

Supplemental Test Information



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Section 1

Introduction



Section 1 - Introduction

How to Use This Document

This document is a supplement to Spectra's test menu listing. Use this document to find additional information pertaining to Spectra's testing services.

Getting Started

Refer to the Table of Contents to find the test section that is of interest to you.

About Spectra Laboratories

Established in 1989, Spectra Laboratories is the leading provider of renal-specific testing services. Spectra utilizes state-of-the art specimen processing, analytical, and reporting techniques to provide accurate and timely results. Spectra has expanded its service offerings to other healthcare related markets including clinical research and correctional healthcare.

Contact Us

If you have any questions regarding the information contained in this document, please contact your local Spectra Customer Service representative:

800-433-3773: Milpitas, California

800-522-4662: Rockleigh, New Jersey

Section 2 General Test Information



Section 2 - General Test Information

Test Information

Whenever possible, each test description includes pertinent information related to the use of the test in the ongoing treatment and monitoring of dialysis patients. All tests are assumed to be drawn pre-dialysis unless specified as post-dialysis tests.

Information for the test listings has been obtained from the following references:

- Chernecky CC and Berger BJ ed. Laboratory Tests and Diagnostic Procedures, 6th ed., Saunders Elsevier; 2012.
- Daugirdas JT, Blake PG, Ing TS, edr. Handbook of Dialysis. 4th ed., Lippincott Williams & Wilkins; 2007.
- Jacobs DS, DeMott WR, Oxley DK, edr. Laboratory Test Handbook, 5th ed., Lexi-Comp, Inc; 2001
- Goldman L and Schaffer ed. Goldman's Cecil Medicine, 24th ed., Elsevier; 2008.
- Greer, JP et al. Wintrobe's Clinical Hematology, 13th ed., Wolters Kluwer/Lippincott Williams and Wilkins; 2014.
- Henry's Clinical Diagnosis and Management by Laboratory Methods, 22nd ed., Elsevier.
- Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 5th ed., Burtis, Ashwood and Bruns, Elsevier.
- Wintrobe's Clinical Hematology, 13th ed., Lippincott Williams & Wilkins.

Specimen Rejection Criteria

Each test listing may include a list of factors that can affect test results (interferences). If a test cannot be performed on a specimen because of the presence of one or more of these factors, the laboratory will request a new specimen. These factors may include conditions such as:

- Hemolysis
- Lipemia
- Clotted
- Improper storage/transport temperature

Other factors that can result in a request for a new specimen include:

- Inappropriate specimen for testing
- Collection of the specimen in the wrong tube/container
- Improper specimen collection techniques
- Specimen unlabeled
- Insufficient quantity to perform all tests

Section 2 - General Test Information

Test Criteria Definitions:

Alert Values

Alert values are test results that may indicate an extreme condition and may require more rapid clinical attention. Alert values are divided into two different tiers of notification from the laboratory (Tier 1 and Tier 2).

Tier 1: Alert values called when released by the laboratory or paged to physician; a report is also transmitted to the clinic

Tier 2: Alert values called on the same day of release (within normal clinic business hours); report is also transmitted to the clinic

Exception Values








Exception values are test results that may indicate a need for treatment changes. They may also indicate the need for monitoring more long term trends in care. Exception values are divided into two different tiers of notification from the laboratory (Tier 3 and Tier 4)

Tier 3: Laboratory transmits a report once results are available (several times per day)

Tier 4: Laboratory transmits a summary of exception values (two times per day)

Order of Draw for Multiple Tube Collections

NOTE: Collect blood cultures **prior to** collecting blood tubes.

1		Serum Separator Tube (SST™)
2		Red (No Gel)
3		Royal Blue
4		Light Blue
5		Mint Green PST™
6		Lavender
7		Gold PST (Post Samples ONLY)

Important Reminders

- Allow each tube to fill completely
- Invert all tubes 5-10 times to mix blood with additives
- Do not place tubes on top of machines
- Place filled tubes in lab area immediately after collection
- Refrigerate light blue, lavender, red, and royal blue top tubes immediately
- Allow SSTs to clot completely before spinning
- Check SSTs and PSTs for complete separation when removing from centrifuge
- Plasma Separator Tubes (PSTs) do not need to clot before spinning

Section 2 - General Test Information

Information Found in Each Test Listing

Heading:	What information can be found
Test Name:	Test name/abbreviation as listed on the requisition form or in your ordering system
(Synonyms)	Common synonyms (including abbreviations) for the test
Specimen Requirements:	The exact specimen requirements for the test Refer to the individual test for specimen collection instructions
Other Requirements:	Any additional specimen collection or handling requirements
Reference Range:	The test reference range for normal, healthy individuals
Exception Value:	The range of test values that may indicate a condition which requires attention
Alert Value:	The range of test values that may indicate an extreme condition that requires immediate attention
Specimen Stability:	Refrigerated xx days
Usage:	What the test is typically used for
Methodology:	The method used for the analysis of the test
Interferences:	Conditions that may alter test results
Confirmatory Tests:	Additional tests performed to confirm positive results
TAT:	The turnaround time for a test (from time of receipt in the lab)
CPT Code:	The Current Procedural Terminology code for standardized identification of laboratory test
LOINC Code:	Logical Observation Identifiers Names and Codes

Section 2 - General Test Information

Turnaround Times and Test Set-Up Days

NOTE: Turnaround times listed are from the time the specimen is received at Spectra.

