immulite	-	immulite	4154
-	Elecsys	-	Elecsys	4171
Elecsys	Elecsys	-	Elecsys	4180
-	-	-	Elecsys	4318
-	-	-	Vidas	5259
-	-	-	-	7001

(A)

()

ELECSYS

(3)

F.PSA ng/mL				T.PSA ng/mL				
	9.78		9.69	average =37.96 Std =4.38	39.01	Average =37.90 Std =4.58	39.34	1010
	17.24		17.22		33.13		32.51	1268
	-		-		36.25		36.42	4171
	-		-		43.45		43.34	4318

ELECSYS

جدول (4)

CEA ng/mL				CA15-3U/mL				
average =2.08 Std =0.48	2.60	Average =1.5 Std =0.6	2.18	Average =15.24 Std =0.94	-	Average= 146.53 Std =11.66	-	1010
	1.93		1.18		15.83		159	1268
	1.7		1.1		14.15		135.9	2240
	-		-		15.73		144.7	4171

VIDAS

المعايرة جدول (5)

F.PSA ng/mL				T.PSA ng/mL				
	-		-	Average =31.79 Std =2.45	30.65	average =31.89 Std =2.09	32.4	1054
	>40		>40		31.2		31.8	1070
	-		-		33.15		32.07	1140
	>10		>10		29.4		29.7	1195
	-		-		28.72		30.07	2085
	-		-		29.56		29.63	2146
	>10		>10		30.67		29.71	2170
	-		-		34.08		33.17	2516
	-		-		32.28		32.29	2518
	-		-		32.9		33.5	3125
	-		-		37.11		36.50	4138

VIDAS

جدول (6)

CEA ng /mL				CA15-3U /mL				
average =0.95	1.14	average = 0.74	0.81	average =17.39	-	average =140.34	-	1054
	0.92		0.79		16.61		129.95	1070
Std =0.11	0.92	Std = 0.06	0.75	Std =0.86	18.22	Std =7.14	135.89	1140
	0.91		0.68		17.2		143.9	1195
	0.85		0.75		17.52		145.72	2146
	-		0.66		-		146.23	2170
	-		-		-		-	-

Immulite

جدول (7)

CEA ng /mL				CA15-3U /mL				
average =	-	average =	-	average =	15.9	average =	86.0	1054
Std =	-	Std =	-	Std =	-	Std =	-	1141
	-		-		-		-	3105
	-		-		-		-	3259
	-		-		-		-	4154

*

.(Immulite)

(AXSYM)

:

(B)

:

-

2004 /

PSA

(8)

(02) F 26.9 = ng /mL F.PSA	(01) F 26.9= ng /mL F.PSA	(02)T 51.8 = ng /mL T.PSA	(01) T 51.8 =ng /mL T.PSA		#
9.78	9.69	39.01	39.34	1010	01
-	-	-	-	1018	02
-	-	30.65	32.4	1054	03
-	-	-	-	1060	04
>40	>40	31.2	31.8	1070	05
-	-	-	-	1112	06
-	-	-	-	1113	07
-	-	33.15	32.07	1140	08
-	-	-	-	1141	09
>10	>10	29.4	29.7	1195	10
-	-	-	-	1231	11
-	-	-	-	1252	12
17.24	17.22	33.13	32.51	1268	13
-	-	-	-	1283	14
-	-	-	-	1286	15
-	-	-	-	1298	16
-	-	-	-	1328	17
-	-	-	-	2021	18
-	-	28.72	30.07	2085	19
-	-	-	-	2121	20
-	-	29.56	29.63	2146	21
>10	>10	30.67	29.71	2170	22
-	-	-	-	2235	23
>10	>10	21.4	17.3	2240	24
-	-	34.08	33.17	2516	25
-	-	32.28	32.29	2518	26
-	-	-	-	3002	27
-	-	-	-	3005	28
-	-	-	-	3058	29
-	-	-	-	3069	30
-	-	-	-	3073	31
-	-	-	-	3105	32
-	-	32.9	33.5	3152	33
-	-	-	-	3259	34
-	-	37.11	36.50	4138	35
-	-	-	-	4154	36
-	-	36.25	36.42	4171	37
-	-	-	-	4180	38
-	-	43.45	43.34	4318	39
-	-	-	-	5259	40
-	-	-	-	7001	41

