

DADE BEHRING

Dimension® clinical chemistry system
Heterogeneous Immunoassay Module

Flex® reagent cartridge

FPSA

Free Prostate Specific Antigen Flex® reagent cartridge

CAUTION: United States Federal law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory; and use is restricted to, by or on the order of a physician.

Warning: The concentration of PSA in a given specimen determined with assays from different manufacturers can vary due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the PSA assay used. Values obtained with different assay methods cannot be used interchangeably. The FPSA method should only be used with the Dimension® TPSA method to calculate the ratio of free PSA to total PSA (percent free PSA).

Intended Use: The FPSA method for the Dimension® clinical chemistry system with the heterogeneous immunoassay module is an *in vitro* diagnostic test intended to quantitatively measure free prostate specific antigen (FPSA) in human serum. Measurements of FPSA are used in conjunction with total PSA (TPSA) method on Dimension® system to calculate FPSA to TPSA ratio expressed as a percent FPSA. The percent FPSA is used as an aid in distinguishing prostate cancer from benign prostate conditions in men 50 years or older with TPSA of 4.0 to 10.0 ng/mL [$\mu\text{g/L}$] and digital rectal examination (DRE) findings not suspicious for cancer.

Prostate biopsy is required for diagnosis of cancer.

Summary: Prostate cancer is the most common type of cancer found in men in the United States and the second leading cause of male cancer mortality, accounting for more than 30,000 deaths in 1999.¹

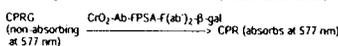
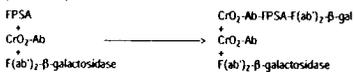
Prior to the use of PSA for early detection of prostate cancer, the traditional method of digital rectal examination (DRE) detected considerably fewer tumors.^{1,2} The most sensitive method for early detection of prostate cancer uses both DRE and PSA. The American Cancer Society and the American Urological Association (AUA) recommend that early detection of prostate cancer should be offered to asymptomatic men 50 years of age or older with an estimated life expectancy of more than 10 years.¹

The specificity of PSA to prostate tissue makes it a significant marker in the early detection and management of prostate diseases.

Prostate specific antigen (PSA) is a serine protease of approximately 30,000 Daltons produced by the epithelial cells of the prostate gland.^{3,4} The level of PSA in serum and other tissues is normally very low. In malignant prostate disease (prostatic adenocarcinoma) and in non-malignant disorders such as benign prostatic hypertrophy (BPH) and prostatitis, the serum level of PSA may become elevated.²

In serum, PSA exists primarily as three forms: complexed with either α -1-antichymotrypsin (ACT) or α -2-macroglobulin and free.^{5,6} The PSA protein associated with α -2-macroglobulin is encapsulated and unavailable for measurement by current immunoassay systems. The Dimension® FPSA assay measures the free components of serum PSA. Measurement of free PSA helps to discriminate between prostate cancer and benign prostatic diseases. The percentage of free PSA has been shown to enhance the specificity of PSA testing for prostate cancer detection.^{7,8} The percentage of free PSA is lower in patients with prostate cancer.

Principles of Procedure: The FPSA method is a one step enzyme immunoassay based on the "sandwich" principle. Sample is incubated with chromium dioxide particles coated with monoclonal antibodies specific for a binding site on free PSA, and conjugate reagent (β -galactosidase labeled monoclonal antibodies specific for a second binding site on the PSA molecule) to form a particle/PSA/conjugate sandwich. Unbound conjugate and analyte are removed by magnetic separation and washing. The sandwich bound β -galactosidase is combined with the chromogenic substrate chlorophenol red- β -D-galactopyranoside (CPRG). Hydrolysis of CPRG releases a chromophore (CPR). The color change measured at 577 nm due to formation of CPR is directly proportional to the concentration of PSA present in the patient sample.



Reagents

Wells*	Form	Ingredient	Concentration ^b	Source
1	Liquid	PSA Ab- β -galactosidase ^c	0.09 mg/mL	Mouse, monoclonal
2	Liquid	Chromic diluent	4.8 mg/mL	
3	Tablet	Antibody-CrO ₂ ^d	1.8 mg/mL	Mouse, monoclonal
4, 5, 6	Tablets	CPRG	10.5 mg/mL	
7	Liquid	CPRG diluent	42 mg/mL	

a. Wells are numbered consecutively from the wide end of the cartridge.
b. Nominal value in hydrated cartridge.
c. Antibody titer and conjugate activity may vary from lot to lot.
d. Tablets contain excipients, buffers, and stabilizers.

