RESULTS *for* LIFE
LAB TESTING: BETTER HEALTH, IMPROVED OUTCOMES

Lab Tests for Chronic Kidney Disease: Stopping a Silent Enemy

Chronic kidney disease is silent—until it's too late. When patients discover it, they often face kidney failure or even death.

"When the doctor said I had Stage Three kidney disease, I freaked. I had these visions of being hooked up to a kidney dialysis machine."

Laboratory tests provide early-warning that allows for medical interventions that can prevent progression of chronic kidney disease (CKD) and help control its damaging effects. Two tests detect the disease in its earliest stages, when it is most treatable:

- ✓ Estimated Glomerular Filtration Rate (eGFR)—to determine how well the kidneys are functioning
- ✓ Urine albumin—to identify excess protein in the urine

These tests tell physicians how severe the disease is and give clues to its likely cause. That helps them select treatments that can halt the disease for many patients and prevent it altogether in others. The result: healthy kidneys.

With 26 million Americans suffering from CKD—and the prevalence, costs, and damage from the disease rising—this power of prevention is vital to America's health and health costs.

Slowing Progression

For many patients, CKD has progressed too far and cannot be stopped—but it can often

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A Virtual Case Study

I Found Out in Time

When Maria, an administrative assistant, turned 40, she felt like she had aged 20 years in six months. For no apparent reason, she felt tired all the time. Her feet were often swollen. Sometimes she felt itchy all over. But the clincher was when her supervisor suggested she see a doctor "about that smoker's cough."

Maria had never smoked a day in her life, but she had to admit that the cough was awful—and it worried her. So she visited her doctor the following week for a check-up, which included a series of blood tests and urine tests.

One was a urine albumin test to determine whether her kidneys were allowing too much protein into her system—a sign of kidney disease. The physician also gave her an eGFR test to figure out how well the filtering function of the kidneys was working. All signs pointed to chronic kidney disease. In addition, her blood pressure and cholesterol were high, and her blood glucose levels suggested pre-diabetes. A family history of kidney disease, as well as her Hispanic heritage, also put her in the high-risk group for kidney disease.

"When the doctor said I had Stage Three kidney disease, I freaked," said Maria. "I had these visions of being hooked up to a kidney dialysis machine. My grandmother died from kidney failure when I was a little girl in Costa Rica. And I wanted no part of it."

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be controlled. Physicians use results from the urine albumin and serum eGFR tests—as well as other tests—to identify the degree of kidney damage. The tests also suggest the likely rate of progression, as well as whether any contributing conditions, such as high blood pressure or diabetes, are present. This information is critical in helping the physician choose the best clinical approach. Often that involves medications to control blood pressure and blood sugar levels, or adjustments in diet and nutrition.

This individualized management of CKD can slow or even stop kidney decline. Diagnosing CKD early, for example, can delay end-stage kidney failure for two years or more. In some patients, complete kidney failure can be prevented.

Controlling Complications

Managing chronic kidney disease is made all the harder because it is often not one disease—but many. Many patients with kidney disease suffer from diabetes and are at risk for cardiovascular disease. Those with more severe stages of CKD face anemia, bone disease, and nerve problems. Here again, with information from lab tests, physicians can be on the look-out for symptoms so they can prevent or control these complications.

Thus, lab testing is critical at every stage of CKD—from identifying the early warning signs to slowing, or halting, the cascading effect of complications and kidney decline.

Guidelines

The National Kidney Foundation physician guidelines underscore the critical role of laboratory medicine in detecting and controlling chronic kidney disease. "Testing for chronic kidney disease facilitates earlier detection, evaluation, and treatment of CKD," according to the group.

"I Found Out in Time" CONTINUED FROM PAGE 1

But the doctor also told her that, with proper care and testing, she could likely avoid kidney failure entirely and probably stop any further damage. He prescribed medication that he said was most appropriate for her current stage and circumstances. He also told her to lose weight, watch her diet, and see him regularly for lab tests.

"He told me that my kidney disease was upsetting the levels of minerals in my body, which was causing the swelling feet, the cough, and the itchiness," said Maria. "But I had trouble following his orders."

Over the course of several months, she gained weight, and her blood and urine tests had slipped a little—her kidneys were getting worse. The doctor adjusted her medications and warned her that she was facing kidney failure if she didn't take action. He also sent her to a registered nutritionist.

"The nutritionist helped me set up a daily routine to take my pills, to plan meals and understand what foods I could eat, and how much to eat and drink," said Maria. "She also pushed me to know my numbers—and to remember to schedule my lab tests. Now I watch my eGFR and the other lab numbers, just like watching my weight and counting calories. I feel more in control of my life, and the treatment plan is working."

Maria has done one more thing. She's made a commitment to make sure all her family members and friends get screened for kidney disease. "So I have written notes to all of them, just saying 'I found out in time. So should you.'"

