In March 2009, a new laboratory test was introduced that assessed the level of omega-3 fatty acids in erythrocyte membranes. The test, “HS-Omega-3® Index”, is part of an overall Fatty Acid Profile that was developed by William S. Harris, PhD, Director of the Cardiovascular Health Research Center at Sanford Research/USD and President of OmegaQuant, LLC, the company he formed to offer the test commercially. Sanford Laboratories refers all requests for HS-Omega-3 Index to OmegaQuant, LLC.

Background of Omega-3
Omega-3 fatty acids are found primarily in fish, especially “oily” fish such as salmon, sardines, mackerel, herring, and albacore tuna. Although there is a type of omega-3 also found in plant oils, particularly flaxseed oil, it has not yet been shown to have the cardiovascular benefits that the fish oil omega-3s have.

The two most important omega-3 fatty acids in fish oils are EPA and DHA, and it is the RBC level of EPA and DHA that constitutes the HS-Omega-3 Index. The current “cardioprotective” level is considered to be 8% of the total RBC fatty acids, a value actually lower than the average of 9.5% in Japan where coronary heart disease and sudden cardiac arrest are very uncommon. Most Americans have levels around 4-5%.

Updated Information…
How Effective Is It?
Since last year, Dr. Harris has published new information on the relationship between the HS-Omega-3 Index and the rate of cellular aging and risk for death from any cause. In both cases, patients with the lowest omega-3 levels had the highest rate of cellular aging and the highest risk for death. Other studies showed that, although only 1% of people who were not taking fish oil supplement had an Index >8%, 17% of those who reported taking supplements were in the target range.

In addition, providing people with information on their omega-3 levels appears to motivate change. For example, at the Sanford Health Fair in March of 2009, approximately 300 people ordered the Omega-3 Index test. At the 2010 Fair, 81 people re-checked their previous levels. On average, their levels increased by 1 percentage point (i.e., 5.3% vs 4.3%, p<0.0001). This data suggests that it is relatively easy to make significant improvements in the HS-Omega-3 Index, reducing risk for heart disease. A change of this magnitude could be associated with a greater than 40% reduction in risk for sudden cardiac death.

Other Fatty Acids and Their Significance
In addition to the omega-3 fatty acids, there are other fatty acids in the RBC membrane that are also included in the Fatty Acid Profile. Most notable are the trans fatty acids or trans fats. These have received a tremendous amount of publicity lately, especially when cities like New York banned them from restaurant foods.

These fats occur naturally at low levels in meat and dairy products as a result of the fermentation process in the animal’s rumens. Trans...
The Sanford Laboratories’ protocol for positive patient identification requires the LEGAL name of the patient for all orders. The legal name (first, last, and middle) along with date of birth and gender must match information in our database to create a patient match. This match will place the results under one patient record.

When the name/DOB/gender does not match a patient already in our system, a new patient record is created. This creates a challenge when searching for results and there are multiple records. This has particularly become a challenge for our long term care patients with multiple laboratory results from various physicians or locations.

Please help us help your patients...always use the LEGAL NAME for your patient (no nicknames or abbreviations please).

(Continued from page 1)

What’s In a Name?

The major dietary sources of trans fatty acids are traditional vegetable shortenings and solid (more so than tub) margarines, salad dressings, crackers, candies, cookies, snack foods, fried foods, baked goods, and other processed foods. The actual amount coming from any of these products is changing rapidly as a result of efforts by food producers to decrease the level of trans fatty acids in their foods. Foods can label their products “Trans-fat free” if there is less than ½ g of trans fats per serving. Recommended intake for trans fats is less than about 2½ g per day—the amount in one serving of hard margarine or a piece of pie.

How Much Is Safe?

What is a “safe” blood levels of trans fats? This is not entirely clear. In the Fatty Acid Profile from OmegaQuant, the target level is set at <1.5% of total RBC fatty acids. This value is the 20th percentile value measured by Dr. Harris in the Framingham Offspring cohort (n=3200). The average level in Framingham is about 2% (see Table 1 for 95% ranges). Clearly, the “average” level should not be the target, hence the suggestion of the 20th percentile value of 1.5%. Tracking changes in the “Trans Index” will give the physician a good idea of the extent to which patients are cutting fast-foods and other processed foods out of their diets.

