ClevelandHeartLab®

Know your risk.

Resource Book

Dear Practitioner and Staff,

Welcome to Cleveland HeartLab! I am pleased to present you with our Customer Resource Book. Cleveland HeartLab has worked with thousands of offices across the United States and as a result created this all-in-one guide for an efficient and successful relationship. Inside you will find everything you need to get started along with tools and ongoing reference materials.

The process for getting started with Cleveland HeartLab is as follows:

1. You will receive your first set of supplies.
2. A Cleveland HeartLab Representative will review this book with you and go over any questions.
3. Send your first samples to Cleveland HeartLab.
4. We will follow up with you to make sure that you were able to access your results and to answer any further questions.

The Cleveland HeartLab Customer Support Team is available to you Monday through Friday, 8 am to 8 pm EST. We are happy to assist in any way from answering a quick question to setting up a video chat.

Our website always has the most current, up-to-date information including our test menu, billing information and access to our web portal to retreive patient results, please visit **www.clevelandheartlab.com**.

Sincerely,

Rachele Rhea
Director, Customer Support
Cleveland HeartLab, Inc.
(866) 358-9828
rrhea@clevelandheartlab.com

Table of Contents

About Cleveland HeartLab

Cleveland HeartLab, Inc. (CHL) is a premier, next-generation clinical reference laboratory committed to advancing cardiovascular risk assessment through unique and proprietary laboratory tests. We focus on novel inflammatory and cardiovascular biomarker technologies that allow for advanced risk assessment leading to personalized treatment recommendations.

We are located in the Cleveland HealthTech Corridor in Cleveland, Ohio and receive thousands of specimens daily from across the United States. Our laboratory services are provided through our CAP-accredited and CLIA-licensed clinical laboratory.

Cleveland HeartLab is committed to Innovation:

We have a robust biomarker discovery and development program with proven success in rapid test commercialization. We have a significant pipeline of tests that are protected by exclusive intellectual property and target unmet market needs.

We maintain our relationship with the Cleveland Clinic and have an agreement which provides us with ongoing access to intellectual property developed at the Cleveland Clinic in the areas of cardiovascular and inflammatory biomarkers. We also have agreements in place with several other leading academic institutions to develop and commercialize next-generation biomarkers. These relationships provide us with the ability to expand our pipeline of proprietary and novel advanced biomarker tests.

Since commercializing our first biomarker, MPO, we have successfully commercialized several other novel and proprietary tests such as F_2-Isoprostanes, a test considered the gold standard for measuring oxidative stress. Our current menu of unique and proprietary biomarkers is protected by 26 issued patents with an additional 30 pending patents.

Cleveland HeartLab is committed to Inflammation Testing ("it"):

We offer unique and proprietary inflammation testing which provides additional and complementary insight into cardiovascular risk beyond cholesterol testing alone. Our Inflammation testing consists of several simple blood and urine tests that aid in identifying inflammatory risk across a risk spectrum. This additional information allows for targeted treatment to reduce risk over one's lifetime. While routine lipid screening plays an important role in cardiovascular risk assessment it does not provide a complete picture of your health. In fact, nearly 50% of all heart attacks and strokes occur in patients with 'normal' cholesterol levels. Recent evidence goes beyond lipids to suggest that inflammation within the artery wall is the primary contributor to this residual risk for heart attack and stroke[1].

Cleveland HeartLab is committed to Clinical Education:

We are committed to educating customers and the community on the advancements in identifying cardiovascular risk. We have team members who are dedicated to providing clinical education on the advancement of cardiovascular risk assessment. Key members of our team include:

Marc S. Penn, MD, PhD, FACC – Chief Medical Officer

Deborah H. Sun, PhD, DABCC, FACB – Vice President of Laboratory Operations

Michelle Beidelschies, PhD – Director of Education and Clinical Affairs

Lynn Cofer-Chase, MSN, CLS, FAHA, FPCNA, FNLA – Clinical Lipid Specialist/Clinical Education Manager

In addition, we offer a CME Webportal which provides a platform for scientific and medical information for practitioners across the country and worldwide. **www.chlcme.com**

For more information, please visit **www.clevelandheartlab.com**

Like us on Facebook
www.facebook.com/ClevelandHeartLab

Follow us on Twitter
@CLEHeartLab

Link to us on Linkedin
www.linkedin.com/company/cleveland-heartlab-inc-

See us on YouTube
www.youtube.com/clevelandheartlab

1. Ridker PM et al. Rosuvastatin to prevent vascular events in men and women with elevated C-reactive protein. *N Engl J Med*. 2008; 359: 2195-2207.