Maria is not a real person, but the facts and information presented here depict accurately the role of lab tests in chronic kidney disease and the circumstances faced by many patients.

What is Chronic Kidney Disease?

Chronic kidney disease reduces the ability of the kidneys to filter waste and perform critical functions such as aiding in the creation of red blood cells.

What are symptoms?	What causes CKD?	How do you control it?
Often, symptoms do not appear until kidneys are damaged. But patients may notice fatigue, muscle cramps, swollen feet, dry skin, or frequent urination.	The two primary causes are high blood pressure and diabetes.	Lab tests are critical in detecting CKD. They give physicians information about the severity of each patient's condition and guidance in selecting the best treatments.

Source: National Kidney Foundation

Lab Tests Identify and Help Control CKD

For many patients, chronic kidney disease may feel like a chain reaction. CKD can develop from diabetes or high blood pressure—or even from urinary stones or infections (among other things). Once a person has CKD, it can lead to additional diseases and complications, such as cardiovascular disease, anemia, or osteoporosis. Added to this is the normal step-by-step progression of decline that many patients experience—as kidneys begin to falter, then fail.

But laboratory tests can interrupt this process by identifying individual problems—or health risks—often before the "chain reaction" starts or gets out of control. They also point clinicians toward solutions—ranging from medications to lifestyle modifications to careful monitoring—that are best suited for each stage and unique circumstances of individual patients.

Risks for Chronic Kidney Disease

- ✓ Diabetes
- ✓ Hypertension
- ✓ Obesity
- ✓ Auto-immune diseases
- ✓ Infections
- ✓ Urinary stones

Tests to identify and help control or prevent risks...

- ✓ Serum eGFR test to estimate kidney filtering ability
- ✓ Urine albumin to detect excess protein
- ✓ Blood urea nitrogen to detect level of waste in blood

Chronic Kidney Disease

Complications of CKD

- ✓ Cardiovascular disease
- ✓ Anemia
- ✓ Diabetes
- ✓ Malnutrition
- ✓ Bone disease

Tests to detect, help control complications...

- ✓ Lipid panel, e.g., cholesterol, triglycerides
- ✓ Complete blood count, hemoglobin
- ✓ Blood glucose
- ✓ Serum albumin
- ✓ Serum calcium, phosphorus, Intact parathyroid hormone, vitamin D levels

Effects of CKD

- ✓ Worsening kidney functions
- ✓ Mild, then serious damage
- ✓ Kidney failure

Tests to monitor severity, guide treatment...

- ✓ Serum eGFR test and urea nitrogen to see if kidneys are worsening
- ✓ Calcium, phosphate, and electrolytes that can be affected by CKD
- ✓ Urine total protein or albumin to judge effects of treatment
- ✓ Hemoglobin to determine whether kidneys are producing substance needed for red blood cells

Medical guidelines recommend testing for kidney disease…

From the National Kidney Foundation— *"Increasing evidence, accrued in the past decades, indicates that the adverse outcomes of chronic kidney disease, such as kidney failure, cardiovascular disease, and premature death, can be prevented or delayed. Earlier stages of chronic kidney disease can be detected through laboratory testing. Treatment of earlier stages of chronic kidney disease is effective in slowing the progression toward kidney failure…."*

Source: National Kidney Foundation Kidney Disease Outcomes Quality Initiative, Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification, and Stratification, 2002

…But kidney tests and treatments are underused…

From the National Institutes of Health— *One of the biggest problems in CKD is that the tests and treatments that can control it are often underused, especially among high-risk groups, such as African-Americans. According to NIH:*

- ✓ *Most medical practices screen for CKD in less than 20 percent of their Medicare patients who have diabetes.*
- ✓ *Patients are referred late to a kidney specialist, especially African-American men.*
- ✓ *Less than one-third of CKD patients received an ACE inhibitor—a drug that slows kidney decline.*

Sources: NIH National Kidney Disease Education Program; Kinchen, *Annals of Internal Medicine*, September, 2002

…And risks are high for many ethnic groups…

From the National Institutes of Health— *The risk of chronic kidney disease that leads to kidney failure is dramatically increased for certain ethnic groups, including African-Americans, Hispanics, Native Americans, and Asian/Pacific Islanders.*

