Prostate Specific Antigen (PSA) – Serum
Siemens Advia Centaur XP Systems

Technical Procedure 3222.T

Principle

Intended Use

The ADVIA Centaur PSA assay is indicated for the measurement of serum PSA as an aid in the detection of prostate cancer in men aged 50 years and older. This assay is also indicated as an aid in the management (monitoring) of patients with prostate cancer.

Clinical Significance

PSA is a single-chain glycoprotein containing 7% carbohydrate by weight normally found in the cytoplasm of the epithelial cells lining the acini and ducts of the prostate gland.[1] PSA is a neutral serine protease of 240 amino acids involved in the lysis of seminal coagulum.[2,3] PSA exists primarily as three forms in serum. One form of PSA is believed to be enveloped by the protease inhibitor alpha-2-macroglobulin and has been shown to lack immunoreactivity. A second form is complexed to another protease inhibitor, alpha-1-chymotrypsin (ACT). A third form is not complexed to a protease inhibitor and is termed free PSA.[4,5,6] The latter two forms are immunologically detectable in commercially available PSA assays and are referred to collectively as total PSA. This assay is an equimolar PSA assay and measures free PSA and PSA-ACT with equal sensitivity.

Prostate cancer is the most common type of cancer found in men in the United States, with an incidence of approximately one case for every ten men. It is also the second leading cause of cancer deaths among American men.[7] A reliable test for detecting early stage prostate cancer, when the tumor is confined to the gland and effective treatment can be provided, can be of great value to the physician.[8] A digital rectal exam (DRE) is a commonly used technique for prostate cancer detection, yet a DRE, as it is generally performed in medical practice, misses a significant number of cancers, including many organ-confined tumors.[9,10,11]

PSA levels increase in men with cancer of the prostate, and after radical prostatectomy PSA levels routinely fall to the undetectable range.[12] If prostatic tissue remains after surgery or metastasis has occurred, PSA appears to be useful in detecting residual and early recurrence of tumor.[13,14] Therefore, serial PSA levels can help determine the success of prostatectomy, and the need for further treatment, such as radiation, endocrine or chemotherapy, and can aid in the monitoring of the effectiveness of therapy.

Measurement of serum PSA levels is not recommended as a screening procedure for the diagnosis of cancer because elevated PSA levels are also observed in patients with benign prostatic hypertrophy. Studies suggest that the measurement of PSA in conjunction with the DRE and ultrasound provide a better method of detecting prostate cancer than DRE alone.[15,16,17]

Methodology

The ADVIA Centaur PSA assay is a two-site sandwich immunoassay using direct chemiluminometric technology, which uses constant amounts of two antibodies. The first antibody, in the Lite Reagent, is a polyclonal goat anti-PSA antibody labeled with acridinium ester. The second antibody, in the Solid Phase, is a monoclonal mouse anti-PSA antibody, which is covalently coupled to paramagnetic particles.

The system automatically performs the following steps:

- Dispenses 35 µL of sample into a cuvette.
- Dispenses 250 µL of Solid Phase and 100 µL of Lite Reagent and incubates for 7.5 minutes at 37^{O}C.
- Separates, aspirates, and washes the cuvettes with reagent water.
- Dispenses 300 µL each of Acid Reagent and Base Reagent to initiate the chemiluminescent reaction.
- Reports results.

A direct relationship exists between the amount of PSA present in the patient sample and the amount of relative light units (RLUs) detected by the system.

Specimen Collection

Acceptable Sample Containers

13 x 75 SST and Red Top BD tubes
SST and Red Top BD microtainers
Optimum volume: 1.0 mL
Absolute minimum volume: 0.25 mL

Unacceptable Specimens

Plasma is an unacceptable specimen for this test.

