

هيئة الطاقة الذرية

هيئة مخابر التحاليل الطبية
اللجنة المركزية



وزارة الصحة
مديرية مخابر الصحة العامة

تقرير مرحلي عن نتائج البرنامج الوطني لتقييم جودة معايرة الواسمات الورمية

الدورة الثانية 2006

إعداد : هيئة الطاقة الذرية - مكتب ضمان الجودة

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البرنامج الوطني لتقييم جودة معايرة الواسمات الورمية

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2006

(Control chart)

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.BIAS

T.PSA

F.PSA

25

62

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(1).

(2) .

ISO/IES-17025:2005

M-10 ISO/IES-17025:2005

(3).

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-2

..% 22

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(4) .

65

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.(34-20

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◀

.(45 -40

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.(Wilm`s Tumor

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◀

Biochemical Substances

Tumor Markers

Tracer

¹²⁵I

Antigenic

cellular tumor markers

humoral tumor markers

monoclonal antibodies

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-1-2

PSA, CEA, CA 15-3 :

.1

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.2

P53, Cerb B2,

-

UPA, EGFR, Cath D,

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-2-2

.1

.2

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.4

.5

.6

.7

: -3

(5).

Z-Score

.1

.RE

.2

.3

.4

.5

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-4

(2)

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-5

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-1-5

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➤

()

➤

Ht

80 -70

Ht

➤

50 -45

45

15 -10 / 3000

1

° 85-

10



UK NEQAS

10



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-2-5



Z-Score



. RE

DIXON



(7 6) .

RE



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

X_{ana}

X_{th} :

:

A

%20

(Aceptable)