Keep in mind that actual turnaround times may be longer than the listed time if a specimen is received on a day that a test is not set up. For example, the turnaround time for a specimen received on a Saturday may be three days longer than the time listed if the test is set up Tuesday through Friday.

Confirmatory and Reflex Testing

Definitions

Reflex testing occurs when a test result triggers additional testing. The additional tests may confirm a result or give the physician additional useful information on that sample. Certain analytical procedures are not specific enough to give an accurate diagnosis and additional testing referred to as **confirmatory testing** is performed. Confirmatory testing is frequently mandated by regulatory agencies and good medical practice.


Policy

Spectra's policy is not to perform reflex or confirmatory testing except where such testing is required by law (HIV or RPR) or is dictated by good medical practice (Culture or Urinalysis). In the latter case, the physician will be given the choice to order the tests individually without the reflex or confirmatory option. If the reflex or confirmatory option is selected and a positive result triggers the additional testing, all testing, including the additional test will be billed to the appropriate party. This policy is in accordance with Spectra's Medicare carrier which requires that a laboratory not perform reflex testing without a specific order from the physician. The case of HBsAg is unique in that all first-time positives are confirmed by neutralization and the neutralization is not billed. The neutralization is not orderable and only occurs as a reflex action for all first-time positives.

The table below indicates those tests for which Spectra offers a reflex option.

Test Ordered	Reflex Test	Performed By	Billing Status	Additional CPT
HIV Antibody	Western Blot	ARUP	Billed	86689
Syphilis Test With Confirmation (STS)	RPR (T pallidum Confirm) Note: Negative reflex tests will be sent for T pallidum Ab by TP-PA	Spectra Laboratories ARUP	Billed	86780
HBsAg	HBsAg Neutralization	Spectra Laboratories	Not Billed	
Cultures	Susceptibility	Spectra Laboratories	Billed	87184 87186
Urinalysis	Microscopic Examination	Spectra Laboratories	Billed	81015

Section 3
Microbiology Testing
Services



Listing of Antibiotic Susceptibilities Performed

If a susceptibility is included in the test listing, the following antibiotic susceptibilities will be performed and reported for the indicated organism unless otherwise indicated. Upon request Spectra Laboratories will provide susceptibilities in addition to those listed.

GRAM POSITIVE ORGANISMS

Staphylococcus - All sites except urine

- a. Ciprofloxacin
- b. Clindamycin
- c. Erythromycin
- d. Gentamicin
- e. Levofloxacin
- f. Linezolid
- g. Moxifloxacin
- h. Oxacillin
- i. Penicillin
- j. Quinupristin/Dalfopristin
- k. Rifampin
- l. Tetracycline
- m. Trimeth-Sulfa
- n. Vancomycin

Staphylococcus- Urine only

Antibiotics a through q above plus:

- r. Nitrofurantoin

Enterococcus sp - All sites except urine

- a. Ampicillin *
- b. Gentamicin HL
- c. Levofloxacin
- d. Linezolid
- e. Penicillin
- f. Quinupristin/Dalfopristin
- g. Streptomycin HL
- h. Tetracycline
- i. Vancomycin*

*Combination therapy with an aminoglycoside may be necessary in cases of endocarditis

Enterococcus sp- Urine only

Antibiotics a through d above plus:

- h. Nitrofurantoin

Listing of Antibiotic Susceptibilities Performed

GRAM POSITIVE ORGANISMS (cont'd)

S. Pneumoniae - All sites

Streptococcus (not Enterococcus sp.) Sterile sites only

Beta Hemolytic Streptococcus Group B

- a. Ampicillin
- b. Cefotaxime
- c. Ceftriaxone
- d. Clindamycin
- e. Erythromycin
- f. Levofloxacin
- g. Linezolid
- h. Moxifloxacin
- i. Penicillin
- j. Tetracycline
- k. Trimethoprim-Sulfamethoxazole
- l. Vancomycin

Listing of Antibiotic Susceptibilities Performed

GRAM NEGATIVE ORGANISMS

Gram Negative Bacilli

Antibiogram is dependent on the bacteria isolated

- a. Acinetobacter sp
- b. Burkholderia cepacia
- c. Enterobacteriaceae
- d. Other Non-Enterobacteriaceae, including Pseudomonas sp
- e. Pseudomonas aeruginosa
- f. Salmonella sp
- g. Shigella sp