Specimen Handling and Storage

- Collect all blood samples observing universal precautions for venipuncture. Allow samples to clot adequately before centrifugation. If plain red top tubes are used, aliquot the serum. Do not use samples that have been stored at room temperature for longer than 8 hours. Tightly cap and refrigerate specimens at 2° to 8°C up to 4 days if the assay is not completed within 8 hours. Save serum or spun SST at -20°C for longer storage. Freeze samples only once and mix thoroughly after thawing.
- Outpatient specimens should be refrigerated during delivery.
- Specimens obtained from patients undergoing prostate manipulation, especially needle biopsy and transurethral resection may show erroneously high results. Care should be taken that PSA samples are drawn before these procedures are performed.
- Before placing samples on the system ensure that:
    - Samples are free of fibrin or other particulate matter.
    - Samples are free of bubbles

Reagents and Supplies

Reagent Pack Kits

Ref	Description	Number of Tests
02676506	5 ReadyPack primary reagent packs containing ADVIA Centaur PSA Lite Reagent and Solid Phase Advia Centaur PSA Master Curve Card	500
or		
06574155	1 ReadyPack primary reagent packs containing ADVIA Centaur PSA Lite Reagent and Solid Phase Advia Centaur PSA Master Curve Card	100

Reagent Pack Contents

Store the reagents upright at 2° - 8°C.

Reagent Pack	Description	Stability
ADVIA Centaur PSA Ready Pack® primary reagent pack	**Lite Reagent** 10.0 mL/reagent pack: polyclonal goat anti-PSA antibody (~77 ng/mL) labeled with acridinium ester in buffered saline with preservatives **Solid Phase** 25.0 mL/reagent pack: monoclonal mouse anti-PSA antibody (~25 ug/mL) covalently coupled to paramagnetic particles in buffered saline with preservatives	**Unopened**: Stable until the expiration date on the pack label. **Onboard** stability - 28 days

Materials Required But Not Provided

Ref	Description	Contents	Storage	Stability
118221 or **118220**	Calibrator Q Calibrator Q	6 vials of low calibrator CAL L 6 vials of high calibrator CAL H 2 vials of low calibrator CAL L 2 vials of high calibrator CAL H	2° - 8°C	**Lyophilized** – until the expiration date on the vial label **Reconstituted** – 21 days
110314	ADVIA Centaur Multi-Diluent 2-pack	2 ReadyPack ancillary reagent packs containing 10 mL/pack, goat serum with sodium azide (0.1%) and preservatives	2° - 8°C	**Unopened**: Stable when stored at 2-8°C until the pack expiration date **Onboard** stability – 28 consecutive days after accessing the ancillary pack
03773025	ADVIA Centaur Wash 1	2 x 2500 mL/pack	18°- 25°C	Until the expiration date on the bottle label or onboard – 28 days
10310026	Acid/Base Kit (~1000 test bottles)	1 each/box	18°- 25°C	Until the expiration date on the bottle label or onboard – 28 days
10309546	Cuvettes	3000/case		
07413317	Pipet Tips (360/box)	18 boxes/case		
10310041	Cleaning Solution	12 bottles/case	2° - 8°C	**Unopened**: Stable until the expiration date on the bottle label **Prepared** solution – 7 days
078-K137-01	Sample Cups	1500/box		

WARNING 1: Reagents in this kit contain sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide buildup. Disposal into drain systems must be in compliance with prevailing regulatory requirements.

WARNING 2: If sodium azide contacts skin, wash immediately with plenty of soap and water.

WARNING 3: While each human serum or plasma donor unit used in the manufacture of this product was tested and found non-reactive for hepatitis B surface antigen (HBsAg), antibody to hepatitis C (HCV), and antibody to HIV-1/2 by FDA-approved methods, all products manufactured using human or non-human source material should be handled as potentially infectious and according to established laboratory practices.

Loading Reagents

1. Ensure that the system has sufficient primary and ancillary reagent packs. This assay uses the ancillary reagent Multi-Diluent 2 for dilutions.
2. Mix all primary reagent packs by hand before loading them onto the system.

> Mix the packs by hand (25 times, turning to 90 degrees with each mix). Visually inspect the bottom of the reagent pack to ensure that all particles are dispersed and resuspended. (For details, refer to the system operating instructions.)