2004 /

CA15-3&CEA

(9)

(02) CEA ng /mL= 0.6	(01) CEA ng /mL= 0.3	(02) CA15-3 U /mL= 15.5	(01) CA15-3 U /mL=118.9		#
2.60	2.18	-	-	1010	01
-	-	-	-	1018	02
1.14	0.81	15.9	86.0	1054	03
-	-	-	-	1060	04
0.92	0.79	16.61	129.95	1070	05
-	-	-	-	1112	06
-	-	-	-	1113	07
0.92	0.75	18.22	135.89	1140	08
-	-	-	-	1141	09
0.91	0.68	17.2	143.9	1195	10
-	-	-	-	1231	11
-	-	-	-	1252	12
1.93	1.18	15.83	159	1268	13
-	-	-	-	1283	14
-	-	-	-	1286	15
-	-	-	-	1298	16
-	-	-	-	1328	17
-	-	-	-	2021	18
-	-	-	-	2085	19
-	-	-	-	2121	20
0.85	0.75	17.52	145.72	2146	21
-	0.66	-	146.23	2170	22
-	-	-	-	2235	23
1.7	1.1	14.15	135.9	2240	24
-	-	-	-	2516	25
-	-	-	-	2518	26
-	-	-	-	3002	27
-	-	-	-	3005	28
-	-	-	-	3058	29
-	-	-	-	3069	30
-	-	-	-	3073	31
-	-	-	-	3105	32
-	-	-	-	3152	33
-	-	-	-	3259	34
-	-	-	-	4138	35
-	-	-	-	4154	36
-	-	15.73	144.7	4171	37
-	-	-	-	4180	38
-	-	-	-	4318	39
-	-	-	-	5259	40
-	-	-	-	7001	41

(01) PSA

(10)

	F.PSA ng/ mL= 26.9		T.PSA ng/ mL= 51.8		#
	9.69		39.34	1010	01
	-		-	1018	02
	-		32.4	1054	03
	-		-	1060	04
	> 40 *		31.8	1070	06
	-		-	1112	07
	-		-	1113	07
	-		32.07	1140	08
	-		-	1141	09
	>10		29.7	1195	10
	-		-	1231	11
	-		-	1252	12
	17.22		32.51	1268	13
	-		-	1283	14
	-		-	1286	15
	-		-	1298	16
	-		-	1328	17
	-		-	2021	18
	-		30.07	2085	19
	-		-	2121	20
	-		29.63	2146	21
	>10		29.71	2170	22
	-		-	2235	23
	>10		17.3 *	2240	24
	-		33.17	2516	25
	-		32.29	2518	26
	-		-	3002	27
	-		-	3005	28
	-		-	3058	29
	-		-	3069	30
	-		-	3073	31
	-		-	3105	32
	-		33.5	3152	33
	-		-	3259	34
	-		36.50	4138	35
	-		-	4154	36
	-		36.42	4171	37
	-		-	4180	38
	-		43.34	4318	39
	-		-	5259	40
	-		-	7001	41

AV=11.4
Std=3.3

AV=32.5
Std=4.9

*

(02) PSA

(11)

	F.PSA ng/ mL = 26.9		T.PSA ng/ mL= 51.8		#
	9.78		39.01	1010	01
	-		-	1018	02
	-		30.65	1054	03
	-		-	1060	04
	> 40 *		31.2	1070	05
	-		-	1112	06
	-		-	1113	07
	-		33.15	1140	08
	-		-	1141	09
	>10		29.4	1195	10
	-		-	1231	11
	-		-	1252	12
	17.24		33.13	1268	13
	-		-	1283	14
	-		-	1286	15
	-		-	1298	16
	-		-	1328	17
	-		-	2021	18
	-		28.72	2085	19
	-		-	2121	20
	-		29.56	2146	21
	>10		30.67	2170	22
	-		-	2235	23
	>10		21.4*	2240	24
	-		34.08	2516	25
	-		32.28	2518	26
	-		-	3002	27
	-		-	3005	28
	-		-	3058	29
	-		-	3069	30
	-		-	3073	31
	-		-	3105	32
	-		32.9	3152	33
	-		-	3259	34
	-		37.11	4138	35
	-		-	4154	36
	-		36.25	4171	37
	-		-	4180	38
	-		43.45	4318	39
	-		-	5259	40
	-		-	7001	41