Contact Information

ONE Phone Number for ALL Your Calls

866.358.9828

- ✔ Customer Support (Option 1)
- ✔ Technical Support (Option 1)
- ✔ Clinical/Educational Support (Option 1)
- ✔ General Information (Option 1)
- ✔ Billing Support (Option 2)

FAX Number
866.869.0148

Customer Support Hours
8:00 a.m. to 8:00 p.m. EST
Monday - Friday

Address
Cleveland HeartLab, Inc.
6701 Carnegie Avenue, Suite 500
Cleveland, OH 44103

Support E-mail
customersupport@clevelandheartlab.com

Educational E-mail
consult@clevelandheartlab.com

Billing E-mail
chlpatient@clevelandheartlab.com

Websites
www.clevelandheartlab.com
www.knowyourrisk.com
www.chlcme.com

This section outlines the four main steps you should follow to ensure a successful start-up with Cleveland HeartLab. Each of these steps will be covered in detail on the following pages.

The four steps are:

Step 1

Order Your Collection Kit

Step 2

Fill Out Requisition Form

Step 3

Collect Test Samples

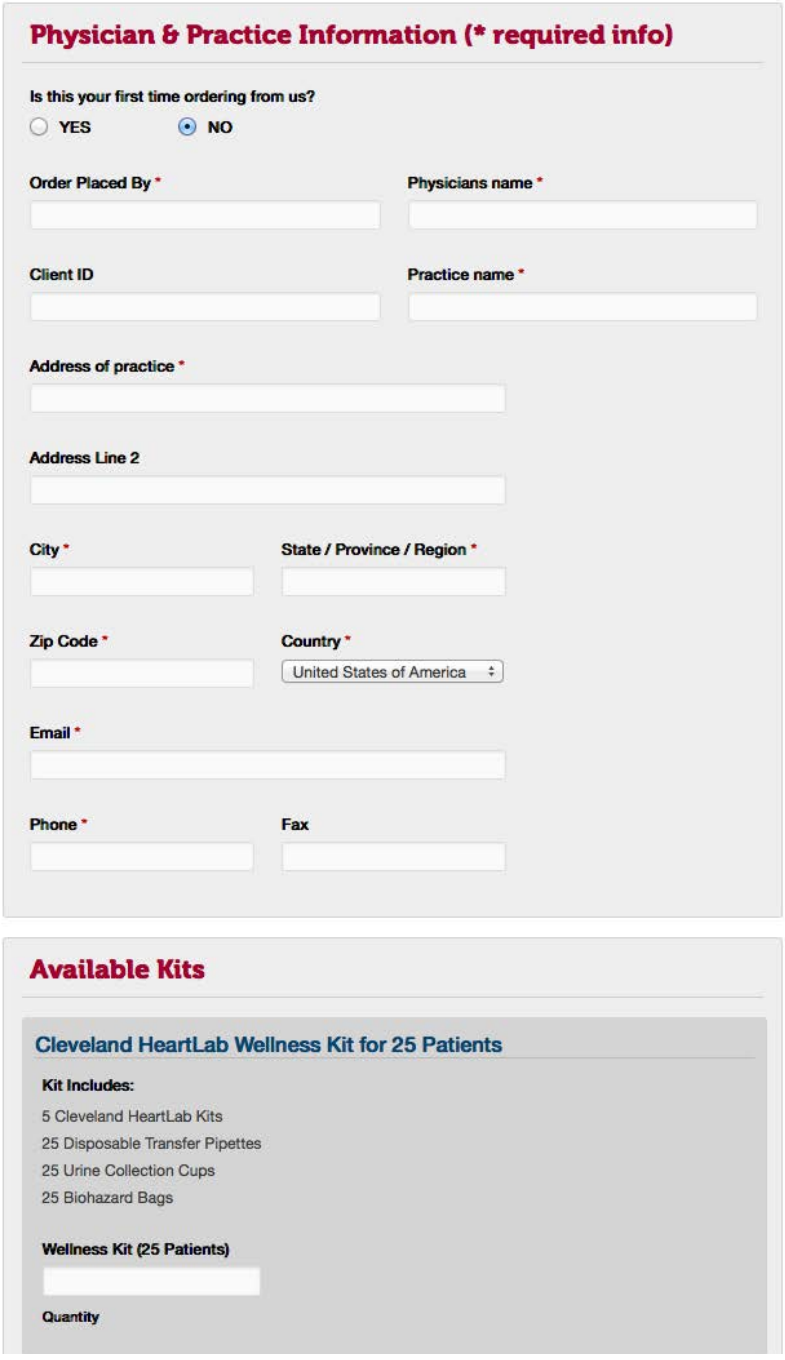
Step 4

Ship Samples & Forms

Ordering Your Collection Kit

Cleveland HeartLab has a conventient online order form that allows you to view all the supplies that are available and place your order online.