Precautions: Used cuvettes contain human body fluids; handle with appropriate care to avoid skin contact or ingestion.
For *in vitro* diagnostic use

Reagent Preparation: Mixing and diluting are automatically performed by the Dimension® system.
Storage Instructions: Store at 2-8°C.

Expiration: Refer to carton for expiration date of individual unopened reagent cartridges. Sealed or unhydrated cartridge wells on the instrument are stable for 30 days. Once wells 1, 2, 3 and 7 have been entered by the instrument, they are stable for 15 days. Once wells 4, 5 and 6 have been entered by the instrument, they are stable for 5 days.

Specimen Collection:

Serum can be collected by normal procedures.⁹ Serum should be separated from cells and refrigerated within 3-4 hours after venipuncture.^{10,11}

Samples should be kept at 4°C and analyzed within 24 hours. Samples held for longer times (up to 4 months) should be frozen at -20°C or colder. Storage at -70°C is preferred for long-term storage. Samples stored at room temperature show a significant loss of immunoreactivity within 4 hours.^{10,11}

Specimens should be free of particulate matter. To prevent the appearance of fibrin in serum samples, complete clot formation should take place before centrifugation. Clotting time may be increased due to thrombolytic or anticoagulant therapy.

Each laboratory should determine the acceptability of its own blood collection tubes and serum separation products. Variations in these products may exist between manufacturers and, at times, from lot to lot.

Known Interfering Substances

The following substances do not interfere with the FPSA method when present in serum at the concentrations indicated. Systemic inaccuracies (bias) due to these substances are less than 10% at FPSA levels of 1.0-2.0 ng/mL [$\mu\text{g/L}$].