AV=11.40
Std= 3.3

AV=32.7
Std= 3.1

*

CA15-3

(12)

	(02) CA15-3=15.5 U/mL		(01) CA15-3=118.9 U/mL		#
	-		-	1010	01
	-		-	1018	02
	15.9		86.0*	1054	03
	-		-	1060	04
	16.61		129.95	1070	05
	-		-	1112	06
	-		-	1113	07
	18.22		135.89	1140	08
	-		-	1141	09
	17.2		143.9	1195	10
	-		-	1231	11
	-		-	1252	12
	15.83		159	1268	13
	-		-	1283	14
	-		-	1286	15
	-		-	1298	16
	-		-	1328	17
	-		-	2021	18
	-		-	2085	19
	-		-	2121	20
	17.52		145.72	2146	21
	-		146.23	2170	22
	-		-	2235	23
	14.15		135.9	2240	24
	-		-	2516	25
	-		-	2518	26
	-		-	3002	27
	-		-	3005	28
	-		-	3058	29
	-		-	3069	30
	-		-	3073	31
	-		-	3105	32
	-		-	3152	33
	-		-	3259	34
	-		-	4138	35
	-		-	4154	36
	15.73		144.7	4171	37
	-		-	4180	38
	-		-	4318	39
	-		-	5259	40
	-		-	7001	41

AV= 16.4
Std= 1.27

AV=133.5
Std= 8.8

*

CEA

(13)

	(02) CEA= 0.6 ng/mL		(01) CEA= 0.3 ng/mL		#
	2.60*		2.18*	1010	01
	-		-	1018	02
	1.14		0.81	1054	03
	-		-	1060	04
	0.92		0.79	1070	05
	-		-	1112	06
	-		-	1113	07
	0.92		0.75	1140	08
	-		-	1141	09
	0.91		0.68	1195	10
	-		-	1231	11
	-		-	1252	12
	1.93*		1.18*	1268	13
	-		-	1283	14
	-		-	1286	15
	-		-	1298	16
	-		-	1328	17
	-		-	2021	18
	-		-	2085	19
	-		-	2121	20
	0.85		0.75	2146	21
	-		0.66	2170	22
	-		-	2235	23
	1.7*		1.1*	2240	24
	-		-	2516	25
	-		-	2518	26
	-		-	3002	27
	-		-	3005	28
	-		-	3058	29
	-		-	3069	30
	-		-	3073	31
	-		-	3105	32
	-		-	3152	33
	-		-	3259	34
	-		-	4138	35
	-		-	4154	36
	-		-	4171	37
	-		-	4180	38
	-		-	4318	39
	-		-	5259	40
	-		-	7001	41

AV =0.94
Std= 0.11

AV=0.74
Std= 0.06

*

(C)

(1010)

(14)

CEA			CA - 15-3			P.S.A free			P.S.A total			
	ng/ml			u/ml			ng/ml			ng/ml		
N	2.18	0.74			133.5	A	9.69	11.4	A	39.34	32.5	01
N	2.60	0.94			16.4	A	9.78	11.4	A	39.01	32.7	02

(1054)

(15)

CEA			CA - 15-3			P.S.A free			P.S.A total			
	ng/ml			u/ml			ng/ml			ng/ml		
A	0.81	0.74	N	86.0	133.5			11.4	A	32.4	32.5	01
W	1.14	0.94	A	15.9	16.4			11.4	A	30.65	32.7	02

(1070)

(16)