To order sample collection kits and other supplies go to our website at www.clevelandheartlab.com/our-lab-services/order-supplies. Supplies typcially arrive in 4-7 business days. You can also contact Cleveland HeartLab Customer Support at 866.358.9828 to order supplies.



Physician & Practice Information (* required info)

Is this your first time ordering from us?
YES NO

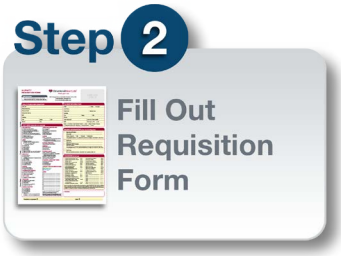
Order Placed By *
Physicians name *
Client ID
Practice name *
Address of practice *
Address Line 2
City *
State / Province / Region *
Zip Code *
Country *
United States of America
Email *
Phone *
Fax

Available Kits

Cleveland HeartLab Wellness Kit for 25 Patients

Kit Includes:
5 Cleveland HeartLab Kits
25 Disposable Transfer Pipettes
25 Urine Collection Cups
25 Biohazard Bags

Wellness Kit (25 Patients)
Quantity

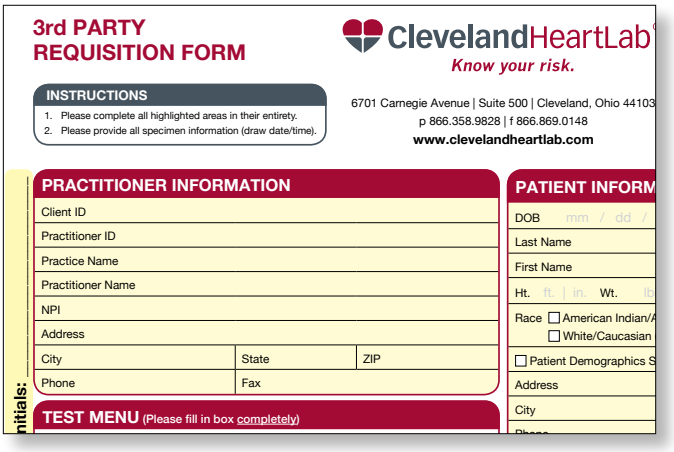


Completing the Requisition Form

Cleveland HeartLab offers three different types of requisition forms to accommodate different office billing policies.

3rd Party Requisition Form

Utilize the 3rd Party Requisition Form when the patient has Medicare, insurance or is self-pay.


3rd PARTY REQUISITION FORM

ClevelandHeartLab® Know your risk.

INSTRUCTIONS
1. Please complete all highlighted areas in their entirety.
2. Please provide all specimen information (draw date/time).

6701 Carnegie Avenue | Suite 500 | Cleveland, Ohio 44103
p 866.358.9828 | f 866.869.0148
www.clevelandheartlab.com

PRACTITIONER INFORMATION
Client ID
Practitioner ID
Practice Name
Practitioner Name
NPI
Address
City | State | ZIP
Phone | Fax

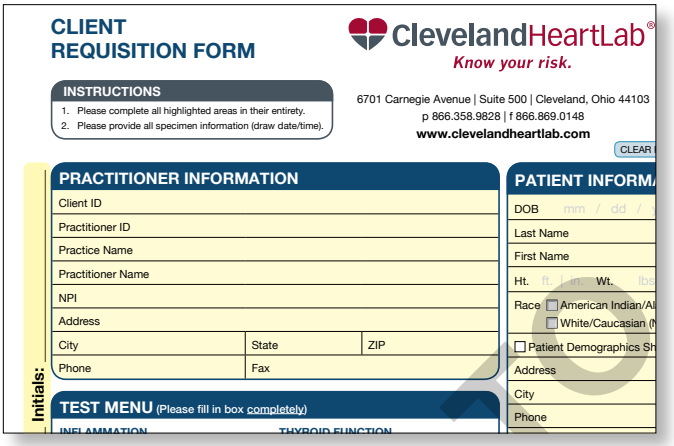
PATIENT INFORM
DOB mm / dd /
Last Name
First Name
Ht. ft. | in. Wt. lb
Race American Indian/A
White/Caucasian
Patient Demographics S
Address
City

Initials:

TEST MENU (Please fill in box completely)

Client Requisition Form

Utilize the Client Requisition Form when the practitioner is billed directly for all tests ordered.