%20

%30

(Acceptable with Warning) W

%30

(8) .(Not acceptable) N

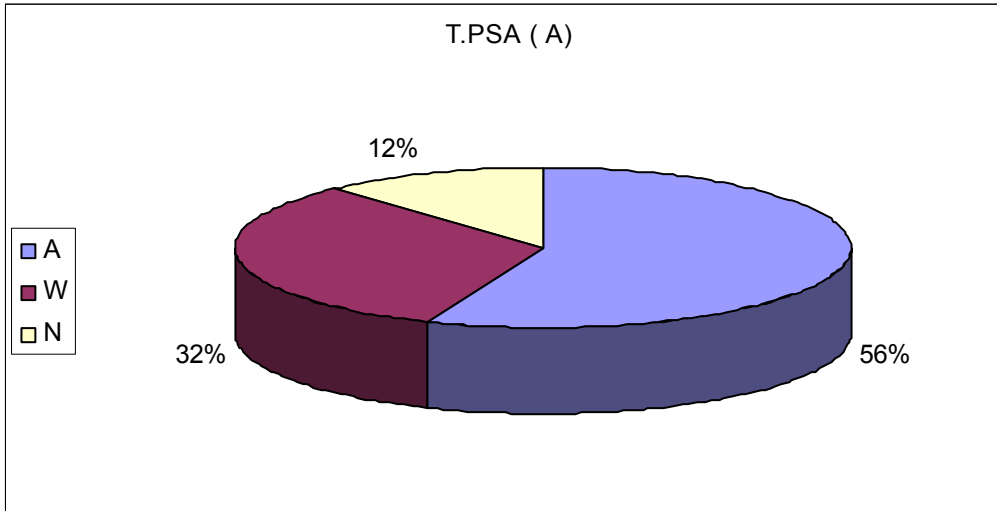


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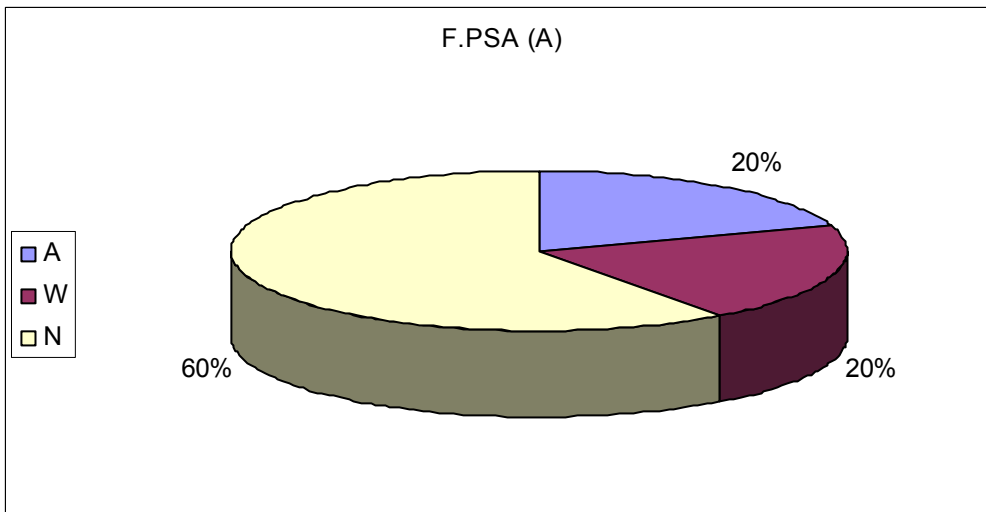
-3-5



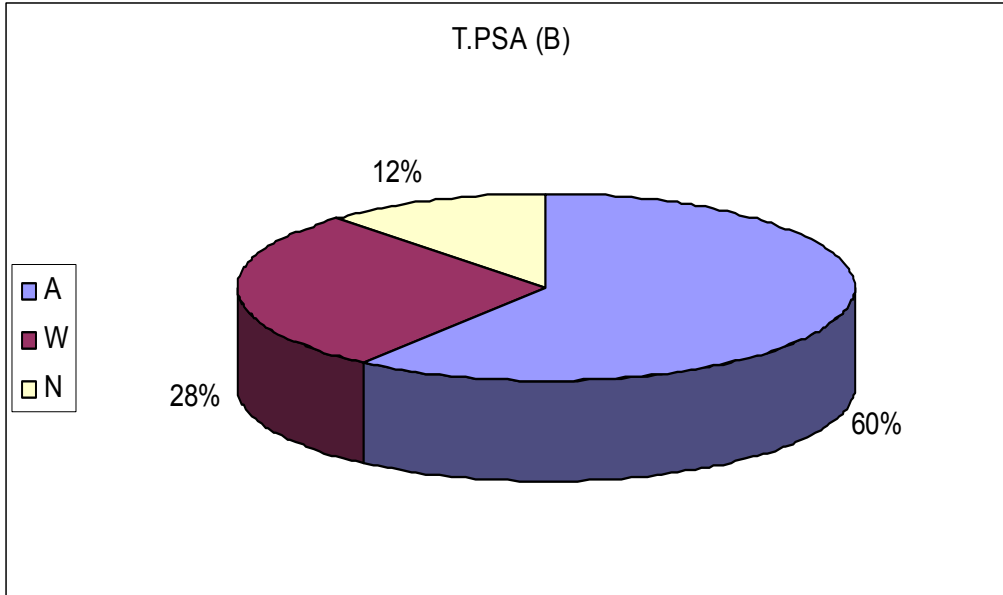
توزع العلامات وفق معايير التقييم في معايرة الواسم T.PSA