Compound	Concentration
Acetaminophen	20 mg/dL [1322 $\mu\text{mol/L}$]
Albumin	6.0 g/dL [60 g/L]
Amitriptyline	15 mg/dL [256 $\mu\text{mol/L}$]
Aminoglutethimide	5 mg/dL [103 $\mu\text{mol/L}$]
Ampicillin	5 mg/dL [143 $\mu\text{mol/L}$]
Ascorbic acid	3 mg/dL [170.3 $\mu\text{mol/L}$]
Bilirubin	60 mg/dL [1026 $\mu\text{mol/L}$]
Caffeine	10 mg/dL [515 $\mu\text{mol/L}$]
Carbamazepine	12 mg/dL [508 $\mu\text{mol/L}$]
Chloramphenicol	25 mg/dL [174 $\mu\text{mol/L}$]
Chloridazepoxide	2 mg/dL [67 $\mu\text{mol/L}$]
Chlorpromazine	5 mg/dL [151 $\mu\text{mol/L}$]
Cholesterol	500 mg/dL [12.9 mmol/L]
Cimetidine	10 mg/dL [397 $\mu\text{mol/L}$]
Creatinine	30 mg/dL [2652 $\mu\text{mol/L}$]
Cyclophosphamide	25 mg/dL [696 $\mu\text{mol/L}$]
Dextran 75	1000 mg/dL [10 g/L]
Diazepam	2 mg/dL [70 $\mu\text{mol/L}$]
Diethylstilbestrol	0.02 mg/dL [700 nmol/L]
Digoxin	5 ng/mL [6.4 nmol/L]
Doxorubicin-HCl	7 mg/dL [121 $\mu\text{mol/L}$]
Erythromycin	20 mg/dL [272 $\mu\text{mol/L}$]
Estramustine phosphate	20 mg/dL [343 $\mu\text{mol/L}$]
Ethanol	350 mg/dL [76 mmol/L]
Ethosuximide	30 mg/dL [2125 $\mu\text{mol/L}$]
Finasteride	0.2 mg/dL [5.4 $\mu\text{mol/L}$]
Flutamide	1 mg/dL [36 $\mu\text{mol/L}$]
Furosemide	2 mg/dL [60 $\mu\text{mol/L}$]
Genitamicin	12 mg/dL [251 $\mu\text{mol/L}$]
Goserelin acetate	0.01 mg/dL [79 nmol/L]
Hemoglobin	1000 mg/dL [10.62 mmol/L] (monomer)
Heparin	8000 U/L [8000 U/L]
Human plasma kallikrein	100 $\mu\text{g/mL}$ [100 $\mu\text{g/mL}$]
Ibuprofen	40 mg/dL [1939 $\mu\text{mol/L}$]
Immunoglobulin G	6 g/mL [60 g/L]
Ketorolac	7 mg/dL [132 $\mu\text{mol/L}$]
Leuprolide acetate	10 mg/dL [86 $\mu\text{mol/L}$]
Lidocaine	6 mg/dL [756 $\mu\text{mol/L}$]
Lipemia	3000 mg/dL [33.9 mmol/L] (triglyceride)
Lithium	3.5 mg/dL [5.04 mmol/L]
Megestrol acetate	2 mg/dL [52 $\mu\text{mol/L}$]
Methotrexate	300 mg/dL [17 mmol/L]
Nicotine	2 mg/dL [123 $\mu\text{mol/L}$]
Penicillin G	25 U/mL [25,000 U/L]
Penicillin V	10 mg/dL [442 $\mu\text{mol/L}$]
Phenobarbital	15 mg/dL [646 $\mu\text{mol/L}$]
Phenytoin	10 mg/dL [396 $\mu\text{mol/L}$]
Primidone	10 mg/dL [458 $\mu\text{mol/L}$]
Propoxyphene	0.4 mg/dL [12 $\mu\text{mol/L}$]
Prostatic Acid Phosphatase	1000 ng/mL [1000 $\mu\text{g/L}$]
Protein (low)	4 g/dL [40 g/L]
Protein (high)	12 g/dL [120 g/L]
Rheumatoid factor	500 U/mL [500 U/mL]
Salicylic acid	50 mg/dL [3.62 mmol/L]
Theophylline	25 mg/dL [1388 $\mu\text{mol/L}$]
Urea	500 mg/dL [83.3 mmol/L]
Uric acid	20 mg/dL [1.2 mmol/L]
Valproic acid	50 mg/dL [3.467 mmol/L]

e. Systeme International d'Unités (SI units) are in brackets.

Procedure

Materials Needed

FPSA Flex® reagent cartridge, Cat. No. RF452
Reaction Vessels, Cat. No. RXV1
Chemistry Wash, Cat. No. RD701
Sample Probe Cleaner, Cat. No. RD703

Test Steps

Sampling, reagent delivery, mixing, separation, processing and printing of results are automatically performed by the Dimension® system with the heterogeneous immunoassay module. For details of this processing, refer to your Dimension® system manual.

Test Conditions

Reaction Vessel	Value
Sample size	60 μL
Antibody - CrO ₂	30 μL
Antibody β -galactosidase	50 μL
Temperature	37.0°C
Incubation period	9 minutes
Reaction Cuvette	
Transfer Volume	60 μL
CPRG Reagent Volume	150 μL
Temperature	37.0 \pm 0.1°C
Reaction period	5 minutes
Wavelength	577 and 700 nm
Type of measurement	Bichromatic Rate
Units	ng/mL [$\mu\text{g/L}$]

Calibration

The general calibration procedure is described in your Dimension® system manual. The following information should be considered when calibrating the FPSA method:

- Assay Range: 0.05 - 45.00 ng/mL [$\mu\text{g/L}$]
- Reference Material: TIF PSA Calibrator Cat. No. RC45Z
- Suggested Calibration Levels: 0.0, 4.0, 10.0, 20.0, 50.0 ng/mL [$\mu\text{g/L}$]
- Calibration Scheme, Replicates: 5, 2, 2, 3, 3 (levels in order, low to high)
- Calibration Frequency: Each new reagent cartridge lot. Every 90 days for any lot.
- Assigned Coefficients:
 - C_1 : -1000.0
 - C_2 : 3000.0
 - C_3 : -2.0
 - C_4 : 200.0
 - C_5 : 0.5

L The TIF PSA calibrator has 6 levels. To calibrate FPSA, use levels: 1, 2, 3, 4, 5.