CEA			CA - 15-3			P.S.A free			P.S.A total			
	ng/ml			u/ml			ng/ml			ng/ml		
A	0.79	0.74	A	129.95	133.5	N	>40	11.4	A	31.8	32.5	01
A	0.92	0.94	A	16.61	16.4	N	>40	11.4	A	31.2	32.7	02

(A) Acceptable
(W) Acceptable with warning
(N) Not Acceptable

(1140)

(17)

CEA			CA - 15-3			P.S.A free			P.S.A total			
	ng/ml			u/ml			ng/ml			ng/ml		
A	0.75	0.74	A	135.89	133.5		11.4	A	32.07	32.5	01	
A	0.92	0.94	A	18.22	16.4		11.4	A	33.15	32.7	02	

(1195)

(18)

CEA			CA 15-3			P.S.A free			P.S.A total			
	ng/ml			u/ml			ng/ml			ng/ml		
A	0.68	0.74	A	143.9	133.5	W	>10	11.4	A	29.7	32.5	01
A	0.91	0.94	A	17.2	16.4	W	>10	11.4	A	29.4	32.7	02

(1268)

(19)

CEA			CA 15-3			P.S.A free			P.S.A total			
	ng/ml			u/ml			ng/ml			ng/ml		
N	1.18	0.74	A	159	133.5	N	17.22	11.4	A	32.51	32.5	01
N	1.93	0.94	A	15.83	16.4	N	17.24	11.4	A	33.13	32.7	02

(A) Acceptable
(W) Acceptable with warning
(N) Not Acceptable

(2085)

(20)

CEA			CA – 15-3			P.S.A free			P.S.A total		
	ng/ml			u/ml			ng/ml			ng/ml	
	0.74			133.5			11.4	A	30.07	32.5	01
	0.94			16.4			11.4	A	28.72	32.7	02

(2146)

(21)

CEA			CA – 15-3			P.S.A free			P.S.A total		
	ng/ml			u/ml			ng/ml			ng/ml	
A	0.75	0.74	A	145.72	133.5		11.4	A	29.63	32.5	01
A	0.85	0.94	A	17.52	16.4		11.4	A	29.56	32.7	02

(2170)

(22)

CEA			CA – 15-3			P.S.A free			P.S.A total			
	ng/ml			u/ml			ng/ml			ng/ml		
A	0.66	0.74	A	146.23	133.5	W	>10	11.4	A	29.71	32.5	01
	0.94			16.4		W	>10	11.4	A	30.67	32.7	02

(A) Acceptable
(W) Acceptable with warning
(N) Not Acceptable

(2240)

(23)

CEA			CA – 15-3			P.S.A free			P.S.A total			
	ng/ml			u/ml			ng/ml			ng/ml		
N	1.1	0.74	A	135.9	133.5	W	>10.0	11.4	N	17.3	32.5	01
N	1.7	0.94	A	14.15	16.4	W	>10.0	11.4	N	21.4	32.7	02

(2516)

(24)

CEA			CA – 15-3			P.S.A free			P.S.A total			
	ng/ml			u/ml			ng/ml			ng/ml		
		0.74			133.5			11.4	A	33.17	32.5	01
		0.94			16.4			11.4	A	34.08	32.7	02

(2518)

(25)

CEA			CA – 15-3			P.S.A free			P.S.A total			
	ng/ml			u/ml			ng/ml			ng/ml		
		0.74			133.5			11.4	A	32.29	32.5	01
		0.94			16.4			11.4	A	32.28	32.7	02

(A) Acceptable
(W) Acceptable with warning
(N) Not Acceptable

(3152)

(26)

CEA		CA - 15-3			P.S.A free			P.S.A total		
	ng/ml		u/ml			ng/ml		ng/ml		
	0.74		133.5			11.4	A	33.5	32.5	01
	0.94		16.4			11.4	A	32.9	32.7	02

(4138)

(27)

CEA		CA - 15-3			P.S.A free			P.S.A total		
	ng/ml		u/ml			ng/ml		ng/ml		
	0.74		133.5			11.4	A	36.50	32.5	01
	0.94		16.4			11.4	A	37.11	32.7	02