Gram Negative Bacilli

- | | |
|--------------------------------------|----------------------------|
| a. Ampicillin | k. Ertapenem |
| b. Ampicillin/Sulbactam | l. Gentamicin |
| c. Aztreonam | m. Levofloxacin |
| d. Cefzazolin | n. Meropenem |
| e. Cefepime | o. Piperacillin/Tazobactam |
| f. Ceftazidime | p. Tobramycin |
| g. Ceftriaxone | |
| h. Trimethoprim/
Sulfamethoxazole | Urine Only |
| | a. Nitrofurantoin |

Stenotrophomonas maltophilia- All sites

- a. Ceftazidime (by request only)
- b. Levofloxacin
- c. Minocycline (by request only)
- d. Ticarcillin/Clavulanic (by request only)
- e. Trimethoprim/Sulfamethoxazole

Section 4
Peritoneal Dialysis
Testing Services



Section 4 - Peritoneal Dialysis Testing Services

Spectra Laboratories provides comprehensive laboratory testing services for the care of peritoneal dialysis patients. We have incorporated the most advanced and widely accepted clinical approaches for evaluating the appropriateness and adequacy of peritoneal dialysis therapy.

Our peritoneal dialysis testing services include:

1. Peritoneal Dialysate Fluid (PDF) Sample Testing
2. Peritoneal Equilibrium Test (PET) and Transport Classification
3. Peritoneal Dialysis Adequacy and Calculations
4. Peritoneal Function Test (PFT)
5. Microbiology Testing for Suspected Peritonitis

NOTE: All PDF Creatinine results are corrected for glucose interference. The Creatinine correction factor for glucose is 0.0002.

Turnaround Time and Test Set-Up Days

NOTE: Turnaround times listed are from the time the specimen is received at Spectra.

Keep in mind that actual turnaround times may be longer than the listed time if a specimen is received on a day that a test is not set up. For example, the turnaround time for a specimen received on a Saturday may be three days longer than the time listed if the test is set up Tuesday through Friday.

PERITONEAL EQUILIBRATION TEST (PET)

Spectra Laboratories offers both Standard and Fast PET testing, calculations, and interpretation. The Standard PET requires four specimens (0 hr PDF, 2 hr PDF, 4 hr PDF, and one serum specimen). The Fast PET requires two specimens (4 hr PDF and one serum specimen). Fast PET data can be used if there are missing or poorly collected specimens for the 0 and 2 hour time points, or if it is inconvenient for the patient to be at the clinic for the entire four hours of the procedure.

PET Requirements:

Standard PET

Serum Glucose and Creatinine at 2 hours (SST Gel Tube)

Dialysate Glucose and Creatinine at 0, 2, 4, hours (Yellow Conical Tubes labeled 0, 2, & 4 hours)

Standard PET with Urea

Same as above plus Serum Urea at 2 hours (SST Gel Tube)

Same as Standard PET plus Dialysate Urea on 0, 2, & 4 hr specimens

Standard PET with Total Protein

Same as above plus Serum Total Protein at 2 hours (SST Gel Tube)

Same as Standard PET plus Dialysate Total Protein at 0, 2, & 4 hr specimens

Standard PET with Sodium

Same as Standard PET plus Serum Sodium at 2 hours (SST Gel Tube)

Same as Standard PET plus Dialysate Sodium at 0, 2, & 4 hr specimens

FAST PET

Serum Glucose and Creatinine at 4 hours (SST Gel Tube)

Dialysate Glucose and Creatinine at 4 hours (Yellow Conical Tube labeled 4 hours)

Section 4 - Peritoneal Dialysis Testing Services

STEPS FOR PERFORMING PET

- Step 1:** 8-12 hours “overnight” 2 L, 2.5% dextrose dwell.
- Step 2:** Prepare 2 L, 2.5 % dextrose solution.
- Step 3:** Drain “overnight” dwell. If submitting sample, collect 8.5 mL PD Fluid in Yellow Conical Tube.
Label Timed PD Fluid
- Step 4:** Infuse fresh solution. 400 mL per 2 minutes. **Note 0 hour dwell.**
- Step 5:** Collect 8.5 mL PD Fluid in Yellow Conical Tube at 0 hour dwell time.
Label PD Fluid 0 hr
- Step 6:** Collect 8.5 mL PD Fluid in Yellow Conical Tube at 2 hour dwell time.
Label PD Fluid 2 hr
- Step 7:** Collect and spin SST at 2 hour dwell time.
- Step 8:** Drain exchange at 4 hour dwell time. Record volume.
- Step 9:** Collect 8.5 mL PD Fluid in Yellow Conical Tube from 4 hour dwell.
Label PD Fluid 4 hr
- Step 10:** Refrigerate and ship samples.