3. Document lot numbers on the Reagent Log. Date and initial packs before loading packs onto the system.
4. Load the ReadyPack reagent packs in the primary reagent area using the arrows as a placement guide. The system automatically mixes the primary reagent packs to maintain homogeneous suspension of the reagents.
5. Load the ancillary pack in the ancillary reagent entry with the barcoded side facing outward.

Onboard Stability and Calibration Interval

Onboard Stability	Calibration Interval
28 days	28 days

The ADVIA Centaur PSA assay requires a two-point calibration:

- with each new lot of reagent
- every 28 days
- when system components are replaced
- when the controls are not within the quality control guidelines

Discard the primary reagent packs at the end of the onboard stability interval.

Do not use reagents beyond the expiration date.

Equipment

This test is performed on the Siemens ADVIA Centaur XP systems; Siemens Healthcare Diagnostics, Tarrytown, New York.

> For technical assistance, call the Siemens Healthcare Diagnostics Technical Support Hotline: 1-877-229-3711

Calibration

Preparation of Calibrators

1. Volumetrically add 2.0 mL of deionized water to each calibrator vial.
2. Allow the calibrators to sit for 15 to 20 minutes at room temperature (18°-30°C) to allow the lyophilized material to dissolve.
3. Gently swirl and invert the vials until homogenous.
4. Once reconstituted, calibrators are stable for 28 days when stored at 2°-8°C.

Enter Calibrator Values

A barcoded Calibrator Assigned Value Card accompanies **each lot of calibrator**. The card contains the calibrator setpoints for several assays. Enter this information when a new lot of Calibrator is opened. Use either the bar-code scanner or the keyboard. (See the ADVIA Centaur Operator's Guide for details on using the cards.)

Enter Master Curve Calibration Values

A multi-point factory determined Master Curve accompanies **each lot of reagent** and must be entered into the Centaur prior to using a new lot. The system adjusts this Curve using a two-point calibration. For each new lot number, use the Master Curve Card to enter the Master Curve information in the System. Use the bar-code scanner or the keyboard.

Using Calibrator Barcode Labels

NOTE: Calibrator barcode labels are lot number specific.

Use the lot-specific Low and High Calibrator bar-code labels that accompany the calibrators to label the tubes.

Scheduling a Calibration

1. At the main screen, select Worklist.
2. Select Schedule.
3. At the Worklist-Schedule window, select Calibrator.
4. Select PSA. The system automatically displays the calibrators previously defined for PSA. Calibrators will not display if:
   - calibrators are not defined
   - Master Curves are not defined
   - no reagent is onboard
   - the calibration material for the defined lot is expired
5. Select a calibrator.
6. Select a reagent lot.

7. Select Save.
8. Aliquot 1 mL of each calibrator into the appropriate tube, or 500 uL of each calibrator in an E-Z Nest Cup. The Low Calibrator cup must precede the High Calibrator cup position.
9. After successful calibration, schedule controls.
10. Print and save a copy of the calibration in the appropriate instrument binder.

Do not return any calibrator back into the vials after calibration. Evaporation can occur which may affect performance. Dispose of any calibrator remaining in the sample cups after four hours. Do not refill calibrator sample cups when the contents are depleted. If required, dispense fresh calibrators.

PSA Standardization

The ADVIA Centaur PSA assay is traceable to an internal standard manufactured using highly purified material. Value (concentration) assignment was based on adjustment to a reference method comparison protocol. [20] The assay standardization is traceable to World Health Organization (WHO) International Standard (96/670). A comparison over the range of the assay gave the following correlation:

ADVIA Centaur PSA = 1.03 (WHO) – 1.2 ng/mL, r = 0.99

Assigned values for calibrators are traceable to this standardization.

Quality Control

Three levels of quality control material will be assayed daily.

Quality control samples should also be assayed after performing a two-point calibration. Treat all quality control samples the same as patient samples.