CLIENT REQUISITION FORM

ClevelandHeartLab® Know your risk.

INSTRUCTIONS
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2. Please provide all specimen information (draw date/time).

6701 Carnegie Avenue | Suite 500 | Cleveland, Ohio 44103
p 866.358.9828 | f 866.869.0148
www.clevelandheartlab.com

CLEAR

PRACTITIONER INFORMATION
Client ID
Practitioner ID
Practice Name
Practitioner Name
NPI
Address
City | State | ZIP
Phone | Fax

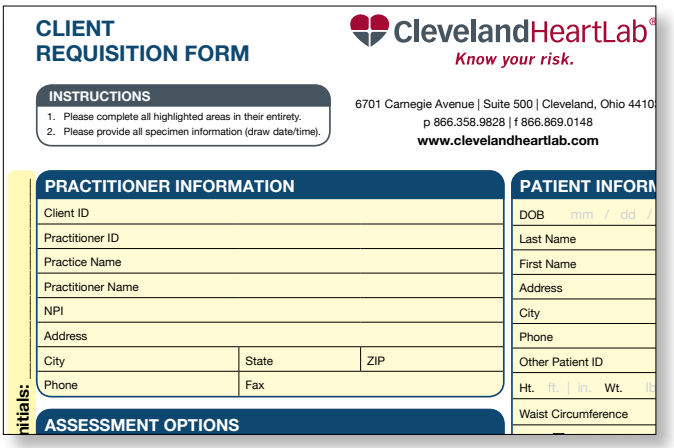
PATIENT INFORM
DOB mm / dd /
Last Name
First Name
Ht. ft. in. Wt. lbs
Race American Indian/Al
White/Caucasian (
Patient Demographics Sh
Address
City
Phone

Initials:

TEST MENU (Please fill in box completely)

Client Health and Wellness Requisition Form

The Health and Wellness requisition form was created as an option for practitioners who are billed directly for testing and would like the convenience of health and wellness panels.


CLIENT REQUISITION FORM

ClevelandHeartLab® Know your risk.

INSTRUCTIONS
1. Please complete all highlighted areas in their entirety.
2. Please provide all specimen information (draw date/time).

6701 Carnegie Avenue | Suite 500 | Cleveland, Ohio 4410
p 866.358.9828 | f 866.869.0148
www.clevelandheartlab.com

PRACTITIONER INFORMATION
Client ID
Practitioner ID
Practice Name
Practitioner Name
NPI
Address
City | State | ZIP
Phone | Fax

PATIENT INFORM
DOB mm / dd /
Last Name
First Name
Address
City
Phone
Other Patient ID
Ht. ft. | in. Wt.
Waist Circumference

Initials:

ASSESSMENT OPTIONS

Requisition Form (Example of a 3rd party requisition form)

*Please visit www.clevelandheartlab.com/our-lab-services/requisition-form to obtain a copy of the most up-to-date requisition form.

The back of our requisition forms inlude our test menu.

For a complete listing of available

The

INDIVIDUAL TESTS

Order Code	Test	Cl
C314	Adiponectin	83
C561	ADMA/SDMA	83
C109	Albumin	82
C111	Alkaline Phosphatase	84
C112	ALT	84
C127	Amylase	82
C604	ApoE Genotype	81
C123	ApoB	82
C122	ApoA1	82
C922	AspirinWorks®	84
C113	AST	84
C115	Bilirubin, Direct	82
C114	Bilirubin, Total	82
C107	BUN	84
C130	CA 125	86
C131	CA 15-3	86
C132	CA 19-9	86
C102	Calcium	82
C135	Carcinoembryonic Antigen (CEA)	82
C106	Chloride	82
C117	Cholesterol, Total	82
C2138	CK-MB	82
C311	Coenzyme Q10*	83
C915	Complete Blood Count w/Differential*	85
C917	Complete Blood Count w/o Differential*	85
C136	C-Peptide	84
C137	Creatine Kinase (CK)	82
C108	Creatinine	82
C603	CYP2C19 Genotype	81
C307	Cystatin C	82
C316	Estradiol	82
C918	F_2-Isoprostanes/Creat ratio	83
C140	Ferritin	82
C334	Fibrinogen Mass	85
C258	Folate	82
C317	Follicle Stimulating Hormone	83
C2164	Fructosamine	82
C315	Galectin-3	82
C165	GGT	82
C101	Glucose	82
C155	GlycoMark®	84
C145	HbA1c	83
C118	HDL Cholesterol, Direct	83
C324	HDL2b	82
C308	Homocysteine	83
C121	hsCRP	86
C146	Insulin, Total	83
C147	Iron	83
C273	Iron Binding Capacity	83
C148	Lactate Dehydrogenase	83
C120	LDL Cholesterol, Direct	83
C292	Lipase	83
C124	Lp(a)	83

SAMPLE REJECTION POLICY

Samples will be rejected for any of the follo

- Samples were shipped on Saturday.
- Friday blood draws arrived on Monday.
- Sample types were incorrect or samples were received in damaged condition (i.e. tube open or cracked, sample not at correct temperature).
- Physician signature is missing.