Quality Control

At least once each day of use, analyze two levels of a quality control material with known FPSA concentrations. The results obtained should fall within acceptable limits defined by the laboratory. For further details refer to your Dimension® system manual.

A system malfunction may exist if the following five-test precision is observed:

FPSA Concentration	S.D.
4.00 ng/mL [$\mu\text{g/L}$]	> 0.27 ng/mL [$\mu\text{g/L}$]
10.00 ng/mL [$\mu\text{g/L}$]	> 0.70 ng/mL [$\mu\text{g/L}$]

Results: Free to Total PSA ratio expressed as a percent FPSA has been shown to be effective in patient management. Both total and free PSA concentrations should be determined on the same specimen/system and used to calculate the percentage of free PSA using the following equation:

$$\frac{\text{Free PSA (ng/mL } [\mu\text{g/L}])}{\text{Total PSA (ng/mL } [\mu\text{g/L}])} \times 100 = \% \text{ FPSA}$$

With the Calculated Results feature activated, the Dimension® system automatically calculates and reports the percent FPSA when both TPSA and FPSA are processed in singlet on the same sample and at the same time.

Limitations of Procedure

- Results: >45 ng/mL [$\mu\text{g/L}$].
 Manual dilution: Make appropriate dilution with Purified Water to obtain results within assay range. Error dilution factor. Reassay. Resulting readout is corrected by dilution.
 Autodilution: Refer to your Dimension® system manual. Recommended Auto Dilute volume is 6 μL .
 Results: < 0.05 ng/mL [$\mu\text{g/L}$] should be reported as "less than 0.05 ng/mL [$\mu\text{g/L}$]."

One step sandwich immunometric assays are susceptible to a high-dose "hook effect", where an excess of antigen prevents simultaneous binding of the capture and detection antibodies to a single analyte molecule.¹² The FPSA method shows no hook effect up to 10,000 ng/mL [$\mu\text{g/L}$]. Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. This assay has been designed to minimize interference from heterophilic antibodies.¹³

The instrument reporting system contains error messages to warn the operator of specific malfunctions. Any report slip containing such error messages should be held for follow-up. Refer to your Dimension® system manual.

Expected values: A multicenter prospective clinical study was conducted to evaluate the effectiveness of percent free PSA (FPSA/TPSA x 100) ratio as measured on the Dimension® system.

The percent FPSA is used as an aid in distinguishing prostate cancer from benign prostate conditions in men 50 years or older with TPSA of 4.0 to 10.0 ng/mL [$\mu\text{g/L}$] by the Dimension® system TPSA method and DRE findings not suspicious for cancer. The study consisted of 691 patients from eight clinical sites referred to a urologist for evaluation of prostate cancer.

All patients underwent a transrectal prostate biopsy. The diagnosis of prostate cancer or benign prostate disease was based on pathological examination of a minimum of six cores from each patient. Ethnic composition of the population studied included 584 (84.5%) Caucasian, 84 (12.2%) African American, 8 (1.2%) Hispanic or Mexican, 7 (1%) Asian, 5 (0.7%) Native American and 3 (0.4%) Filipino men. The median age for both cancer and benign disease groups was 65.1 years. The table below displays the distribution of FPSA, TPSA and %FPSA by biopsy result.

Distribution of FPSA, TPSA and % FPSA by biopsy result

FPSA (ng/mL)	Biopsy Result	Count	Mean	Median	Standard Error of Mean	95% Lower Bound	95% Upper Bound	Prostate Range vs. Malignant
FPSA (ng/mL)	Benign	487	0.93	0.83	0.021	0.89	0.97	
	Malignant	204	0.75	0.66	0.029	0.69	0.81	
TPSA (ng/mL)	Benign	487	6.11	5.7	0.074	6.0	6.2	0-145
	Malignant	204	8.80	8.5	0.108	8.4	8.8	
%FPSA	Benign	487	15.4	14	0.200	14.6	16.0	< 0.001
	Malignant	204	11.5	10	0.420	10.7	12.3	

Analysis of the mean values of % FPSA for the benign and malignant disease groups indicates a significant difference exists between the groups.

The % FPSA result may be used in two ways:

1. provide an individual patient risk assessment of prostate cancer, or
2. use a single cutoff to indicate the need for additional follow up.

