ACL Laboratories
Every Sample is a Life™

Test Bulletin

June 2017

Did You Know... June is Men's Health Month

Prostate Cancer Screening: Should you get a Prostate Specific Antigen (PSA) Test?

Prostate cancer is common and is a frequent cause of cancer death in men. In the United States, it is the most common non-skin cancer and second only to lung cancer as the leading cause of cancer death. Approximately 15 - 20 % of American men will be diagnosed with prostate cancer during the course of their lifetimes.

The main risk factors for prostate cancer include:

- **Age.** The risk of prostate cancer increases as a man's age increases. After age 50, the chance of having prostate cancer increases substantially. The majority of prostate cancers are found in men age 65 or older.
- **Race.** For reasons that aren't well understood, black men have a higher risk of developing and dying of prostate cancer.
- **Family history.** If a close family member was diagnosed with prostate cancer before age 65, the risk of getting prostate cancer is increased.
- **Diet.** A high-fat diet and obesity may increase the risk of prostate cancer.

One of the ways to screen for prostate cancer is to measure the amount of prostate specific antigen (PSA) in the blood. Ordinarily, small amounts of PSA circulate in the blood, but levels can be increased in cancer and other conditions. For men who have already been diagnosed with prostate cancer, the PSA test is useful to monitor the effectiveness of treatment and check for recurring cancer.

The advantages of routine PSA screening include:

- Detection of prostate cancer at an early stage, thus allowing for timely treatment options.
- Early treatment can help catch the cancer before it becomes life-threatening or causes serious symptoms.
- Identifying cancer early often means less aggressive treatment — thus reducing the risk of certain side effects, such as erectile dysfunction and incontinence.

The drawbacks of routine PSA screening include:

- PSA can be elevated in non-cancerous conditions, including an enlarged prostate (benign prostatic hyperplasia, or BPH), an inflamed or infected prostate (prostatitis) and increased age.
- In many cases, men who are diagnosed with prostate cancer can have a normal PSA level, and not be detected by PSA testing.
- Not all prostate cancers need treatment. An elevated result could result in unnecessary treatment of a non-life threatening cancer. Potential treatment complications can include urinary incontinence, erectile dysfunction and bowel dysfunction.

Professional organizations, including the American Cancer Society and the American Urologic Society, vary in their recommendations about who should — and who shouldn't — get a PSA screening test. Organizations that do recommend PSA screening generally recommend the test for men between the ages of 50 and 70, and for men with an increased risk of prostate cancer. Testing continues until life expectancy is less than 10 years. After that, the likelihood that prostate cancer would cause significant problems is small.

Bottom Line:

A positive PSA test can be a lifesaver and early detection and treatment of cancer results in better outcomes. Given the limitations of screening, it is important that men talk with their physician about their individual risk of developing prostate cancer, as well as the overall risks and benefits of PSA testing, so that an informed decision can be made.

Erythrocyte Sedimentation Rate (ESR) Reference Range Change

Effective Wednesday, June 28, 2017, there will be a change in the erythrocyte sedimentation rate (Test Order Code RESR) reference range for males only.

Current Reference Range:	New Reference Range:	Reference Range for Females
0- 15 mm/hr	0-20 mm/hr	0 – 20 mm/hr.

The erythrocyte sedimentation rate is a non-specific measure of inflammation and values tend to rise with age.

Re-standardization of Insulin (INSUFR) Testing

ACL Laboratories insulin testing has been standardized to the World Health Organization (WHO) 1st IRP 66/304 Standard. As a result of this re-standardization, patient results may be lower than previously reported. The reference interval for insulin is not impacted as a result of this change and will remain: 3 – 29 mUnits/mL. The manufacturer is not recommending a review of previously generated results.

Insulin testing is not generally used in isolation in clinical practice. Additional laboratory testing is typically performed along with insulin, including glucose, HbA1c, C-peptide, and proinsulin.

Please contact Ken Copeland, PhD, Technical Director-Chemistry with any questions or concerns. Kenneth.Copeland@aurora.org.

HDL Cholesterol Flagging Range Update

In January 2017, changes were made in the definition of age breaks and related reference ranges for lipid testing, which included changes in the cutoff level for flagging abnormal HDL results.

The ACL lipid reference range flagging changes were made to align with the optimal levels as cited in the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III).

Based on recent feedback received, effective Wednesday, June 28, 2017, a change in the range at which HDL will flag as abnormal will be made for adults age 25 years and older. Rather than flag below optimal HDL levels, HDL will flag when the value is below the "low" level cutoff. The flagging levels will also be different for males and females. The appended interpretive chart will remain the same. Refer to the chart below.

Test Order Code	Test Name, Units	Current Abnormal Flagging Range	New Abnormal Flagging Range
HDL	HDL Cholesterol mg/dL	<60	Males: <40 Females: <50