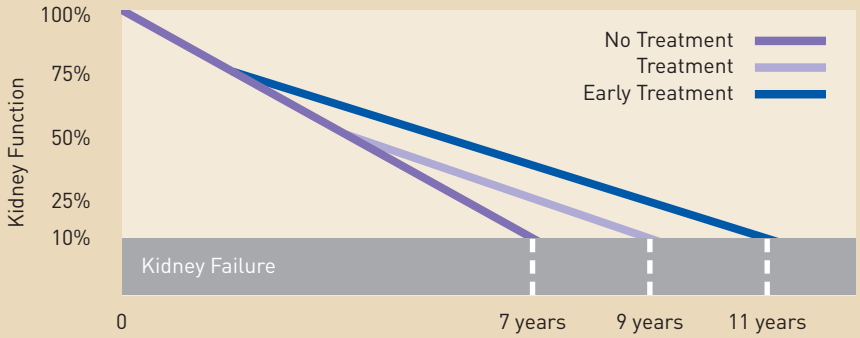
Relative Risks of Kidney Failure Compared to Non-Hispanic Whites	
African-American	3.8 X
Native American	2.0 X
Asian/Pacific Islander	1.3 X
The relative risk of Hispanics compared to non-Hispanics is about	1.5 X

Sources: NIH National Kidney Disease Education Program; US Renal Data System, 2004

Early Detection = Delayed Kidney Failure

Early diagnosis of chronic kidney disease can delay total kidney failure—called end-stage renal disease (ESRD)—for two years *even after* the kidneys have lost 25 percent of their filtering ability. In some patients, early detection even means preventing ESRD completely. Considering end-stage renal disease costs Medicare more than $20 billion every year—with rapid growth ahead—early detection means dollars saved (along with all those kidneys).

Early detection means delaying ESRD and its high costs...



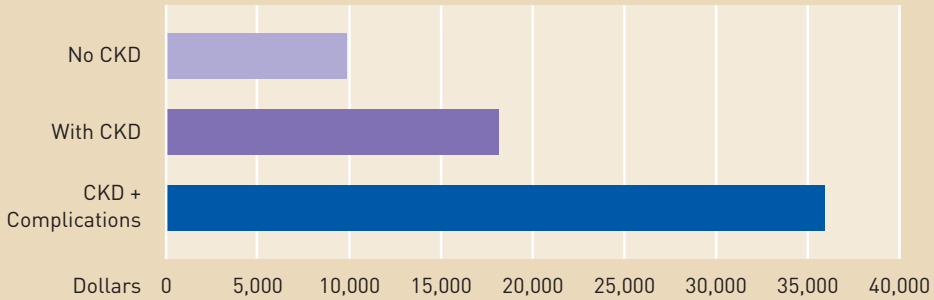
Sources: National Kidney Disease Education Program, 2005; US Renal Data System, 2007 Annual Data Report; Brenner, *New England Journal of Medicine*, Sept 2001; Lewis, *New England Journal of Medicine*, Sept 2001

Early Detection = Lower Costs

Chronic kidney disease is expensive. In 2005, CKD cost Medicare $59.8 billion (including $20 billion for ESRD). The disease is especially costly because it is often more than one disease—occurring frequently with heart disease, diabetes, and high blood pressure (among other complications). Recent studies underscore the significant savings that can come from preventing the progression of CKD—but also preventing the complications that come along with CKD.

A 2004 study found that the costs of care for patients with chronic kidney disease were roughly double those of patients who did not suffer from the disease—$18,000 vs. $9,800. In addition, the costs of complications and related disorders drove costs much higher. The costs for patients who also suffered from additional complications—such as heart failure or diabetes—reached almost $36,000, more than three times the cost of those who avoided the disease entirely.

Costs per Patient with/without CKD + Complications



Source: Smith, DH, et. al., "Cost of Medical Care for Chronic Kidney Disease and Comorbidity among Enrollees in a Large HMO Population," *Journal of the American Society of Nephrology,* Vol 15, pp 1300–1306, 2004

When Silence is not Golden

Routine testing strategies for those groups that are at higher risk of CKD is important clinically because CKD is usually a silent condition until its late stages. Early detection can only occur if patients who generally feel well undergo blood and urine testing. Individuals at increased risk for CKD include those with diabetes, high blood pressure, cardiovascular disease, or a family history of CKD, as well as certain ethnic groups and individuals who are over age 60.

The broad reach of chronic kidney disease touches many lives in many different ways...

13% of US population	18% of Medicare spending	$2–$4 billion in lost income each year	80% higher cost to treat CKD patients vs. patients without CKD	1000-3000% greater risk of cardiovascular disease

Sources: Coresh, *Journal of the American Medical Association*, November, 2007; Smith, *Journal of the American Society of Nephrology*, 2004; Schoolwerth, *Preventing Chronic Disease: Public Health Research, Practice, and Policy*, April, 2006

Kidney tests include:

- ✓ **Blood Urea Nitrogen test:** Evaluates kidney function by measuring the amount of a waste product called urea that is in the blood.
- ✓ **Estimated Glomerular Filtration Rate test:** Evaluates kidney function by estimating how well the kidneys are filtering waste from the blood.
- ✓ **Urine Albumin test:** Detects excess protein in the urine.

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