What Else is Included

The Fatty Acid Profile also includes other fatty acid classes—saturated, monounsaturated, total omega-6, and total omega-3—for which specific target levels have not yet been set. They are provided (along with the range seen in Framingham) in Table 1 as a reference for providers.

Fatty acids—both healthful and harmful species—are attracting increasing attention in risk prediction. For physicians, following these levels in patients who are at increased risk for coronary heart disease can indicate how compliant patients are to the following advice: “eat more fish (or take 1-2 fish oil pills) and try to cut back on fast/fried foods!”

Table 1: Example of the Fatty Acid Panel Output

<table>
<thead>
<tr>
<th>FATTY ACID CLASS</th>
<th>PATIENT</th>
<th>NORMAL RANGE (95%)</th>
<th>TARGET</th>
</tr>
</thead>
<tbody>
<tr>
<td>HS-Omega-3 Indexa</td>
<td>6.10%</td>
<td>2.20%</td>
<td>9.00%</td>
</tr>
<tr>
<td>Transb</td>
<td>1.60%</td>
<td>0.80%</td>
<td>3.50%</td>
</tr>
<tr>
<td>Total Omega-6c</td>
<td>30%</td>
<td>27%</td>
<td>34%</td>
</tr>
<tr>
<td>Total Omega-3d</td>
<td>9.40%</td>
<td>5%</td>
<td>12%</td>
</tr>
<tr>
<td>Saturatedef</td>
<td>38%</td>
<td>37%</td>
<td>42%</td>
</tr>
<tr>
<td>Monounsaturatefi</td>
<td>15%</td>
<td>12%</td>
<td>18%</td>
</tr>
<tr>
<td>Omega-6/Omega-3</td>
<td>1.9</td>
<td>5.7</td>
<td>-</td>
</tr>
</tbody>
</table>

a  EPA-DHA
b  includes trans species of oleic and linoleic acids
c  primarily composed of linoleic acid and arachidonic acid
d  besides EPA and DHA, this includes the plant omega-3 alpha-linolenic acid, and DPA, intermediate between DHA and EPA.
e  major saturated fatty acids in RBCs include palmitic and stearic acid
f  the primary fatty acid in this category is oleic acid

Ordering Information

To order the Fatty Acid Profile from Sanford Laboratories that includes all of these elements, please use Sanford Laboratories Test Code 9899, Fatty Acid Profile, RBC. The required specimen is 4 mL EDTA whole blood from a first morning fasting specimen; non–fasting is also acceptable. Chargeable CPT codes for this test include: 82544 x 4 and 0111T. Please call Sanford Laboratories Client Support for any additional information.

REFERENCE LIST

On March 23, President Obama signed healthcare reform legislation into law with a goal of extending health insurance coverage to 33 million uninsured Americans. Most people in the healthcare community knew that Congress had to find some way of paying for such an ambitious plan that broadens coverage to millions more Americans.

Since Congress has reduced Medicare payments to labs in the past, laboratorians had good reason to expect more cuts from the new law. The hope is that the planned cuts to the laboratory (fee schedule) might be offset by the projected increase in testing coming from broader preventive coverage and increases in the roles of insurance companies and Medicare. The law includes laboratory services as part of the basic coverage that will be offered to the Americans who currently lack insurance.

The Pitfalls
Laboratories narrowly avoided the scenario of a 20% co-pay by patients. The co-pay itself would have been equivalent to a 20% reduction of the lab fee schedule, said Alan Mertz, president of the American Clinical Laboratory Association (ACLA). “Labs would have been asked to collect that 20% of the fee schedule, and with the collection costs it could have surpassed $20 billion dollars over ten years.”

With opposition from lab groups (ACLA) and the American Association of Retired Persons (AARP), the copay plan was dropped partially because it would increase beneficiary out of pocket costs. It was replaced with a $750 million annual tax that would have been applied to all laboratory revenue permanently if it had been approved.

The End Result
In September 2009, lab advocates working with Congress made the decision that a temporary cut to the lab fee schedule update, which sets rates for billing Medicare, would be less painful than a permanent tax on labs themselves. The lab fee schedule is updated every year according to the Consumer Price Index and is intended to keep the fee schedule at pace with inflation, but Congress has usually acted to reduce or eliminate the update.