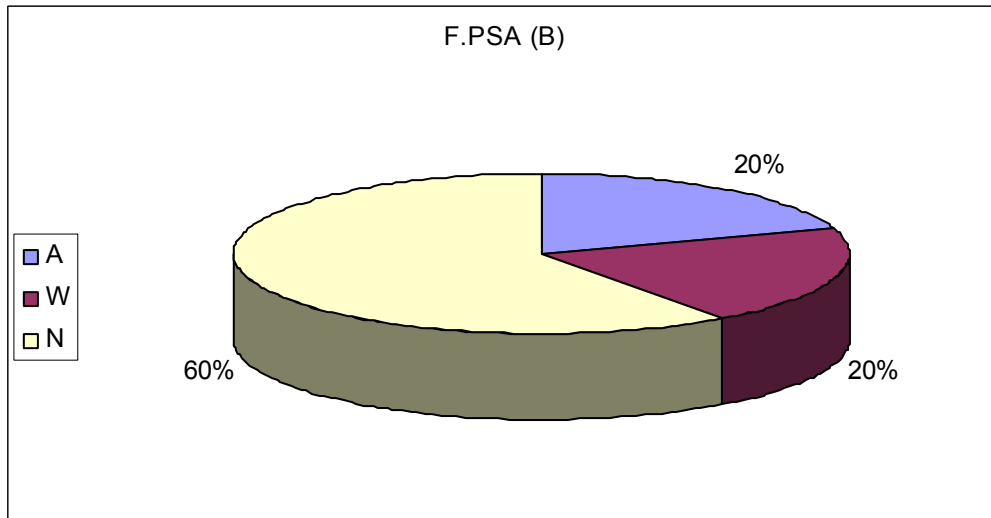
توزع العلامات وفق معايير التقييم في معايرة الواسم F.PSA (A)



T. PSA (B) توزيع العلامات وفق معايير التقييم في معايرة الواسم



F. PSA (B) توزيع العلامات وفق معايير التقييم في معايرة الواسم



CEA	CA-15-3	P.S.A. free	P.S.A. total	
-	-	Elecsys	Elecsys	1333
-	-			1252
-	-	-	LIAISON	1283
-	-	Gamma counter	Gamma counter	1750
-	-	Immulite	Vidas	1286
-	-	-	Immulite	2170
-	-	Elecsys	Elecsys	2240
-	-	-	LIAISON	3259
-	-	-	Vidas	3152
-	-	-	RIA	4154
-	-	Elecsys	Elecsys	4180
-	-	-	Elecsys	4171
-	-	-	Elecsys	4318
-	-	-	Elecsys	3069
-	-	Immulite	Isocomp I	3105
-	-			5259
-	-	Immulite	Immulite	1140
-	-	-	Vedas	1317
-	-	-	Vedas	3209
-	-	Mini Vedas	Mini Vedas	1070
-	-	Axsym	Axsym	1067
-	-	Elecsys	Elecsys	1010
-	-	Vidas	Vidas	1401
-	-	-	Mini Vedas	1003
-	-	Immulite	Immulite	2146

2006 /

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PSA

(3)

(B) F 2.47 = ng /mL	(A) F 0.75 = ng /mL	(B)T 3.24 = ng /mL	(A) T 0.99 =ng /mL	
F.PSA	F.PSA	T.PSA	T.PSA	
-	-	2.93	0.868	1140
-	-	3.19	1.03	1003
4.13	1.21	3.38	1.07	1401
-	-	3.01	0.474	2146
-	-	3.13	0.80	1317
-	-	3.80	1.04	1333
0.393	0.136	3.37	1.04	1010
3.87	1.24	3.14	1.02	1070
-	-	4.395	1.388	1252
-	-	2.65	1.00	1283
2.77	1.17	2.98	2.49	1067
4.4	1.33	2.8	0.89	1286
3.1	0.82	3.5	1.02	1750
-	-	3.40	0.90	2170
1.59	0.38	3.46	0.82	2240
-	-	2.68	0.83	3259
1.0	0.31	3.7	1.07	3105
-	-	3.65	0.953	3069
-	-	2.92	1.02	3152
-	-	3	0.82	3209
-	-	1.28	0.58	4154
1.79	0.43	3.96	1.04	4180
1.65	0.457	2.89	0.827	4171
-	-	4.01	0.91	4318
-	-	3.81	0.79	5259

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(A) PSA

(4)

	F.PSA ng/ mL= 0.99		T.PSA ng/ mL= 1.1	
	-		0.868	1140
	-		1.03	1003
	1.21		1.07	1401
	-		*0.474	2146
	-		0.80	1317
	-		1.04	1333
	*0.136		1.04	1010
	1.24		1.02	1070
	-		1.388	1252
	-		1.00	1283
	1.17		*2.49	1067
	1.33		0.89	1286
AV = 1.04 SD= 0.33	0.82	AV=0.96 SD= 0.14	1.02	1750
	-		0.90	2170
	*0.38		0.82	2240
	-		0.83	3259
	*0.31		1.07	3105
	-		0.953	3069
	-		1.02	3152
	-		0.82	3209
	-		*0.58	4154
	*0.43		1.04	4180
	0.457		0.827	4171
	-		0.91	4318
	-		0.79	5259