(4171)

(28)

CEA		CA - 15-3			P.S.A free			P.S.A total		
	ng/ml		u/ml			ng/ml		ng/ml		
	0.74	A	144.7	133.5		11.4	A	36.42	32.5	01
	0.94	A	15.73	16.4		11.4	A	36.25	32.7	02

(4318)

(29)

CEA		CA - 15-3			P.S.A free			P.S.A total		
	ng/ml		u/ml			ng/ml		ng/ml		
	0.74		133.5			11.4	N	43.34	32.5	01
	0.94		16.4			11.4	N	43.45	32.7	02

(A) Acceptable
(W) Acceptable with warning
(N) Not Acceptable

	:	-7
%38.09	:	.1
	.%58.53	
	T.PSA	.2
	F.PSA	.3
	> <	
. CA 15-3 & CEA		.4
F.PSA, CA15-3&)		.5
	(CEA	.6
	:	
	:	-8

: -9

[1] Prescriptions Générales Concernant la Compétence des Laboratoires d'étalonnage et d'Essais- 1991- Ottawa-Ontario-Canada.

[2] Harmonised Guidelines for Internal Quality Control in Analytical Chemistry Laboratories-1994- ISO/REMCO.

[3] General Requirements for The Competence of Testing and Calibration Laboratories- ISO/IEC- 17025:1999.

[4] International Soil-Analytical Exchange “ Quarterly Reports” for years from 1995 to 1999.

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[10].2003 / -

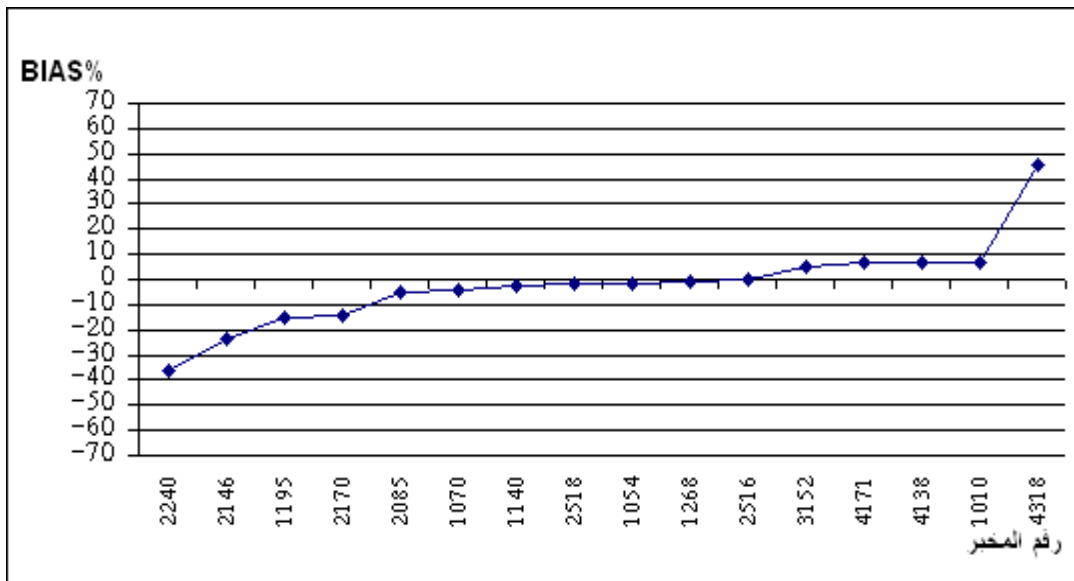
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(D)

(Histogram)