STANDARD PET CALCULATIONS

GLUCOSE TRANSPORT CLASSIFICATION

Step 1:
$$\frac{2 \text{ hr D/DO} = 2 \text{ hr Peritoneal Dialysate Glucose}}{0 \text{ hr Peritoneal Dialysate Glucose}}$$

$$\frac{4 \text{ hr D/DO} = 4 \text{ hr Peritoneal Dialysate Glucose}}{0 \text{ hr Peritoneal Dialysate Glucose}}$$

This determines Creatinine Transport Classification

Step 2:
$$\frac{0 \text{ hr D/P} = 0 \text{ hr Peritoneal Dialysate Creatinine}}{\text{Serum Creatinine}}$$

$$\frac{2 \text{ hr D/P} = 2 \text{ hr Peritoneal Dialysate Creatinine}}{\text{Serum Creatinine}}$$

$$\frac{4 \text{ hr D/P} = 4 \text{ hr Peritoneal Dialysate Creatinine}}{\text{Serum Creatinine}}$$

- Step 3:** Additional Patient Solute Transport Classification information may be obtained by plotting the post PET drain volume.

Section 4 - Peritoneal Dialysis Testing Services

FAST PET CALCULATIONS

Step 1: Plot 4 hr Peritoneal Dialysate Glucose to determine **Glucose Transport Classification**

$$\frac{4 \text{ hr D/P} = 4 \text{ hr Peritoneal Dialysate Fluid Creatinine}}{\text{Serum Creatinine}}$$

This determines Creatinine Transport Classification

Step 2: Additional Patient Solute Transport may be obtained by plotting the Post PET Drain Volume.

If all points plotted fall within the same range (within two adjacent classification categories, typically on either side of the dividing line), the test results are considered to be consistent and the actual **Patient Solute Transport Classification** probably falls between the reported Glucose and Creatinine Transport Classifications.

If all points plotted do not fall within the same range, the test results are considered to be “inconsistent.” If the patient’s clinical condition does not correlate with the **Glucose and Creatinine Solute Transport Classifications**, a repeat PET may be advisable.

ADEQUACY OF DIALYSIS

Monitoring Kt/V and Protein Catabolic Rate/Protein Nitrogen Appearance (PNA) has become widespread due to the growing body of research that indicates that they are the best indicators developed for PD Adequacy evaluation. Spectra’s comprehensive Adequacy of Dialysis includes the testing and calculations needed to provide PD Fluid and Urine Clearance, Kt/V, and nPCR (nPNA) for both adults and children.

PNA estimates the patient’s dietary protein intake by measuring the rate at which protein by-products are removed from the blood. Spectra Laboratories performs all laboratory tests and calculations, and provides reports containing the data, calculations, and final results.

Adult Adequacy Includes:

1. Urea Clearance (PD)
PD Volume and Collection Time
2. Measured Creatinine Clearance (PD)
(See #3 for requirements)
3. Kt/V Measured PD
Dialysate Total Volume
Dialysate Total Time
Urine Total Volume
Urine Total Time
Height and Weight of the Patient
Amputee Status (if appropriate)

Section 4 - Peritoneal Dialysis Testing Services

Pediatric Adequacy includes:

Same information as for Adult Adequacy (see previous page)

Specimen Requirements:

Creatinine and Urea Nitrogen Serum (SST Gel Tube)

Creatinine and Urea Clearances PD

Creatinine, Urea, and Glucose 24 hr PD Fluid (Yellow Conical Tube) with Total Volume recorded

Creatinine and Urea Clearance Urine

Creatinine and Urea Urine timed (hr) collection (Yellow Conical Tube) with Total Volume recorded

Kt/V Measured PD for Adult and Children includes:

PNA, nPNA, PD Creatinine and Urine Clearances, weekly calculations, PD Fluid Kt/V, Urine Kt/V if urine is provided, Urea Volume, and Total Kt/V.

To perform calculations, all tubes must be provided. All patient data (height, weight, and amputee status) and specimen volumes and collection times are necessary.

CALCULATIONS

1. Urine Creatinine Clearance:

$$\frac{\text{Timed Urine Creatinine (mg/dL)} \times \text{Timed Urine Volume (mL)}}{\text{Serum Creatinine (mg/dL)} \times \text{Urine Collection Time (min)}} = \text{Urine Creatinine Clearance (mL/min)}$$

2. Urine Urea Clearance:

$$\frac{\text{Timed Urine Urea Nitrogen (mg/dL)} \times \text{Time Urine Volume (mL)}}{\text{Serum Urea Nitrogen (mg/dL)} \times \text{Urine Collection Time (min)}} = \text{Urine Urea Clearance (mL/min)}$$