*

(B) PSA

(5)

	F.PSA ng/ mL = 3.2		T.PSA ng/ mL= 3.9	
	-		*2.93	1140
	-		3.19	1003
	4.13		3.38	1401
	-		3.01	2146
	-		3.13	1317
	-		3.80	1333
	*0.393		3.37	1010
	3.87		3.14	1070
	-		4.395	1252
	-		*2.65	1283
	2.77		*2.98	1067
	*4.4		*2.8	1286
AV = 2.47 SD = 0.64	3.1	AV= 3.52 SD = 0.39	3.5	1750
	-		3.40	2170
	*1.59		3.46	2240
	-		*2.68	3259
	*1		3.7	3105
	-		3.65	3069
	-		*2.92	3152
	-		3	3209
	-		*1.28	4154
	*1.79		3.96	4180
	*1.65		*2.89	4171
	-		4.01	4318
	-		3.81	5259

*

(1140)

(6)

P.S.A free			P.S.A total			
	ng/ml			ng/ml		
	0.99	W	0.868	1.1	A	
	3.2	W	2.93	3.9	B	

(1003)

(7)

P.S.A free			P.S.A total			
	ng/ml			ng/ml		
	0.99	A	1.03	1.1	A	
	3.2	A	3.19	3.9	B	

(1401)

(8)

P.S.A free			P.S.A total			
	ng/ml			ng/ml		
W	1.21	0.99	A	1.07	1.1	A
W	4.13	3.2	A	3.38	3.9	B

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

(2146)

(9)

P.S.A free			P.S.A total			
	ng/ml			ng/ml		
	0.99	N	0.474	1.1	A	
	3.2	W	3.01	3.9	B	

(1317)

(10)

P.S.A free			P.S.A total			
	ng/ml			ng/ml		
	0.99	W	0.80	1.1	A	
	3.2	A	3.13	3.9	B	

(1333)

(11)

P.S.A free			P.S.A total			
	ng/ml			ng/ml		
	0.99	A	1.04	1.1	A	
	3.2	A	3.80	3.9	B	

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

(1010)

(12)

P.S.A free			P.S.A total			
	ng/ml			ng/ml		
N	0.136	0.99	A	1.04	1.1	A
N	0.393	3.2	A	3.37	3.9	B

(1070)

(13)

P.S.A free			P.S.A total			
	ng/ml			ng/ml		
W	1.24	0.99	A	1.02	1.1	A
W	3.87	3.2	A	3.14	3.9	B

(1252)

(14)

P.S.A free			P.S.A total			
	ng/ml			ng/ml		
		0.99	W	1.388	1.1	A
		3.2	A	4.395	3.9	B

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

(1283)

(15)

P.S.A free			P.S.A total			
	ng/ml			ng/ml		
	0.99	A	1.00	1.1	A	
	3.2	N	2.65	3.9	B	

(1067)

(16)

P.S.A free			P.S.A total			
	ng/ml			ng/ml		
A	1.17	0.99	N	2.49	1.1	A
A	2.77	3.2	W	2.98	3.9	B

(1286)

(17)

P.S.A free			P.S.A total			
	ng/ml			ng/ml		
N	1.33	0.99	A	0.89	1.1	A
N	4.4	3.2	W	2.8	3.9	B

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

(1750)

(18)

P.S.A free			P.S.A total			
	ng/ml			ng/ml		
A	0.82	0.99	A	1.02	1.1	A
A	3.1	3.2	A	3.5	3.9	B

(2170)

(19)

P.S.A free			P.S.A total			
	ng/ml			ng/ml		
		0.99	A	0.90	1.1	A
		3.2	A	3.40	3.9	B