Advance Beneficiary Notice (ABN) Update

ACTION REQUIRED

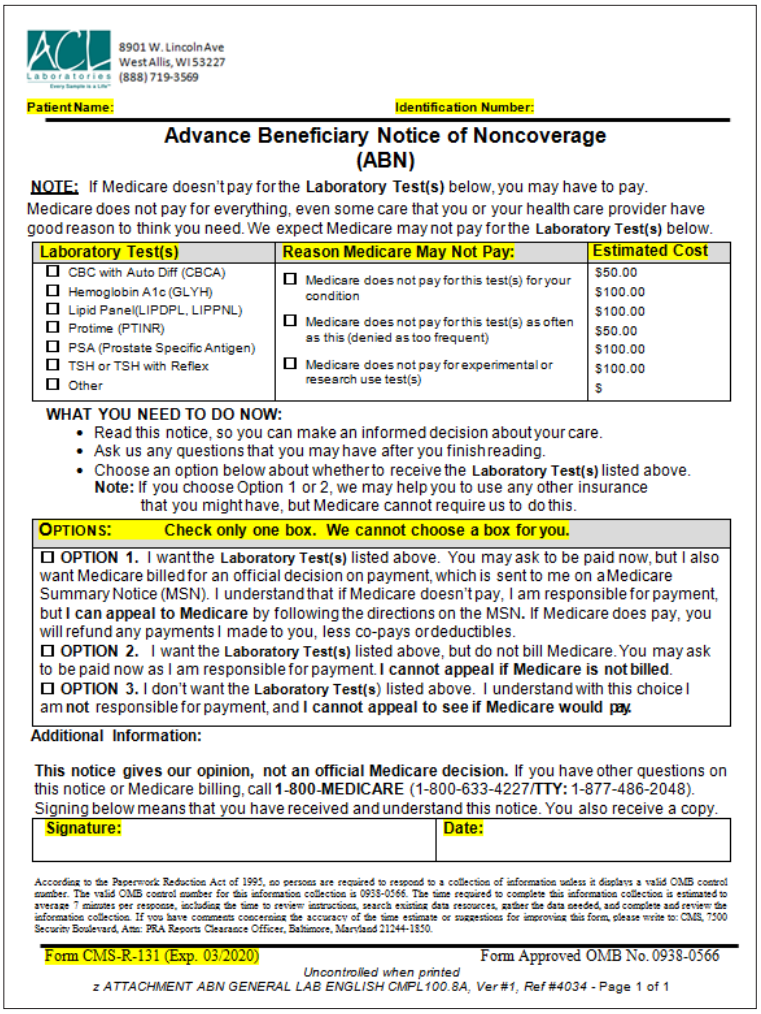
The ABN, Form CMS-R-131, and form instructions have been updated and approved by the Office of Management and Budget (OMB) for renewal. While there are no changes to the form itself, providers should note the added expiration date on the form.

The new version of the ABN form expires March 2020. Clients are expected to ***exclusively*** use the new version of the ABN. The date of ***mandatory*** use of newly approved notices is ***Wednesday, June 21, 2017***.

A sample of the ABN form is shown below with mandatory fields highlighted.

Required Action Steps:

- Update all EMR's with new ABN form with March 2020 as the expiration date.
- Discard old ABN forms and replace with new ABN form if using paper version.
- Comply with CMS effective versions.
- Complete ABN's in full, otherwise it will be null and void.



ACL Laboratories
8901 W. Lincoln Ave
West Allis, WI 53227
(888) 719-3569

Patient Name: Identification Number:

Advance Beneficiary Notice of Noncoverage (ABN)

NOTE: If Medicare doesn't pay for the **Laboratory Test(s)** below, you may have to pay. Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the **Laboratory Test(s)** below.

Laboratory Test(s)	Reason Medicare May Not Pay:	Estimated Cost
☐ CBC with Auto Diff (CBCA)	☐ Medicare does not pay for this test(s) for your condition	$50.00
☐ Hemoglobin A1c (GLYH)	☐ Medicare does not pay for this test(s) as often as this (denied as too frequent)	$100.00
☐ Lipid Panel(LIPDPL, LIPPNL)	☐ Medicare does not pay for experimental or research use test(s)	$100.00
☐ Protime (PTINR)		$50.00
☐ PSA (Prostate Specific Antigen)		$100.00
☐ TSH or TSH with Reflex		$100.00
☐ Other		$

WHAT YOU NEED TO DO NOW:

- Read this notice, so you can make an informed decision about your care.
- Ask us any questions that you may have after you finish reading.
- Choose an option below about whether to receive the **Laboratory Test(s)** listed above.
  Note: If you choose Option 1 or 2, we may help you to use any other insurance that you might have, but Medicare cannot require us to do this.

OPTIONS: Check only one box. We cannot choose a box for you.

☐ **OPTION 1.** I want the **Laboratory Test(s)** listed above. You may ask to be paid now, but I also want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn't pay, I am responsible for payment, but **I can appeal to Medicare** by following the directions on the MSN. If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.
☐ **OPTION 2.** I want the **Laboratory Test(s)** listed above, but do not bill Medicare. You may ask to be paid now as I am responsible for payment. **I cannot appeal if Medicare is not billed.**
☐ **OPTION 3.** I don't want the **Laboratory Test(s)** listed above. I understand with this choice I am **not** responsible for payment, and **I cannot appeal to see if Medicare would pay.**

Additional Information:

This notice gives our opinion, not an official Medicare decision. If you have other questions on this notice or Medicare billing, call **1-800-MEDICARE** (1-800-633-4227/**TTY:** 1-877-486-2048). Signing below means that you have received and understand this notice. You also receive a copy.

Signature:	Date:

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0566. The time required to complete this information collection is estimated to average 7 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

Form CMS-R-131 (Exp. 03/2020) Form Approved OMB No. 0938-0566

Uncontrolled when printed

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The updated FORM CMS-R-131 can be found on our website at https://www.acllaboratories.com/patient-info/billing/.

For additional information, please contact ACL Laboratories at 1.800.877.7016.