The following controls will be used in accordance with package instructions for use inserts:

Control	Storage
MAS Omni-Immune 1	2° to 8°C
MAS Omni-Immune 2	2° to 8°C
MAS Omni-Immune 2	2° to 8°C

36 month shelf Life at -25° to -15°C; 30 days open-vial at 2° to 8°C.

Thaw controls at room temperature (18° to 25°C) on a rocker until liquid and then immediately store at 2° to 8°C. Thoroughly mix the control bottles before each use by mixing on a rocker for five minutes. Use immediately and return bottles to 2° to 8°C after use.

Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on Centaur XP Reagent Log sheets.

If the quality control results do not fall within the expected values or within the established ranges, do not report patient results. Take the following actions:

- Verify that the materials are not expired.
- Verify that required maintenance was performed.
- Verify that the assay was performed according to the instructions for use.
- Rerun the assay with fresh quality control samples.
- Recalibrate assay if controls are still out of control.
- If necessary, contact your local technical support provider or distributor for assistance.

Sample Volume

This assay requires **35 µL** of sample for a single determination. This volume does not include the unusable volume in the sample container (~400 µL) or the additional volume required when performing duplicates or other tests on the same sample. For detailed information about determining the minimum required volume, refer to *Sample Volume Requirements* in the *Siemens ADVIA Centaur XP Immunoassay System Operator's Guide*.

NOTE: The sample volume required to perform onboard dilution differs from the sample volume required to perform a single determination. Refer to the following information for sample volume required to perform onboard dilutions:

Dilution	Sample Volume (uL)
1:2	75
1:5	30
1:10, 1:50, 1:100	40

Assay Procedure

For detailed procedural information, refer to the *Siemens ADVIA Centaur XP Immunoassay System Operator's Guide* or to the *online* help system.

Ensure that samples have no fibrin or bubbles in them. Samples loaded in racks must be oriented so that barcode labels are clearly visible through the slot in the rack.

Dilutions

Samples with PSA levels **> 50.0 ng/mL** must be diluted and retested to obtain accurate results. Patient samples with high total PSA levels can cause a paradoxical decrease in the RLUs (high-dose hook effect). Because of problems with "hook effects" on extremely elevated samples, the top of the PSA linear range will be 50.0 ng/mL.

Patient samples can be automatically diluted by the system or manually diluted. The Centaur will dilute x5 all samples greater than 50.0 ng/mL.

Additionally, you can program the Centaur to perform online dilutions of x2, x5, x10, x50, or x100 (using the ancillary Multi-Diluent 2). Online dilutions will be calculated by the Centaur.

If an off-line manual dilution must be performed, use Multi-Diluent 2 for manual dilutions and calculate the final result using the appropriate dilution factor.

> If a manual dilution is required because the onboard x100 dilution is not high enough (result is > 5,000 ng/mL), perform a manual x4 dilution using 100 uL of sample and 300 uL of MD2. Program this x4 dilution for an onboard dilution x100. This reaches our CRR (Clinical Reporting Range, or Maximum Dilution Result) of 20,000 ng/mL. Evaluate the result and determine whether additional lesser or greater dilutions must be made. Another technologist must check manual dilution volumes and calculated factor.

Standard Reporting Format

Report results to the tenth place in ng/mL.

Conversion

To convert ng/mL (mass units) to µ(SI units), use the formula:

1 ng/mL = 1 µL

Disposal

Dispose of hazardous or biologically contaminated materials according to laboratory protocols. Discard all materials in a safe and acceptable manner, and in compliance with all federal, state, and local requirements.