(2240)

(20)

P.S.A free			P.S.A total			
	ng/ml			ng/ml		
N	0.38	0.99	W	0.82	1.1	A
N	1.59	3.2	A	3.46	3.9	B

(3259)

(21)

P.S.A free			P.S.A total			
	ng/ml			ng/ml		
		0.99	W	0.83	1.1	A
		3.2	N	2.68	3.9	B

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

(3105)

(22)

P.S.A free			P.S.A total			
	ng/ml			ng/ml		
N	0.31	0.99	A	1.07	1.1	A
N	1.0	3.2	A	3.7	3.9	B

(3069)

(23)

P.S.A free			P.S.A total			
	ng/ml			ng/ml		
		0.99	A	0.953	1.1	A
		3.2	A	3.65	3.9	B

(3152)

(24)

P.S.A free			P.S.A total			
	ng/ml			ng/ml		
		0.99	A	1.02	1.1	A
		3.2	W	2.92	3.9	B

(3209)

(25)

P.S.A free			P.S.A total			
	ng/ml			ng/ml		
		0.99	W	0.82	1.1	A
		3.2	W	3	3.9	B

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

(4154)

(26)

P.S.A free			P.S.A total			
	ng/ml			ng/ml		
	0.99	N	0.58	1.1	A	
	3.2	N	1.28	3.9	B	

(4180)

(27)

P.S.A free			P.S.A total			
	ng/ml			ng/ml		
N	0.43	0.99	A	1.04	1.1	A
N	1.79	3.2	A	3.96	3.9	B

(4171)

(28)

P.S.A free			P.S.A total			
	ng/ml			ng/ml		
N	0.457	0.99	W	0.827	1.1	A
N	1.65	3.2	W	2.89	3.9	B

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

(4318)

(29)

P.S.A free			P.S.A total			
	ng/ml			ng/ml		
	0.99	A	0.91	1.1	A	
	3.2	A	4.01	3.9	B	

(5259)

(30)

P.S.A free			P.S.A total			
	ng/ml			ng/ml		
	0.99	W	0.79	1.1	A	
	3.2	A	3.81	3.9	B	

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

: -8

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.% 40 .1

T.PSA .2

(F.PSA) .3

% 20 % 20

.% 60

.(F.PSA) .4

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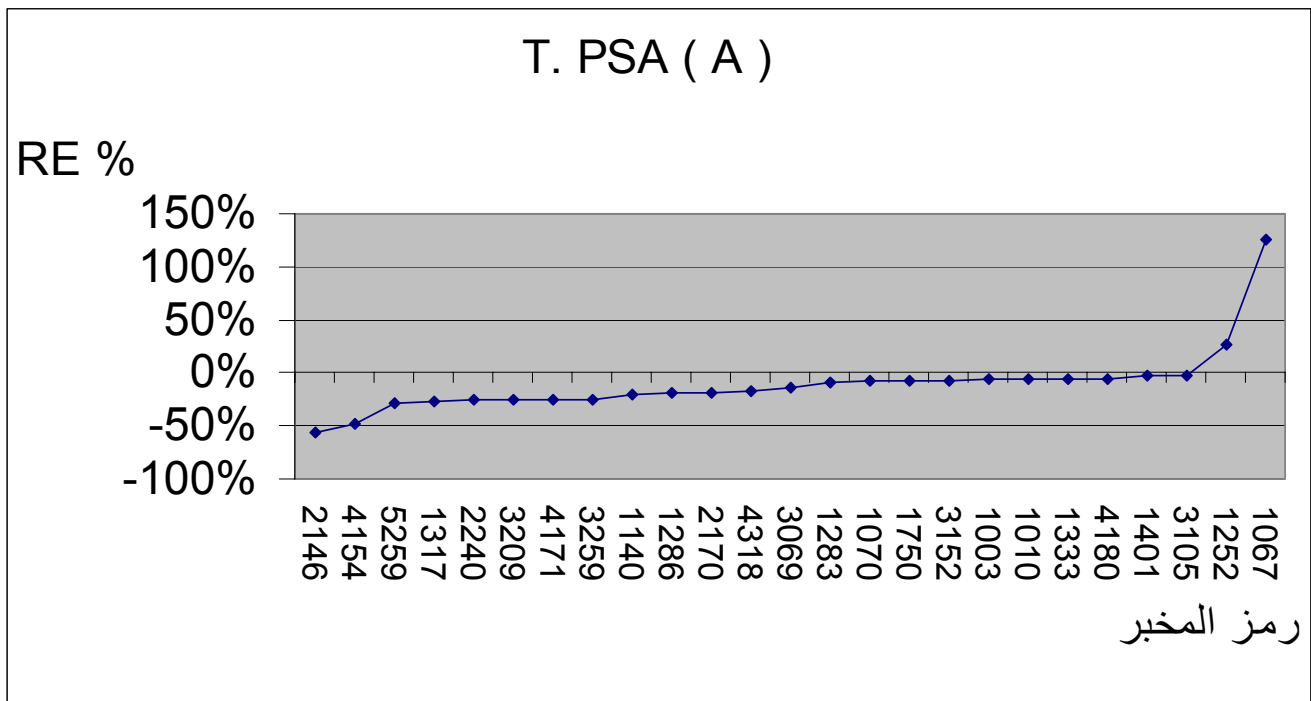
: **-10**