3. PD Fluid Creatinine Clearance:

$$\frac{\text{Timed PD Fluid Creat. (mg/dL)} \times \text{Timed PD Fluid Volume (mL)}}{\text{Serum Creatinine (mg/dL)} \times \text{PD Fluid Collection Time (min)}} = \text{PD Fluid Creatinine Clearance (mL/min)}$$

NOTE: Clearances are normalized to patient's body surface area.
PDF Creatinine Corrected For Glucose

$$\text{Normalized Clearance (mL/min)} = \text{Clearance} \times (1.73 \text{ m}^2 / \text{Patient's Body Surface Area})$$

NOTE: Body Surface Area (BSA) calculation (DuBois & DuBois):

$$(0.007184 \text{ WT})^{0.425} \times (\text{HT})^{0.725}$$

WT is the weight in kg

HT is the height in cm

Section 4 - Peritoneal Dialysis Testing Services

4. **PD Fluid Urea Clearance:**

$$\frac{\text{Time PD Fluid Urea (mg/dL)}}{\text{Serum Urea (mg/dL)}} \times \frac{\text{Timed PD Fluid Volume (mL)}}{\text{PD Fluid Collection Time (min)}} = \text{PD Fluid Urea Clearance (mL/min)}$$
5. **Weekly Urine Creatinine Clearance:**

$$\frac{\text{Urine Creatinine Clearance} \times 10,080 \text{ min/week}}{1,000 \text{ mL}} = \text{Weekly Urine Creatinine Clearance (L/week)}$$
6. **Weekly PD Fluid Creatinine Clearance:**

$$\frac{\text{PD Fluid Creatinine Clearance} \times 10,080 \text{ min/week}}{1,000 \text{ mL}} = \text{Weekly PD Fluid Creatinine Clearance (L/week)}$$
7. **Weekly Urine Urea Clearance:**

$$\frac{\text{Urine Urea Clearance} \times 10,080 \text{ min/week}}{1,000 \text{ mL}} = \text{Weekly Urine Urea Clearance (L/week)}$$
8. **Total Weekly Creatinine Clearance:**

$$\text{Weekly Urine Creatinine Clearance (L/week)} + \text{Weekly PD Fluid Creatinine Clearance (L/week)} = \text{Total Weekly Creatinine Clearance (L/week)}$$
9. **Total Weekly Urea Clearance:**

$$\text{Weekly Urine Urea Clearance (L/week)} + \text{Weekly PD Fluid Urea Clearance (L/week)} = \text{Total Weekly Urea Clearance (L/week)}$$
10. **Total Body Water/Urea Volume Distribution (Hume & Weyers) Adult Male:**

$$\text{Urea Volume (L)} = - 14.012934 + [0.296785 \times \text{Wt (kg)} + (0.192786 \times \text{Ht (cm)})]$$
11. **Urea Volume Distribution Adult Female:**

$$\text{Urea Volume (L)} = - 35.270121 + [0.183809 \times \text{Wt (kg)} + (0.344547 \times \text{Ht (cm)})]$$
12. **Urea Volume Distribution (Mellits-Cheek Formula) Pediatric Female:**

$$\begin{aligned} \text{Urea Volume (L)} &= 0.076 + 0.507 \times \text{Wt (kg)} + 0.013 \times \text{Ht (cm)} \text{ when Ht} < 110.8 \text{ cm} \\ &= - 10.313 + 0.252 \times \text{Wt (kg)} + 0.154 \times \text{Ht (cm)} \text{ when Ht} > 110.8 \text{ cm} \end{aligned}$$
13. **Urea Volume Distribution Pediatric Male:**

$$\begin{aligned} \text{Urea Volume (L)} &= - 1.927 + 0.465 \times \text{Wt (kg)} + 0.045 \text{ Ht (cm)} \text{ when Ht} < 132.7 \text{ cm} \\ &= - 21.993 + 0.406 \times \text{Wt (kg)} + 0.209 \times \text{Ht (cm)} \text{ when Ht} > 132.7 \text{ cm} \end{aligned}$$
14. **Kt/V:**

$$\text{Kt/V} = \text{Total Weekly Urea Nitrogen Clearance (L/Week)} / \text{Urea Volume}$$
15. **PNA and nPNA:**

$$\text{Urea Generation Rate (UGR)} = \frac{0.01 \times [(\text{PDF vol (mL)} \times \text{PDF Urea Nitrogen (mg/dL)}) + (\text{Urine Vol (mL)} \times \text{Urine Urea Nitrogen (mg/dL)})]}{[\text{PD Collection Time (min)}] + [\text{Urine Collection Time (min)}]}$$

$$\begin{aligned} \text{PNA (g/day)} &= 10.76 \times 0.01 \times \text{UGR} + 1.46 \\ \text{PNA (g/kg/day)} &= \text{PNA/Weight} \\ \text{nPNA} &= [\text{PNA (g/day)} / (\text{Ideal Weight})] \\ \text{Ideal Weight} &= \text{Urea Volume Distribution}/0.58 \end{aligned}$$

Section 4 - Peritoneal Dialysis Testing Services

PERITONEAL FUNCTION TEST (PFT)

The Peritoneal Function Test (PFT) measures the peritoneal mass transfer area coefficient during routine exchanges instead of under highly controlled conditions required for the PET. In addition to peritoneal transport and fluid balance, this test allows the clinician to access the total delivered dose for Urea and Creatinine and collect information on protein and calorie nutrition.