OFFICE PACKING

Samples should be stored at 2-8° C immediately after they are collected and processed.

1) Place cold or frozen sample(s) in the biohazard bags.
2) Place completed requisition (and insurance information if applicable) for each sample in the pouch of the biohazard bag.
3) Place biohazard bag (with sample(s) and requisition form) in the Styrofoam box.
4) Place a frozen ice pack on top of the samples in the Styrofoam box.
5) Place Styrofoam box into UPS Laboratory Shipping Pak.

UPS/FEDEX PICK-UP

	UPS	FedEx
Phone Number	(800) 742-5877	(800) 463-3339
Request Instructions	Ask to schedule a "RETURN SERVICE LABELED PICK-UP"	Ask to schedule a "PRE-PAY AIRBILL PICK-UP"

Have your shipping label available when calling for a pick-up.

Ship for next day delivery (with provided label) to: Cleveland HeartLab, Inc. 6701 Carnegie Ave, Suite 500, Cleveland, OH 44103, Phone: 866-358-9828. Samples can be shipped Monday through Friday.

RLF-0003-z

6701 Carnegie Avenue | Suite 500 | Cleveland, Ohio 44103 | p 866.358.9828 | f 866.869.0148 | www.clevelandheartlab.com

3rd PARTY REQUISITION FORM

ClevelandHeartLab®
Know your risk.

INSTRUCTIONS
1. Please complete all highlighted areas in their entirety.
2. Please provide all specimen information (draw date/time).

6701 Carnegie Avenue | Suite 500 | Cleveland, Ohio 44103
p 866.358.9828 | f 866.869.0148
www.clevelandheartlab.com

CLEAR FORM

LAB USE ONLY

Initials:
Time:
Draw Date:

PRACTITIONER INFORMATION

Client ID
Practitioner ID
Practice Name
Practitioner Name
NPI | PECOS Validated? ☐ Yes ☐ No
Address
City | State | ZIP
Phone | Fax

PATIENT INFORMATION

DOB mm / dd / yyyy | ☐ Male ☐ Female
Last Name
First Name | Middle Initial
Ht. ft. | in. Wt. lbs. BMI | Fasting? ☐ Yes ☐ No
Race ☐ American Indian/Alaskan Native ☐ Asian ☐ Black/African-American ☐ White/Caucasian (Non-Hispanic) ☐ Hispanic/Latino ☐ Other
☐ Patient Demographics Sheet Attached
Address
City | State | ZIP
Phone
Other Patient ID | Last Four Digits of SSN

TEST MENU (Please fill in box completely)

INFLAMMATION
☐ Myeloperoxidase (83876)
☐ Lp-PLA$_2$ (The PLAC® Test) (83698)
☐ High-Sensitivity CRP (hs-CRP) (86141)
☐ Microalbumin/Creat Ratio (82043/82570)
☐ Oxidized LDL (83516)
☐ F_2-Isoprostanes/Creat Ratio (83789/82570)

ENDOTHELIAL FUNCTION
☐ ADMA/SDMA (83789)

LIPIDS
☐ Standard Lipid Panel *(Includes non-HDL cholesterol)* (80061)
☐ If TGs >400 mg/dL, reflex to a Direct LDL (83721)
☐ ApoB (82172)
☐ ApoA1 (82172)
☐ sdLDL (83701)
☐ Lp(a) (83695)
☐ HDL2b (82664)
☐ The VAP® Test (83701/84478)
☐ The VAP®+ Test (VAP® with VLP) (83704/84478)
☐ *NMR LipoProfile®* with Lipids (83704/80061)*
☐ *NMR LipoProfile®* without Lipids (83704)*

METABOLIC
☐ Glucose (82947)
☐ Insulin (83525)
☐ Reflex to Adiponectin if indicated (83516)
☐ OGTT (82951)
☐ GlycoMark® (84378)
☐ HbA1c (83036)
☐ Reflex to GlycoMark® if indicated (84378)
☐ Adiponectin (83516)
☐ Fructosamine (82985)
☐ C-Peptide (84681)
☐ Cystatin C (82610)
☐ Homocysteine (83090)