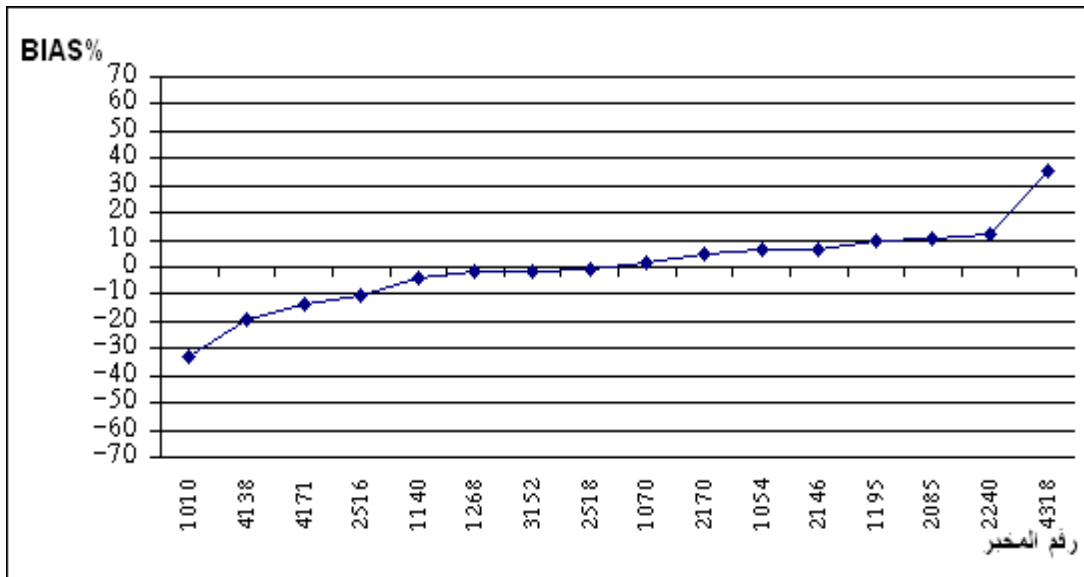
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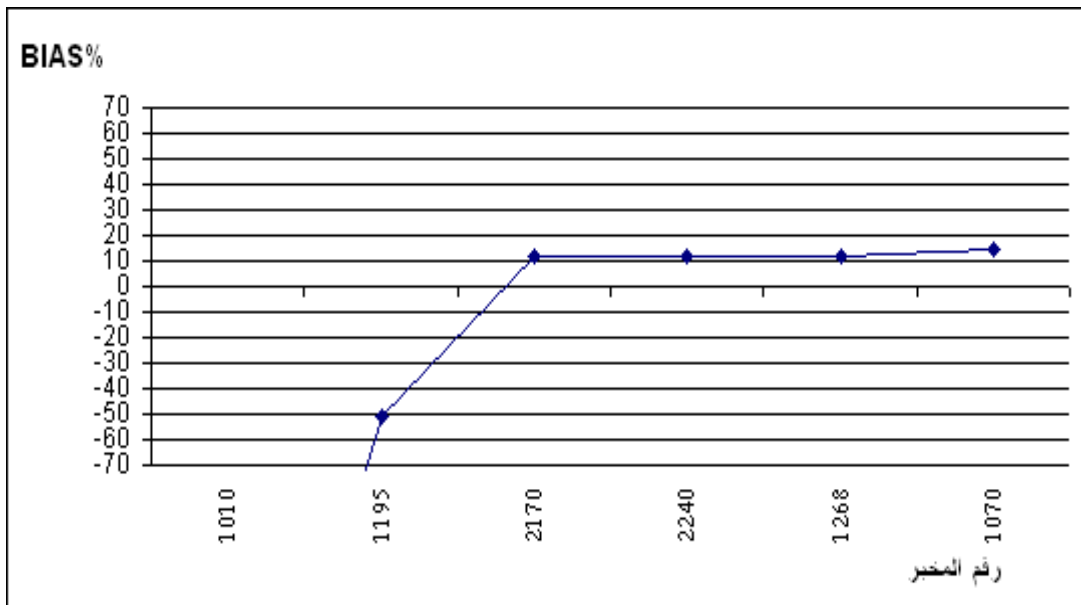
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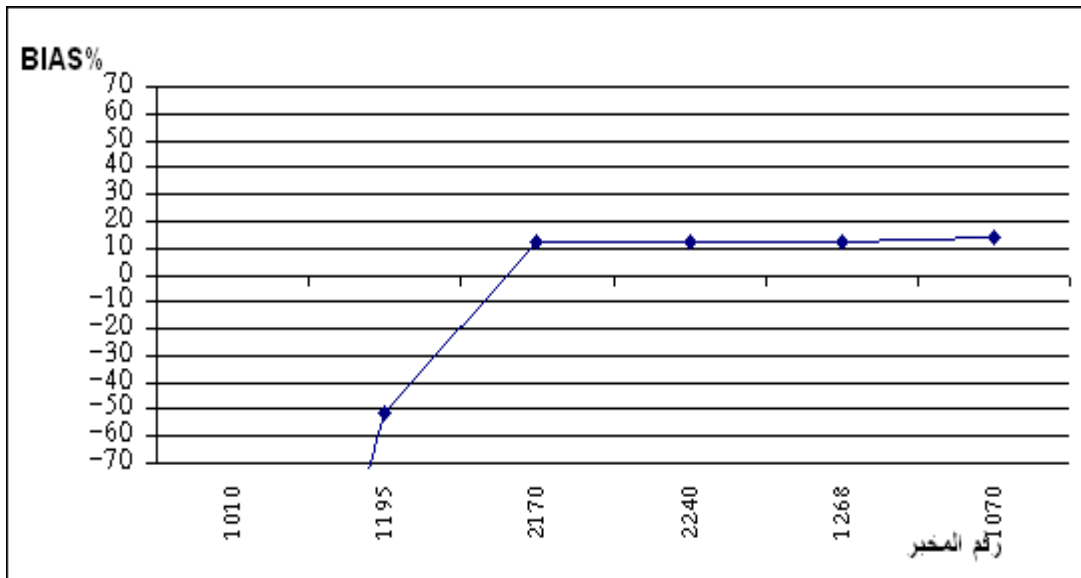