The PFT requires:

1. A sampling of each exchange
2. A written record of each exchange
3. Inflow and outflow volume and glucose concentration
4. Duration of dwell for each exchange in the 24 hours before a clinic visit
5. A urine collection and blood sample at the end of the collection
6. An exchange drained in the clinic at the time of the visit (QA sample) as a control

Specimen Requirements:

1. 1 to 5 PDF samples in Yellow Conical Tubes
Tests required: Urea Nitrogen, Creatinine, Glucose, and Protein
2. Time Urine in Yellow Conical Tube
Tests required: Urea Nitrogen, Creatinine
3. Serum (SST Gel Tube)
Tests required: BUN, Creatinine, Glucose, Protein, and Albumin

Data Needed:

1. Collection Time for each PDF specimen
2. Volume in each PDF specimen (inflow volume)
3. Volume out for each PDF specimen (outflow volume)
4. Urine Collection Time, 24 hours
5. Urine Volume

Procedure for PFT

On the day of the PFT:

The overnight exchange is discarded. All exchanges for the next 24 hours are collected. The exchange schedule would look like the following:

1. Overnight exchange completed and discarded. All other exchanges during the next 24 hours are collected.
2. 12 noon exchange. This becomes bag #1. Record the following information:
Drain Time Begins
Fill Time Begins
Solution Percentage
Outflow Volume
3. The third exchange is performed and recorded as bag #2.
4. The fourth exchange is performed and recorded as bag #3.

Section 4 - Peritoneal Dialysis Testing Services

5. The overnight exchange which is drained the next am is bag #4.
(If 5 exchanges are done in the 24 hours, the times and bag numbers would reflect the additional exchange).
6. The morning exchange that is done will be drained in the clinic by the nurse and is labeled as the Quality Assurance (QA) exchange. This exchange should occur 2 to 4 hours after the morning drain.
7. All dialysate bags and urine collection should be measured for volumes and samples should be correctly labeled and recorded.

Section 4 - Peritoneal Dialysis Testing Services

NOTE: No calculations will be performed for PFT. Only raw data will be reported.

See Collection and Data Worksheet below:

BASELINE PERITONEAL FUNCTION TEST SPECIMEN COLLECTION AND DATA WORKSHEET								
Patient _____		DOB _____		Date _____				
M or F Clinic _____			Physician _____					
Exchanges on Day of Test	Drain Time Begins	Fill Time Begins	Solution %	Outflow Volume	Refrigerate all saved outflow bags			
#1				From overnight exchange	Throw this drain bag out			
#2				From exchange #1	Save outflow and label as #1			
#3				From exchange #2	Save outflow and label as #2			
#4				From exchange #3	Save outflow and label as #3			
#5 (If doing 5/day)				From exchange #4	Save outflow and label as #4 (If doing 5/day)			
Next Morning								
#1				From exchange #4 or 5	Save outflow and label as #4 (If doing 4/day or #5 if doing 5)			
#2 or QA					Come to CAPD Unit to do second exchange of the day.			
24 hour Urine Collection:		Start Date: _____		Time: _____				
		End Date: _____		Time: _____				
Weight (lb/kg) _____		Height _____						
	Exchange Schedule			Laboratory Results				
	Volume IN (L)	Dex. (%)	Time (hrs)	Urea N (mg/dl)	Creat. (mg/dl)	Gluc. (mg/dl)	Prot. (g/dl)	Volume outflow (ml)
URINE SAMPLE	-----	-----	-----			-----	-----	
SERUM SAMPLE	-----	-----	-----					-----
QA EXCHANGE								
BAG 1								
BAG 2								
BAG 3								
BAG 4								
BAG 5								
								Serum Albumin (g/dl)
470082 Rev. B 8/94						©1994. All rights reserved. Fresenius USA, Inc. 2637 Shadelands Dr. Walnut Creek, CA 94598 (800) 227-2572		