Limitations

According to the manufacturer:

Serum specimens that have:	Have an insignificant (< 5%) effect on the assay up to:
Hemolysis	500 mg/dL of hemoglobin
Lipemia	1000 mg/dL of triglycerides
Icterus	40 mg/dL of bilirubin

Prostate cancer patients undergoing treatment with anti-androgens and LHRH agonists may exhibit markedly reduced levels of PSA. Also, men treated for benign prostatic hyperplasia with inhibitors or 5 alpha-reductase (finasteride) may demonstrate a significant reduction in PSA levels compared to values prior to treatment.[18]

The concentration of PSA in a given specimen determined with assays from different manufacturers can vary because of differences in assay methods, calibration, and reagent specificity.[19] PSA in serum and seminal fluid exists primarily in complexed and free forms, respectively.[20] Quality control samples may be produced by introducing seminal fluid PSA into serum matrices. PSA levels in these controls, determined with different manufacturers' assays, will vary depending on the method of standardization, antibody specificity, and different reactivity with complexed and free forms of PSA.

Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with *in vitro* immunoassays.[21] Patients routinely exposed to animals or animal serum products can be prone to this interference and anomalous values may be observed.

Expected Results

The manufacturer analyzed serum samples from healthy subjects and patients with various malignant diseases using the ACS:180 PSA. The patients included in this study represent a variety of disease states from active, progressive malignancy to no clinical evidence of disease. The frequency of positive PSA results is significantly lower in patients with no evidence of active disease compared to those with active disease.

% Distribution of PSA by Diagnostic Category

		ng/mL of PSA				
Patient Diagnosis	**N**	**0.0-4.0**	**4.1-10**	**10.1-40**	**>40**	**Median PSA**
Apparently Healthy						
Female	100	100.0	0.0	0.0	0.0	< 0.06
Male < 40	71	100.0	0.0	0.0	0.0	0.73
Male 40-50	50	100.0	0.0	0.0	0.0	0.53
Male 50-60	54	100.0	0.0	0.0	0.0	0.61
Male 60-70	50	100.0	0.0	0.0	0.0	0.85
Male > 70	58	100.0	0.0	0.0	0.0	0.77
Total Males	283	100.0	0.0	0.0	0.0	0.71
Prostate Cancer						
Stage A	42	69.0	26.2	4.8	0.0	3.92
Stage B	50	60.0	32.0	8.0	0.0	3.52
Stage C	43	20.9	72.1	4.7	2.3	5.25

Stage D	46*	56.5	21.7	19.6	2.2	3.48
Total Prostate	191	51.6	38.0	9.3	1.1	4.04
Benign Disease						
Prostate Hypertrophy (BPH)	152	46.7	32.9	20.4	0.0	4.37
Genitourinary (GU)	50	90.0	8.0	2.0	0.0	1.38
Prostatitis	18	27.8	5.6	5.6	61.1	125.9
Rheumatoid Factor	5	100.0	0.0	0.0	0.0	0.58
Other Cancers						
Breast	10	100.0	0.0	0.0	0.0	0.08
Renal	6	100.0	0.0	0.0	0.0	0.37
Pulmonary	10	100.0	0.0	0.0	0.0	0.08
Misc. GU	39	92.3	5.1	2.6	0.0	0.42
Gastrointestinal	12	91.7	0.0	0.0	8.3	0.9
Other	18	100.0	0.0	0.0	0.0	0.45

*Includes sera from treated patients

Expected Values in the Detection of Prostate Cancer

The manufacturer evaluated the effectiveness of PSA when used along with DRE in detecting prostate cancer. A total of 291 biopsied men aged 50 years or older were included in the study. In the population of 291 subjects 76 men, or 26.1%, were found to have cancer. The positive predictive value (PPV) of PSA at the cutoff of 4.0 ng/mL was 28.4%. The study also demonstrated that PSA testing, when used in conjunction with DRE was more effective than DRE alone.

PSA elevations greater than 4.0 ng/mL may warrant additional testing even if the DRE is negative. However, the converse is also true: a subject with a suspicious DRE and normal PSA may also require additional testing since DRE detected 17% (13/76) of cancers that PSA determinations did not.

Refer to the following table for a summary of the study results.