Individual Patient Risk Assessment: There is an increased probability of detecting prostate cancer upon biopsy as the PSA levels increase. The TPSA range of 4 - 10 ng/mL [$\mu\text{g/L}$] has been described as the "gray zone". Percent free PSA is of increased utility in this area as seen in the table below.

The probability of detecting cancer upon biopsy by percent free PSA increases with the age of men as shown below:

Probability (%) of detecting Prostate Cancer: Men with Non-Suspicious DRE Results (Parentheses indicate Binomial 95% Confidence Intervals)

Total PSA Range 4.0 to 10.0 ng/mL	% Free PSA	Age Group (Years)		
		50-59	60-69	70+
4.0 to 10.0 ng/mL	≤ 10%	40.2 (33.1-50.9)	47.1 (37.3-58.2)	66.0 (52.1-79.1)
	11%-19%	14.7 (9.1-23.5)	24.1 (17.9-32.0)	31.6 (23.4-41.9)
	≥ 20%	7.1 (1.8-33.8)	14.3 (7.3-27.2)	12.5 (6.8-22.4)
Prostate Cancer Prevalence (%)		25.9	29.5	32.7

Single cutoff: A single cutoff may be used for men of all age groups. Sensitivity (% of prostate cancer (PCA) detected) and specificity (% of biopsies avoided in men without PCA) for various % free PSA cutoffs are shown below. A cutoff of 19% results in the detection of 91.2% of prostate cancers and avoids unnecessary biopsy in 27.9% of men without prostate cancer.

% FPSA	Benign Biopsies		Malignant Biopsies	
	Percent of Patients with negative biopsies indicated at the cutoff N=487	95% CI*	Percent of Patients with positive biopsies indicated at the cutoff N=204	95% CI*
17	36.7 (179/487)	32.5 - 41.2	87.2 (178/204)	82.4 - 91.5
18	32.4 (158/487)	28.3 - 36.8	89.7 (183/204)	85.3 - 93.5
19	27.9 (136/487)	23.8 - 32.1	91.2 (186/204)	87.0 - 94.7
21	19.5 (95/487)	16.0 - 23.3	94.1 (192/204)	90.5 - 96.9
23	12.9 (63/487)	10.0 - 16.2	95.1 (194/204)	91.8 - 97.6
25	9.4 (46/487)	7.0 - 12.4	96.1 (196/204)	93.0 - 98.3
32	0 (0/487)	N/A	99.5 (203/204)	98.2 - 100.0

*95% CI = 95% Confidence Interval
 N/A = not applicable

Serum FPSA concentrations, regardless of the value, should not be interpreted as definitive evidence for the presence or absence of prostate cancer. Prostate biopsy is required for the diagnosis of cancer.

Each laboratory should establish its own expected values for percent free PSA as performed on the Dimension® system.

When changing PSA assays in the course of monitoring a patient, additional sequential testing should be carried out to confirm baseline values.

Specific Performance Characteristics

Material	Reproducibility %		
	Mean ng/mL [$\mu\text{g/L}$]	Within-Run SD (%CV)	Total SD (%CV)
Serum pool 1	1.35	0.02 (1.8)	0.04 (3.0)
Serum pool 2	17.24	0.30 (1.7)	0.53 (3.1)
Liquichek™ 1	0.28	0.02 (5.6)	0.02 (8.5)
Liquichek™ 2	1.57	0.02 (1.6)	0.04 (2.7)
Liquichek™ 3	12.15	0.23 (1.9)	0.32 (2.6)

Liquichek™ Immunoassay Plus Control is a trademark of Bio-Rad Laboratories, Irvine, CA 92618.

- g. All specific performance characteristics tests were run after normal recommended equipment quality control checks were performed (refer to your Dimension® system with heterogeneous immunoassay module manual).
- h. Reproducibility testing was done in accordance with the NCCLS Approved Guideline for Evaluation of Precision Performance of Clinical Chemistry Devices (EP5-A, Feb 1999).
- i. Specimens at each level were analyzed in duplicate, twice a day, for 20 days. The within-run and total standard deviations were calculated by analysis of variance method.