PERITONEAL EQUILIBRATION TEST

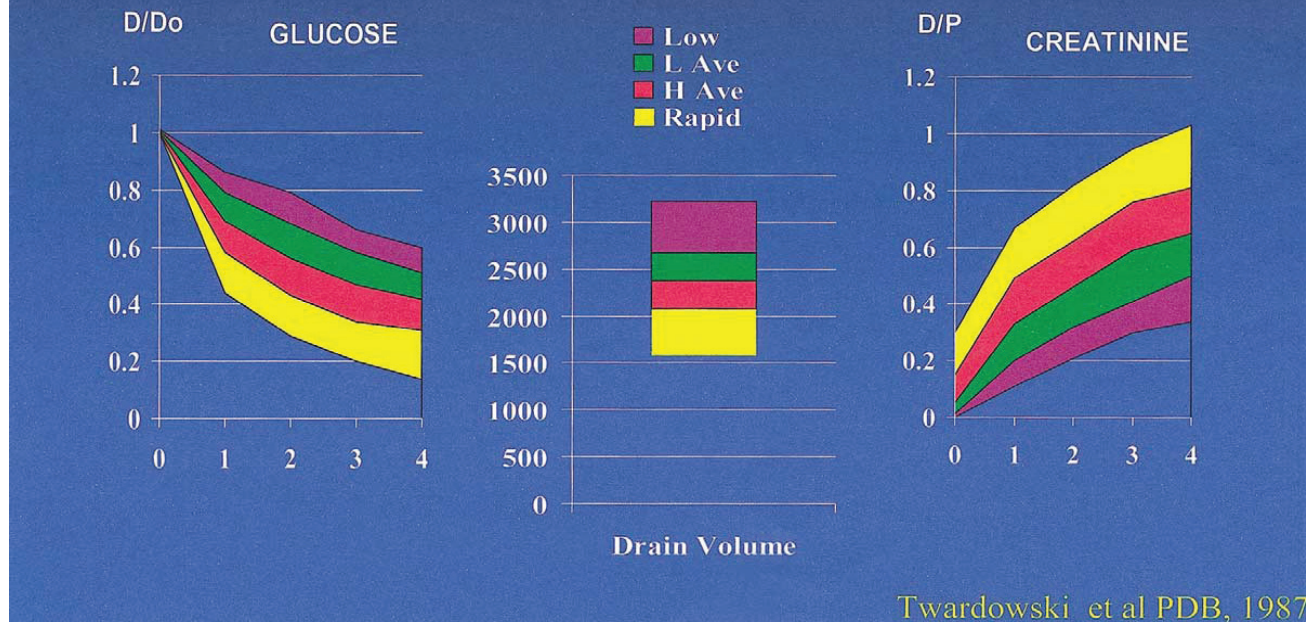


Fig. 1

Solute Transport	2 hr D/DO Glucose	4 hr D/DO Glucose	2 hr D/P Creatinine	4 hr D/P Creatinine	Ultra Filtration Volume
High	0.43-0.24	0.25-0.12	0.63-0.87	0.82-1.03	1580-2084
Average High	0.54-0.44	0.37-0.26	0.49-0.62	0.66-0.81	2085-2367
Average	0.55	0.38	0.48	0.65	2368
Average Low	0.66-0.56	0.49-0.39	0.34-0.47	0.50-0.64	2369-2650
Low	0.78-0.67	0.61-0.50	0.23-0.33	0.34-0.49	2651-3266

To determine Patient Solute Transport Classification, the dialysate to plasma (D/P) ratio for creatinine and the ratio of glucose in the dialysate compared to its initial concentration (D/D₀) 4 hours are calculated and plotted on the standard PET graph (Fig 1).

Additional Patient Solute Transport Classification information may be obtained by plotting the POST PET Drain Volume.

NOTE: Patient solute transport classification using post PET drain volume data may be invalid if patient serum glucose levels are greater than 300 mg/dL.

Section 4 - Peritoneal Dialysis Testing Services

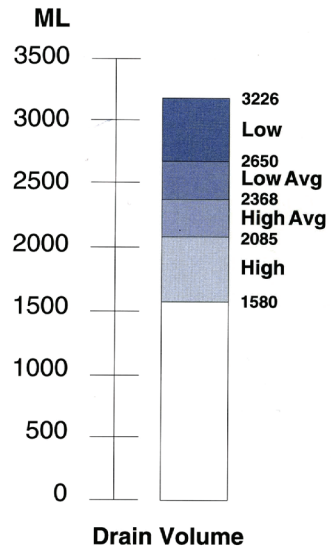
Standard or Fast P.E.T.