HYPERTENSION/HEART FAILURE
☐ Galectin-3 (82777)
☐ NT-proBNP (83880)*

VITAMINS/SUPPLEMENTS
☐ Coenzyme Q10 (83789)**
☐ Vitamin D, 25 OH (82306)
☐ Vitamin D2/D3 (82306)
☐ Folate (82746)
☐ RBC Folate (82747)
☐ Vitamin B12 (82607)

FATTY ACIDS
☐ OmegaCheck™ (82541)

HORMONES
☐ Testosterone, Total (84403)
☐ Estradiol (82670)
☐ FSH (83001)
☐ Luteinizing Hormone (83002)
☐ Progesterone (84144)

THYROID FUNCTION
☐ T4, Free (84439)
☐ T4, Total (84436)
☐ T3, Free (84481)
☐ T3, Total (84480)
☐ TSH (84443)
☐ Reflex to T4, Free if indicated (84439)
☐ Reflex to T3, Free if indicated (84481)

ANEMIA/IRON METABOLISM
☐ Ferritin (82728)
☐ Iron (83540)
☐ Serum Iron & IBC (83540/83550)

CANCER
☐ PSA, Total (84153)
☐ Reflex to PSA, Free if indicated (84154)
☐ PSA, Total (G0103; Medicare)
☐ Reflex to PSA, Free if indicated (84154)

COAGULATION/PLATELET FUNCTION
☐ AspirinWorks® (84431/82570)
☐ Fibrinogen Mass (85385)

GENETICS
☐ CYP2C19 (81225)
☐ ApoE (81401)
☐ MTHFR (81291)

ROUTINE PANELS
☐ Basic Metabolic Panel (80048)
☐ Comprehensive Metabolic Panel (80053)
☐ Hepatic Function Panel (80076)
☐ Renal Function Panel (80069)
☐ Electrolyte Panel (80051)

STANDARD LABORATORY TESTS
☐ CBC/Auto Diff (85025)*
☐ CBC (85027)*
☐ Urinalysis (81001)*
☐ Uric Acid (84550)
☐ Creatine Kinase (82550)

CLEVELAND CLINIC WELLNESS PROGRAMS
☐ Go!® Foods for You
☐ Stress Free Now
☐ Go!® to Sleep

OTHER
☐ _____ _____
☐ _____ _____
☐ _____ _____
☐ _____ _____
☐ _____ _____
☐ _____ _____
☐ _____ _____
☐ _____ _____
☐ _____ _____
☐ _____ _____
☐ _____ _____
☐ _____ _____

* Sample must be shipped the same day collected.
** Sample must be protected from light.

BILLING INFORMATION (Check only one billing option)

☐ **Insurance:** Please attach a copy of **BOTH** sides of patient's insurance card.

☐ **Medicare#** _____
Please attach a copy of **BOTH** sides of patient's Medicare card.
Note: *A patient approved Medicare ABN Form required for all genetic tests and all general adult medical examination diagnostic codes; otherwise testing will not be performed.*

☐ **Self-Pay:** CHL, Inc. will bill the patient.

DIAGNOSIS (ICD-10 Code)

☐ Iron deficiency anemia, unspecified D50.9
☐ Anemia, unspecified D64.9
☐ Other iodine-deficiency related thyroid disorders and allied conditions E01.8
☐ Subclinical iodine-deficiency hypothyroidism E02
☐ Unspec. hypothyroidism E03.9
☐ Type 2 diabetes mellitus with hyperglycemia E11.65
☐ Type 2 diabetes mellitus without complications E11.9
☐ Other spec. diabetes mellitus w/o mention of complications E13.9
☐ Vitamin D deficiency, unspecified E55.9
☐ Other obesity due to excess calories E66.09
☐ Other obesity E66.8
☐ Obesity, unspecified E66.9
☐ Disorders of sulfur-bearing amino-acid metabolism, unspecified E72.10
☐ Homocystinuria E72.11
☐ Pure hypercholesterolemia E78.0
☐ Pure hyperglyceridemia E78.1
☐ Mixed hyperlipidemia E78.2
☐ Other hyperlipidemia E78.4
☐ Hyperlipidemia, unspecified E78.5
☐ Hyperuricemia w/o signs of inflammatory arthritis and tophaceous disease E79.0
☐ Metabolic Syndrome E88.81
☐ Essential (primary) hypertension I10
☐ Unstable angina I20.0
☐ Atherosclerotic heart disease of native coronary artery w/o angina pectoris I25.10
☐ Atherosclerotic heart disease of native coronary artery with unstable angina pectoris I25.110
☐ Unspec. systolic (congestive) heart failure I50.20
☐ Heart failure, unspecified I50.9
☐ Unspec. atherosclerosis I70.90
☐ Generalized atherosclerosis I70.91
☐ Shortness of breath R06.02
☐ Neoplastic (malignant) related fatigue R53.0
☐ Weakness R53.1
☐ Other malaise R53.81
☐ Other fatigue R53.83
☐ Other general symptoms and signs R68.89
☐ Impaired fasting glucose R73.01
☐ Impaired glucose tolerance test (oral) R73.02
☐ Other specified abnormal findings of blood chemistry R79.89
☐ Abnormal finding of blood chemistry, unspecified R79.9
☐ Encounter for screening for malignant neoplasm of prostate Z12.5
☐ Long-term (current) use of aspirin Z79.82
☐ Family history of ischemic heart disease and other diseases of the circulatory system Z82.49
☐ Family history of diabetes mellitus Z83.3
☐ Other _____ _____
☐ Other _____ _____
☐ Other _____ _____
☐ Other _____ _____
☐ Other _____ _____