- [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.
- [5] Quality Systems- Model for quality Assurance in Design Development, Production, installation and Servicing – ISO 9001- 2000.
- [6] Control Charts- General Guide and Introduction – ISO 7870-1993.
- [7] Control Charts for arithmetic average with warning limits–ISO 7873-1993.
- [8] Basic Statistics , James E.D_E Muth , USA, 1999.

RE (D) (Histogram)

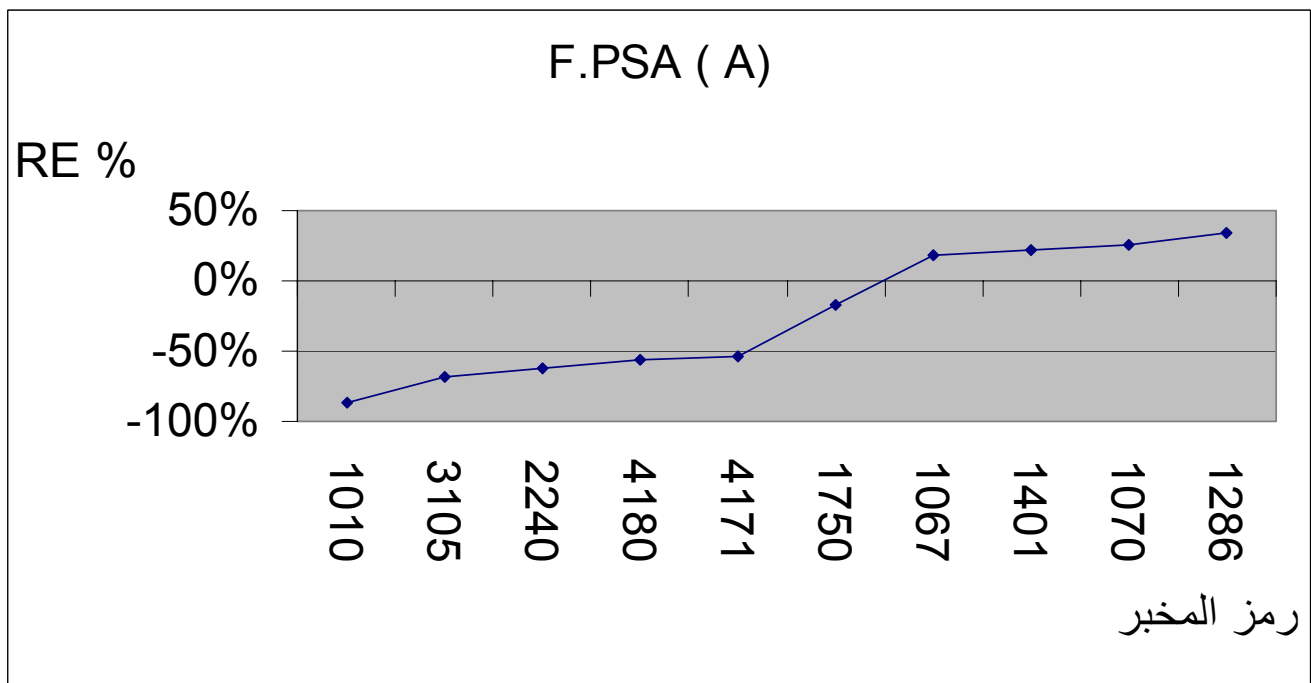
T.PSA-A

RE



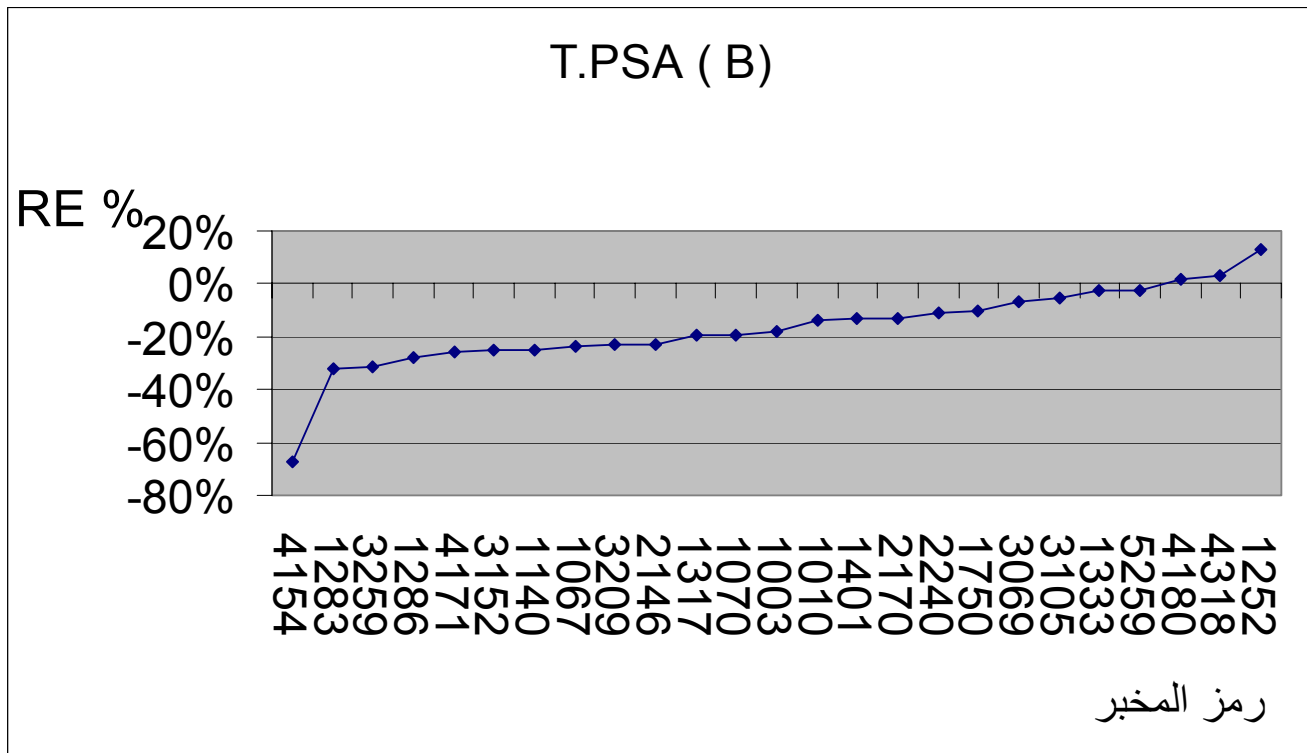
F.PSA-A

BIAS



T.PSA-B

BIAS



F.PSA-B

BIAS