Post P.E.T. Drain Volume

1. Plot post P.E.T. drain volume to determine **Patient Solute Transport Classification.**

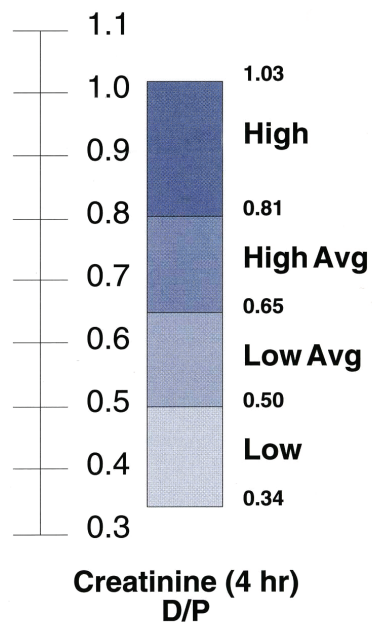
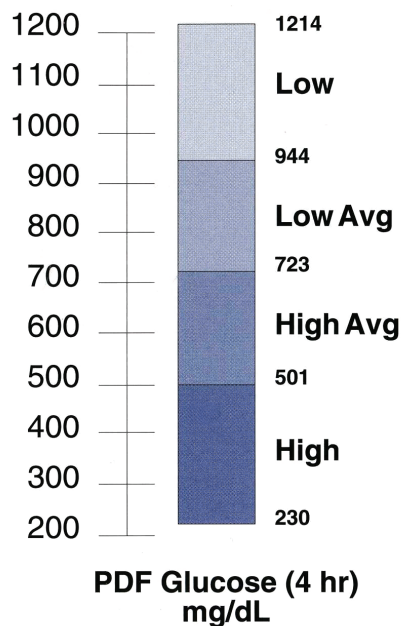
Note: Patient solute transport classification using post P.E.T. drain volume data may be invalid if patient serum glucose levels are greater than 300 mg/dL.

Post P.E.T. Drain Volume (Standard or Fast P.E.T.)



Fast P.E.T.

Fast P.E.T. Results



Section 5 - Water & Dialysate Testing Services

Background Theory

Dialysis patients are typically exposed to 360 liters of water per week. This is 25 times more water than the average patient who is not on dialysis. Poor water quality can lead to inflammatory complications. Possible contamination of water or dialysate could adversely affect every patient in the facility.

Spectra Laboratories provides quality water and dialysate testing.

At Spectra the following can be tested:

- Colony Count for water, bicarbonate and dialysate
- Endotoxin testing on water, bicarbonate and dialysate
- Chemical analysis for electrolytes and bicarbonate on dialysate
- AAMI testing for chemical contaminants

Colony Count

Description: Colony Count is the quantitative enumeration of the number of viable microorganisms present in water/dialysate sample submitted for examination. It is a measure of bacterial contamination following culture and incubation on microbiological medium. Colony Count is expressed in CFU/mL (Colony Forming Units per milliliter).

Method: Heterotrophic Plate Count (HPC) - spread plate technique. Plate is incubated and colony count is reported in 48 hours.

Specimens: Dialysis Water sample, Dialysate sample, Bicarbonate Solution sample

- Collected in a sterile cup (Yellow Cup) with integrated sampling device
- Transferred to a Clear Top Vacutainer® Tube without additive
- The tube must be immediately refrigerated after collection and until ready to be shipped to Spectra
- Shipped to Spectra using the supplied WATER AND DIALYSATE SHIPPING BOX and ice packs
- Ensure that all samples are properly labeled with the Spectra barcode to identify the sample

TVMC Ultra pure Colony Count

Description: Colony Count is the quantitative enumeration of the number of viable microorganisms present in water/dialysate sample submitted for examination. It is a measure of bacterial contamination following culture and incubation on microbiological medium. Colony Count is expressed in CFU/ml (Colony Forming Units per milliliter).

Method: Membrane filtration using 100 ml of water, dialysate or bicarb fluid. Plate is incubated and colony count reported at 7 days. Interim reports are issued at 48 hrs, and 4 days.

Specimens: Dialysis water, Dialysate, Bicarb fluid

- 100 ml of water, dialysate or bicarb fluid is collected in a sterile cup (orange cup)
- Sterile container must be immediately refrigerated after collection and until ready to be shipped to Spectra
- Shipped to Spectra (Rockleigh only) using the supplied WATER AND DIALYSATE SHIPPING BOX with ice packs
- Ensure that all samples are properly labeled with the Spectra barcode to identify the sample

Section 5 - Water & Dialysate Testing Services

Endotoxin Testing (LAL)

Description: Endotoxin is a major component of the outer membrane of the cell wall of gram negative bacteria and is released upon the rupture or destruction of the bacterial cell wall. Endotoxins are in large part responsible for clinical manifestations of a syndrome characterized by fever, shaking, chills, hypotension, and multiple organ failure if allowed to enter the circulation in a sufficient dose.

Method: Kinetic Quantitative Chromogenic

Specimens: Dialysis Water sample, Dialysate sample, Bicarbonate Solution sample

- Collected in a sterile cup with integrated sampling device
- Then transferred to a Clear Top Vacutainer Tube without additive
- Refrigerated in Clear Top Tubes immediately for at least 2 hours prior to shipment
- Shipped to Spectra using the supplied WATER AND DIALYSATE SHIPPING BOX and ice packs
- Ensure that all samples are properly labeled with the Spectra barcode to identify the sample



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