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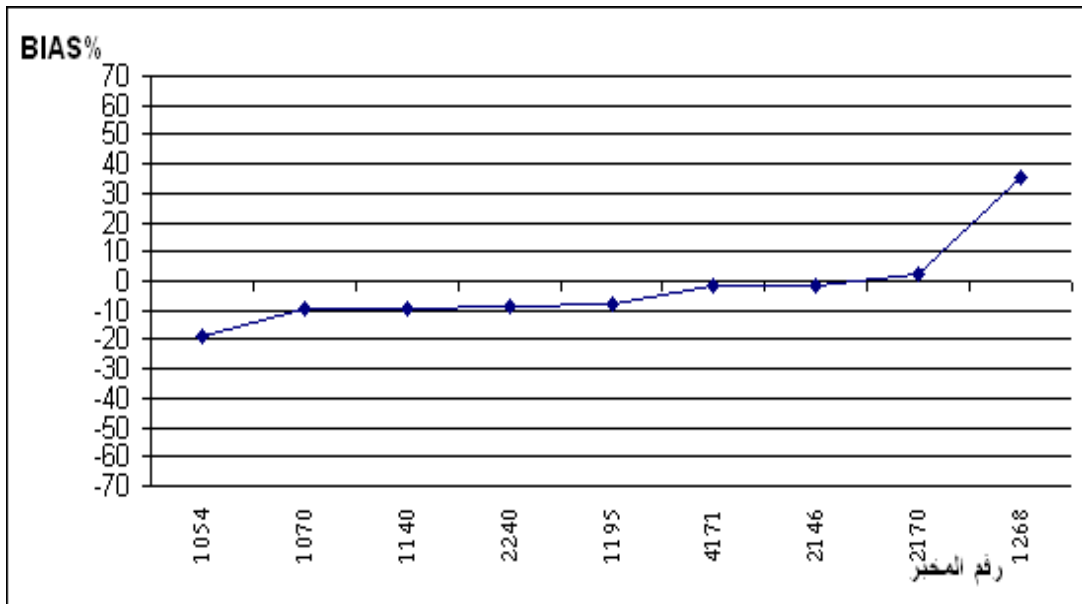
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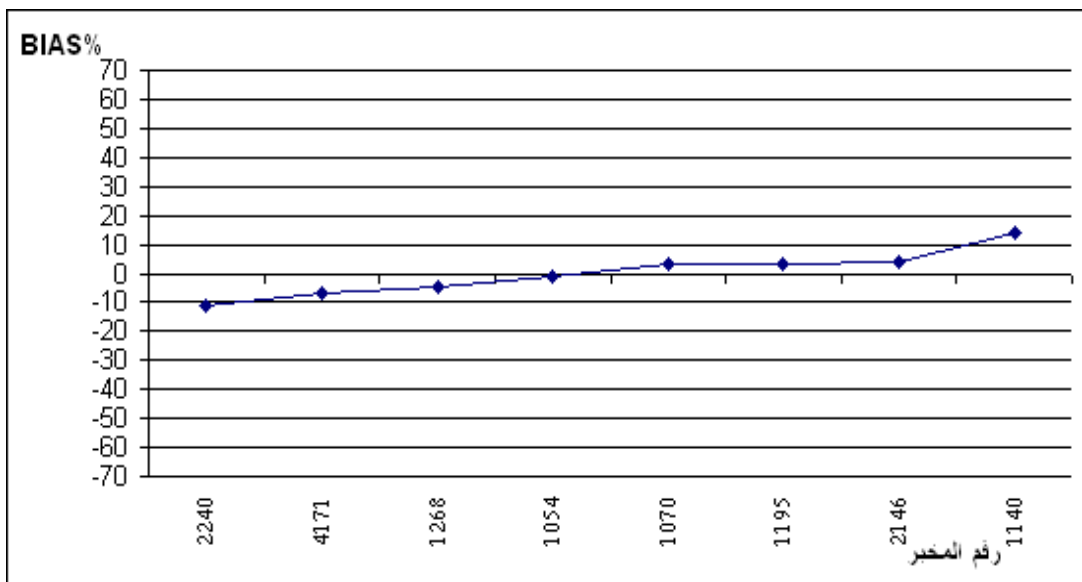