Note: The provided ICD-10 codes are listed as a convenience. Ordering practitioners should report the diagnosis code that best describes the reason for performing the test, regardless of whether the code is listed above or not. Only tests that are medically reasonable and necessary for the diagnosis or treatment of a Medicare or Medicaid patient will be reimbursed. The Office of the Inspector General takes the position that a physician who orders medically unnecessary tests for Medicare or Medicaid reimbursement may be subject to civil penalties under the False Claims Act.

COMMENTS:

Practitioner's Signature: X Date: X

Completing the Requisition Form

The following 6 sections provide you detailed instructions on how to properly and completely fill out a Cleveland HeartLab requisition form. We have provided you with these instructions as missing or incomplete information may cause a delay in testing.

Section 1 Complete Practitioner Information

PRACTITIONER INFORMATION		
Client ID		
Practitioner ID		
Practice Name*		
Practitioner Name*		
NPI		
Address		
City	State	ZIP
Phone	Fax	

* Minimum required information for this section is the Practice Name and Practitioner's Name

Please let your customer support representative know if you would like a pre-filled electronic form sent to you. We can pre-fill your office information to make filling out the requisition form quick and easy.

Cleveland HeartLab Helpful Hint: Save a pre-filled requisition form to your desktop to always have an electronic version ready to complete when a patient arrives.

Completing the Requisition Form (continued)

Section 2 Fill in all Patient Information

PATIENT INFORMATION		
DOB mm / dd / yyyy	☐ Male ☐ Female	
Last Name		
First Name	Middle Initial	
Ht. ft. | in. Wt. lbs. BMI	Fasting? ☐ Yes ☐ No	
Race ☐ American Indian/Alaskan Native ☐ Asian ☐ Black/African-American ☐ White/Caucasian (Non-Hispanic) ☐ Hispanic/Latino ☐ Other		
☐ Patient Demographics Sheet Attached		
Address		
City	State	ZIP
Phone		
Other Patient ID	Last Four Digits of SSN	

DOB: The patient's Date of Birth is required for two main reasons:

- DOB is often used as a unique identifier for the patient.
- Some reference ranges are based on age; without a date of birth we are unable to result these tests (ex. CBC).

GENDER: Some reference ranges are gender-specific and unless we have the proper gender, we are unable to result these tests with the reference range.

PATIENT NAME: It is important that the patient's full name (full legal name) is written clearly for identification purposes. For Medicare patients, the name must match their medicare card exactly.

ADDRESS: A patient's address must be provided when their testing is being submitted to insurance. This information must accompany any insurance claim. Without a complete address, their insurance claim may be denied.

LAST FOUR DIGITS OF SSN: This is another important unique identifier and is required for Historical Reporting. See more about Historical Reporting in the next section.

FASTING: The fasting status of your patient is not required but this information will appear on the results if indicated.

BMI: Some reference ranges are BMI specific and unless we have the patient's BMI, we are unable to report these tests with the reference range.

RACE: Some reference ranges are race specific and unless the patients race is indicated, we are unable to result these tests with the reference range.