Analytical Sensitivity

The sensitivity of the FPSA method is 0.05 ng/mL [$\mu\text{g/L}$] and represents the lowest concentration of FPSA that can be distinguished from zero. This sensitivity is defined as the concentration at two standard deviations above the level 1(0 ng/mL [$\mu\text{g/L}$]) Calibrator (n= 20).

Analytical Specificity

See known interfering substances section for details. The following substance does not cross-react with the FPSA assay at the concentration indicated:

Substance	Concentration	Apparent FPSA Concentration
PSA ACT	100 ng/mL	0.23 ng/mL [$\mu\text{g/L}$]

Recovery

Multiple dilutions of serum samples with PSA values of 5.8 to 39.8 ng/mL [$\mu\text{g/L}$] were made with water. Sample FPSA concentrations were measured and the percent recovery calculated. Recovery ranged from 100 to 104 % with an average recovery of 101 %.

Symbols Key: See adjacent panel.

Bibliography: See adjacent panel.

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* An asterisk in the margin denotes a revised section.

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Dimension® FPSA Inert Sheet
 PN 755452.001 Flex D
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6.0" @ 100%

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2nd fold

12" @ 100%

W_2003-01-09 (FDA Changes) D PN 755452.001-US

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Bibliography/Literatur/Bibliographie/Bibliografia/Bibliografía/
Bibliografía:

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Symbols Key Symbolschlüssel Explication des Symboles Interpretazione simboli Clave de los Símbolos	
	Manufactured by / Hergestellt von / Fabriqué par / Prodotto da / Fabricado por / Fabricado por
	Authorized Representative / Bevollmächtigter / Mandataire / Rappresentanza autorizzata / Representante Autorizado / Representante Autorizado
	In Vitro Diagnostic Medical Device / In Vitro Diagnostikum / Dispositif Médical Diagnostique / In Vitro Diagnostico Medico per Diagnostica in Vitro / Producto sanitario para el Diagnostico in Vitro / Dispositivo Médico para Diagnostico in Vitro
	Batch Code / Charge / Numéro de Lot / Lotto / Código de Lote / Código do Lote
	"Use By" date in year-month-day format / Verfallsdatum im Jahr-Monat-Tag Format / Utiliser jusqu'à la date AAAA-MM-JJ / Scadenza: AAAA-MM-GG / Caducidad año-mes-día / A data em "UTILIZAR antes de" encontra-se no formato ano-mês-dia (AAAA-MM-DD)
	Temperature Limitation / Lagertemperatur / Umite de Temperatura / Conservazione / Limitación de Temperatura / Limitação de Temperatura
	CE Mark / CE Zeichen / Marquage CE / Marchio CE / Marca CE / Marca CE
	Catalogue Number / Katalog Nummer / Référence / Codice Catalogo / Número de Catálogo / Número de Catálogo
	Consult Instructions for Use / Gebrauchshinweise beachten / Consulter la Notice d'Utilisation / Instruções per Função / Consultar Instruções para el Uso / Consulte as Instruções de Utilização

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Dimension® FPSA Insert Sheet
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DADE BEHRING

Dimension® clinical chemistry system
Heterogeneous Immunoassay Module

T/F PSA Calibrator

Symbols Key
Symbolschlüssel
Explication des Symboles
Interpretazione simboli
Clave de los Símbolos
Chave dos Símbolos

Manufactured by / Hergestellt von / Fabriqué par / Prodotto da / Fabricado por / Fabricado por

EC REP Authorized Representative / Bevollmächtigter/ Mandataire / Rappresentanza autorizzata / Representante Autorizado / Representante Autorizado

IVD *In Vitro* Diagnostic Medical Device / *In Vitro* Diagnosticum / Dispositif Médical Diagnostique *In Vitro* / Dispositivo Médico per Diagnostica *In Vitro* / Producto sanitario para el Diagnóstico *In Vitro* / Dispositivo Médico para Diagnóstico *In Vitro*

LOT Batch Code / Charge / Numéro de Lot / Lotto / Código de Lote / Código do Lote

EXP "Use By" date in year-month-day format / Verfalldatum im Jahr-Monat-Tag Format / Utiliser jusqu'à la date: AAAA-MM-JJ / Scadenza: AAAA-MM-GG / Caducidad año-mes-día / A data em "Utilizar antes de" encontra-se no formato ano-mês-dia (AAAA-MM-DD)