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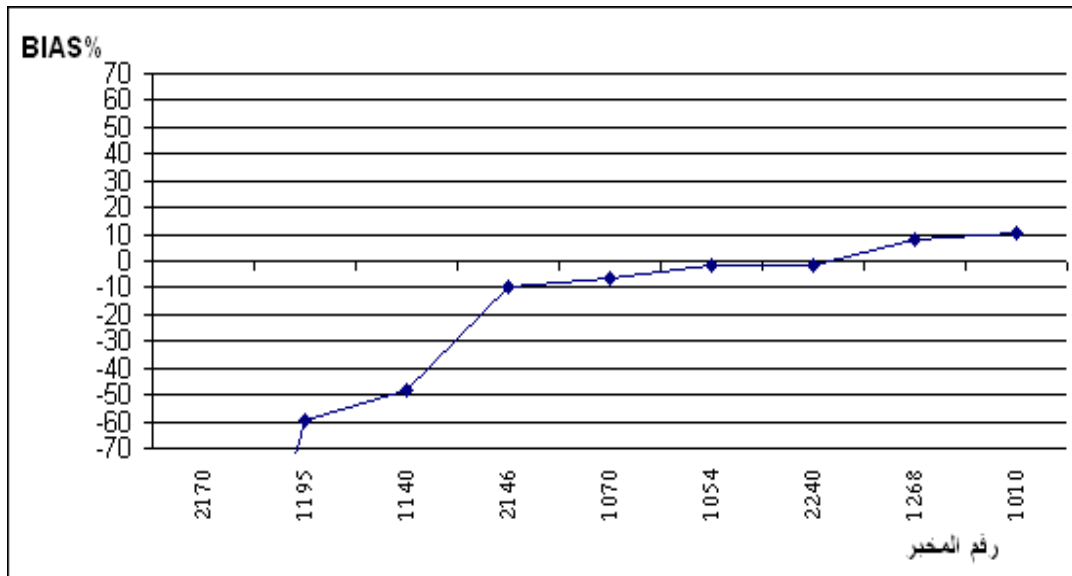
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CEA-01

BIAS



CEA-02

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