	Number of Subjects	Number of Cancers	% Positive Biopsies
All subjects	291	76	26.1
PSA > 4.0 ng/mL	218	62	28.4
DRE +	127	55	43.3
PSA < 4.0 ng/mL, DRE -	32	1	3.1
PSA > 4.0 ng/mL, DRE -	132	20	15.2
PSA , < 4.0 ng/mL, DRE +	41	13	31.7
PSA > 4.0 ng/mL, DRE +	86	42	48.8

Reference Interval

≤ 4.0 ng/mL

UCDMC In-house Study

A limited in-house study included 22 males and 19 females: medical students, and some staff. This study showed a range of < 0.1 to 0.38 ng/mL for females and a range of 0.31 to 1.20 ng/mL for males. The ages of those tested ranged from 22 to 56 years old, with most individuals in their 20s and 30s. All values were within the suggested reference interval of 0 to 4.0 ng/mL. Our female medial value was < 0.1 (0.01) ng/mL and our male median value was 0.68 ng/mL. These numbers look similar to the medians provided by the manufacturer's package insert.

Performance Characteristics

Analytical Measurement Range

0.1 – 50.0 ng/mL.

The manufacturer states that the ADVIA Centaur PSA assay measures total PSA concentrations up to 100 ng/mL with a minimum concentration of 0.01 ng/mL.

According to the manufacturer, patient samples with high total PSA levels can cause a paradoxical decrease in the RLUs (high dose hook effect). In this assay, patient samples with total PSA levels as high as 10,000 ng/mL will assay greater than 100 ng/mL. Samples greater than 10,000 ng/mL may assay within the linear range of the assay.

Because of the possible hook effect, the AMR at UCDMC will be 0.1 – 50.0 ng/mL.

Clinical Reportable Range

0.1 - 20,000 ng/mL

Results less than 0.1 ng/mL will be reported as **< 0.1 ng/mL**.

Results greater than 20,000 ng/mL will be reported as **> 20,000 ng/mL**.

Specificity

There are no known cross-reactants for PSA.

The potential interference of chemotherapeutic agents, therapeutic drugs, and tumor marker antigens was tested by adding these substances to serum pools containing PSA ranging from 0.77 to 7.12 ng/mL. The level of PSA in each of these pools was then determined using the ADVIA Centaur PSA assay and normalized to the level without the respective drugs or antigen.

Substance	Amount Added (ug/mL)	Mean % Recovery (Spike/control X 100)
Cyclophosphamide	700	100.5
Doxorubicin Hydrochloride	51.8	100
Methotrexate	22.72	101
Megestrol acetate	39.6	101
Diethylstilbestrol	5.0	100
Leuprolide (LUPRON)	15.0	100
Estramustine Phosphate	81.7	99
Flutamide	10.0	100
Zoladex (Goserelin Acetate)	7.2	98
Trypsin Proscar (Finasteride	0.37	102
Cardura	0.8	100

Interference testing was determined according to CLSI Document EP7-A2[19]

Sensitivity

0.1 ng/mL

The ADVIA Centaur PSA assay has a minimum detectable concentration (analytical sensitivity) of 0.01 ng/mL. Analytical sensitivity is defined as the concentration of total PSA that corresponds to the RLUs that are two standard deviations greater than the mean RLUs of 20 replicate determinations of the PSA zero standard. This sensitivity was verified in-house using 6 replicates of the zero standard.

Linearity

0.1 – 50.0 ng/mL

Linearity/Reportable Range Verification determined by UCDMC

Centaur XP-IRL96830930

Level	N	Mean	%CV	Target
1	3	0.00	N/A	0.00
2	3	0.86	4.39	0.80
3	3	3.43	5.41	3.42
4	3	26.2	3.41	24.6
5	3	43.2	2.39	47.7
6	2	92.1	3.92	100.0

Centaur XP-IRL13981026

Level	N	Mean	%CV	Target
1	3	0.00	N/A	0.00
2	3	0.85	4.24	0.80
3	3	3.41	3.97	3.42
4	3	25.5	3.73	24.6
5	3	43.5	5.89	47.7
6	1	88.2	0.00	90.0

Precision

As determined by the manufacturer: six serum samples were assayed 3 times in 8 runs, on 4 systems (n=24 for each sample), over a period of 3 days. The following results were obtained:

Mean (ng/mL)	Within-run % CV	Run-to-Run % CV	Total % CV
0.44	4.38	4.05	5.97
0.708	3.08	20.7	3.71
1.831	20.9	4.67	5.12
1.934	20.8	1.56	2.60
11.308	2.97	3.61	4.68
17.706	2.29	2.40	3.31

As determined by UCDMC

Centaur XP-IRL96830930

Type of Precision	Sample Type	n	Mean	SD	% CV
Within-run	Siemens Control Level 1	20	0.80	0.31	3.82
	Siemens Control Level 2	20	2.77	0.80	2.89
	Siemens Control Level 3	20	23.1	0.86	3.74
Between-run	MAS OMNI Control Level 1	20	0.78	0.03	3.86
	MAS OMNI Control Level 2	20	2.75	0.12	4.21
	Mass OMN Control Level 3	20	23.4	0.78	3.35

Centaur XP-IRL13981026

Type of Precision	Sample Type	n	Mean	SD	% CV
Within-run	Siemens Control Level 1	20	0.82	0.21	2.53
	Siemens Control Level 2	20	2.82	0.05	1.77
	Siemens Control Level 3	20	23.8	0.73	3.05
Between-run	MAS OMNI Control Level 1	20	0.80	0.02	3.11
	MAS OMNI Control Level 2	20	2.75	0.09	3.40
	MAS OMNI Control Level 3	20	23.9	3.40	2.41

Method Comparison

As determined by the manufacturer: Six-hundred sixty-one (661) samples in the range of 0.07 to 93.3 ng/mL were evaluated. The relationship between the ADVIA Centaur PSA assay and the ACS:180 PSA assay is described by the following equation:

ADVIA Centaur PSA = 0.99 (ACS:180 PSA) – 0.99

Correlation coefficient (R) = 0.99

As determined by UCDMC: Forty-five (45) samples in the PSA range of 0.10 to 33.9 ng/mL were evaluated. The relationship between ADVIA Centaur (XP-IRL96830930) versus comparison method (ADVIA Centaur, S/N: 2051) is described below:

Y (XP-IRL96830930) = 0.91x + 0.07
Correlation coefficient (R): 0.99
Mean Bias (ng/mL): -0.34
Mean Bias (%): -7.9

An additional 45 PSA specimens ranging from 0.00 to 28.6 ng/mL were evaluated between the ADVIA Centaur (XP-IRL13981026) versus ADVIA Centaur (XP-IRL96830930) serving as the comparison method. The relationships between these two instruments are described below:

Y (XP-IRL13981026) = 1.01x + 0.02
Correlation coefficient (R): 1.00
Mean Bias (ng/mL): 0.09
Mean Bias (%): 2.3

Dilution Recovery

The manufacturer diluted six serum samples with total PSA in the range of 41.90 to 85.36 ng/mL with Multi-Diluent 2 and assayed for recovery and parallelism. The recoveries ranged from 94.4% to 109.0% with a mean of 102.4%.

Sample	Amount Added (ng/mL)	Observed (ng/mL)	Recovery %
1	-	0.81	
	24.8	25.39	99.1
	43.7	47.68	107.3
	63.4	61.31	95.4
	Mean		100.6
2	-	1.05	
	24.8	24.66	95.2
	43.7	43.38	96.9
	63.4	59.73	92.6
	Mean		94.9
3	-	<0.06	
	17.5	18.26	104.3
	30.4	32.56	107.1
	44.3	42.42	95.8
	Mean		102.4
4	-	2.31	
	24.8	27.51	101.6
	43.7	47.68	103.8
	63.4	61.31	93.1
	Mean		99.5
5	-	2.73	
	24.8	26.90	97.5
	43.7	47.97	103.5
	63.4	66.13	100.0
	Mean		100.3
6	-	3.05	
	24.8	27.81	99.8
	43.7	46.28	98.9
	63.4	64.74	97.3
	Mean		98.7
Mean			**99.4**

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