The law will cut the Consumer Price Index (CPI) update to the lab fee schedule in two ways for at least the next 5 years. After negotiations, the final deal signed into law includes a 1.75% cut to the fee schedule update for 5 years—a measure believed to be more preferable than the permanent $750 million 2–3% tax taken against all laboratory revenue originally on the table.

In addition to the 1.75% cut, the law also establishes a permanent productivity adjustment to the fee schedule update, another type of cut. The law imposes the productivity adjustment across the board on all Medicare Part B providers, not just labs, and has been estimated to range from 1.1% to 1.4% over the next 10 years.

Taken together, the temporary 1.75% cut and the productivity adjustment will reduce the CPI update by about 3 points. This means that the CPI needs to be at least 3% in order for the fee schedule to stay flat. However, if inflation is not too high, then the reductions to the CPI update will turn into cuts to the lab fee schedule.

A New Focus – Prevention
Critics of the health reform law point out that it seems to be more of a health insurance reform law than a U.S. healthcare system comprehensive reform. Even though most of the big changes have to do with offering more Americans health insurance—and the cuts and taxes needed to pay for it—part of the law’s focus shifts from healthcare to prevention.

Under the new law, Medicare will cover 100% of the cost of preventive services, such as screening tests. Other private health plans must also provide coverage for preventive services. The catch is that coverage is only guaranteed for preventive services if they are rated A or B by the U.S. Preventive Services Task Force (USPSTF), an independent panel that reviews evidence of effectiveness and develops recommendations for preventive services under the guidance of the Agency for Healthcare Research and Quality (AHRQ).

Under the law, USPSTF recommendations must consider clinical preventive best practice recommendations from numerous organizations including AHRQ, the National Institutes of Health, the Centers for Disease Control and Prevention, the Institute of Medicine, specialty medical associations, patient groups, and scientific societies.

As USPSTF shifts to accommodate the new law, adding more tests to its list of A or B-graded recommendations will probably happen slowly, and will probably result from outside pressure. Making screening tests and other preventive care accessible to more people is a goal of the new legislation, but whether the public takes advantage of these new benefits remains to be seen.

Long-Term Concerns
Vince Stine, American Association for Clinical Chemistry’s (AACC) director of government affairs, pointed out there is no single template for how healthcare reform will affect labs, so each lab will need to develop its own business model for how it responds. “In developing their plans, laboratories need to keep in mind that the healthcare reform changes are staggered over the next few years,” he said. “Legislators frontloaded the payment cuts, so that they take effect as early as 2011, whereas the testing increases won’t materialize until 2014.” It will be important to examine the source of any increased volume of testing, Stine noted. “More than half of the newly covered will be through the Medicaid program, which typically pays less than other insurers,” he said. “Laboratories will need to take this into consideration as they make adjustments to their operations.” He also added “You may see some uptake in testing, but we’re paying for it in another way.”

REFERENCES
In Medicare B News Issue 259 dated January 13, 2010, Centers for Medicare and Medicaid Services (CMS) solidified its stance on the need for patient-specific physician orders in relation to complete blood counts and urine cultures. CMS additionally stated that according to Comprehensive Error Rate Testing (CERT) analysis, providers are performing additional testing based on standard or implied protocol.

During a CMS CERT OPPS (Comprehensive Error Rate Testing – Outpatient Prospective Payment System) Question and Answer session in July 2010, it was clarified that urine microscopy was also included in CMS oversight if a laboratory’s protocol orders reflex microscopic testing when only a Urinalysis was ordered. CMS’s position is that physicians must order additional testing based on patient condition, not based on laboratory protocol.

To comply with CMS standards, Sanford Laboratories is in the process of modifying laboratory requisitions to better assist physicians and remove reflex testing from the above mentioned tests. If you have old requisitions please discard them as you receive the revised requisitions. Please use the new requisitions immediately as they will have direct impact on the correct ordering and the billing of laboratory tests.

If you have any questions regarding this, please call Bobbi Andera, Billing and Regulatory Manager, at 605-328-5435 or 800-522-2561 ext 85435.