2-8°C Temperature Limitation / Lagertemperatur / Limite de Température / Conservazione / Limitación de Temperatura / Limitação da Temperatura

CE CE Mark / CE Zeichen / Marquage CE / Marchio CE / Marca CE

REF Catalogue Number / Katalog Nummer / Référence / Codice Catalogo / Número de Catálogo / Número de Catálogo

Consult Instructions for Use / Gebrauchshinweise beachten / Consulter la Notice d'Utilisation / Istruzioni per l'uso / Consultar Instruções para el Uso / Consulte as Instruções de Utilização 2002-02-06

DADE BEHRING

Dimension® clinical chemistry system
Heterogeneous Immunoassay Module

T/F PSA Calibrator

Total/Free Prostate Specific Antigen Calibrator

Intended Use

The T/F PSA Calibrator is an *in vitro* diagnostic product intended to be used to calibrate the Total (TPSA) and Free (FPSA) Prostate Specific Antigen methods for the Dimension® clinical chemistry system with the heterogeneous immunoassay module. This product was designed to meet the needs of users to assure accurate results over the assay range of these methods.

Constituents

The T/F PSA Calibrator is a liquid product. Calibrator levels 2 through 6 contain human prostate specific antigen (free PSA) in a bovine serum albumin base. Level 1 is a horse serum base with no detectable PSA. The kit consists of twelve vials, two at each of six levels.

Precautions

This Product Contains Dry Natural Rubber.

Irritant. Level 1 contains chloroacetamide. May cause sensitization by skin contact. Avoid contact with skin. Wear suitable gloves. If swallowed, seek medical advice immediately and show this container or label.

Contains sodium azide (< 0.1%) as a preservative. Sodium azide can react with copper or lead pipes in drain lines to form explosive compounds. Proper disposal of this product as a biohazard will minimize this possibility.

Contains human source material. When available a blood sample from the donor was tested and found negative for the presence of the antibody to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2), for Hepatitis B Surface Antigen (HBsAg), and for the antibody to Hepatitis C Virus (HCV). Where no donor blood sample was available, an extract of the starting material was tested and found negative for HIV-1, HIV-2, HBsAg, and HCV. Because no testing can offer complete assurance that these, or other infectious agents are absent, this material should be handled using good laboratory practice to avoid skin contact and ingestion. Manuals are available which detail laboratory biosafety level criteria and practices.¹

For *in vitro* diagnostic use.

Preparation

Allow to equilibrate to room temperature (22 - 28°C) and swirl to mix before use.

Storage

Store at 2 - 8°C before and after opening.

Stability

Unopened Product: See Expiration Date.

Opened Product: Once opened, the assigned values are stable for 30 days when stored securely capped at 2 - 8°C.

Calibration Procedure

Refer to the instruction manual for the Dimension® clinical chemistry system.

Six levels are provided.

To calibrate TPSA, use levels: 1, 2, 4, 5, 6

To calibrate FPSA, use levels: 1, 2, 3, 4, 5

LOT XXXXXX **EXP** YYYY-MM-DD

	Constituent	Assigned Value ^{a,b}		Units	S.I. Units ^c
		TPSA	FPSA		
Level 1	PSA	X.XX	X.XX	ng/mL	µg/L
Level 2	PSA	X.XX	X.XX	ng/mL	µg/L
Level 3	PSA	----	XX.XX	ng/mL	µg/L
Level 4	PSA	XX.XX	XX.XX	ng/mL	µg/L
Level 5	PSA	XX.XX	XX.XX	ng/mL	µg/L
Level 6	PSA	XXX.XX	----	ng/mL	µg/L

a. The assigned values are referenced to the WHO Standard for free PSA, 1st IS 1999, 96/668, formerly known as Stanford Reference Materials for PSA.
 b. Users of this product will be notified if there is a change in the assigned values.
 c. Système International d'Unités.

Symbols Key: See adjacent panel.

Bibliography

- Biosafety in Microbiological and Biomedical Laboratories, HHS Publication No. (CDC) 88-8395, Superintendent of Documents, US Government Printing Office, Washington, DC 20402.

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