Completing the Requisition Form (continued)

Section 3 Select the Appropriate Diagnosis

ICD-10 Coding

DIAGNOSIS (ICD-10 Code)

- ☐ Iron deficiency anemia, unspecified..... D50.9
- ☐ Anemia, unspecified..... D64.9
- ☐ Other iodine-deficiency related thyroid disorders and allied conditions..... E01.8
- ☐ Subclinical iodine-deficiency hypothyroidism..... E02
- ☐ Unspec. hypothyroidism..... E03.9
- ☐ Type 2 diabetes mellitus with hyperglycemia..... E11.65
- ☐ Type 2 diabetes mellitus without complications..... E11.9
- ☐ Other spec. diabetes mellitus w/o mention of complications..... E13.9
- ☐ Vitamin D deficiency, unspecified..... E55.9
- ☐ Other obesity due to excess calories..... E66.09
- ☐ Other obesity..... E66.8
- ☐ Obesity, unspecified..... E66.9
- ☐ Disorders of sulfur-bearing amino-acid metabolism, unspecified..... E72.10
- ☐ Homocystinuria..... E72.11
- ☐ Pure hypercholesterolemia..... E78.0
- ☐ Pure hyperglyceridemia..... E78.1
- ☐ Mixed hyperlipidemia..... E78.2
- ☐ Other hyperlipidemia..... E78.4
- ☐ Hyperlipidemia, unspecified..... E78.5
- ☐ Hyperuricemia w/o signs of inflammatory arthritis and tophaceous disease..... E79.0
- ☐ Metabolic Syndrome..... E88.81
- ☐ Essential (primary) hypertension..... I10
- ☐ Unstable angina..... I20.0
- ☐ Atherosclerotic heart disease of native coronary artery w/o angina pectoris..... I25.10
- ☐ Atherosclerotic heart disease of native coronary artery with unstable angina pectoris..... I25.110
- ☐ Unspec. systolic (congestive) heart failure..... I50.20
- ☐ Heart failure, unspecified..... I50.9
- ☐ Unspec. atherosclerosis..... I70.90
- ☐ Generalized atherosclerosis..... I70.91
- ☐ Shortness of breath..... R06.02
- ☐ Neoplastic (malignant) related fatigue..... R53.0
- ☐ Weakness..... R53.1
- ☐ Other malaise..... R53.81
- ☐ Other fatigue..... R53.83
- ☐ Other general symptoms and signs..... R68.89
- ☐ Impaired fasting glucose..... R73.01
- ☐ Impaired glucose tolerance test (oral)..... R73.02
- ☐ Other specified abnormal findings of blood chemistry..... R79.89
- ☐ Abnormal finding of blood chemistry, unspecified..... R79.9
- ☐ Encounter for screening for malignant neoplasm of prostate..... Z12.5
- ☐ Long-term (current) use of aspirin..... Z79.82
- ☐ Family history of ischemic heart disease and other diseases of the circulatory system..... Z82.49
- ☐ Family history of diabetes mellitus..... Z83.3
- ☐ Other _____ _____
- ☐ Other _____ _____
- ☐ Other _____ _____
- ☐ Other _____ _____
- ☐ Other _____ _____

Note: The provided ICD-10 codes are listed as a convenience. Ordering practitioners should report the diagnosis code that best describes the reason for performing the test, regardless of whether the code is listed above or not. Only tests that are medically reasonable and necessary for the diagnosis or treatment of a Medicare or Medicaid patient will be reimbursed. The Office of the Inspector General takes the position that a physician who orders medically unnecessary tests for Medicare or Medicaid reimbursement may be subject to civil penalties under the False Claims Act.

The provided ICD-10 codes are listed as a convenience. Ordering practitioners should report the diagnosis code that best describes the reason for performing the test, regardless of whether the code is listed above or not. Only tests that are medically reasonable and necessary for the diagnosis or treatment of a Medicare or Medicaid patient will be reimbursed. The Office of the Inspector General takes the position that a physician who orders medically unnecessary tests for Medicare or Medicaid reimbursement may be subject to civil penalties under the False Claims Act.

Section 4 Sample Collection

Draw Date

Draw Date: _____ **Time:** _____ **Initials:** _____

TEST MENU

- Client ID
- Practitioner ID
- Practice Name
- Practitioner Name
- NPI
- Address
- City
- Phone

- Please provide draw date, time and phlebotomist initials.
- Draw date and time are required to ensure the sample is still within the proper time frame for accurate resulting.
- Draw date is also required to submit a Medicare claim.

Completing the Requisition Form (continued)

Section 5 Fill The Box of the Test(s) You Want to Order

TEST MENU (Please fill in box completely)

INFLAMMATION
- ☐ Myeloperoxidase (83876)
- ☐ Lp-PLA$_2$ (The PLAC® Test) (83698)
- ☐ High-Sensitivity CRP (hs-CRP) (86141)
- ☐ Microalbumin/Creat Ratio (82043/82570)
- ☐ Oxidized LDL (83516)
- ☐ F$_2$-Isoprostanes/Creat Ratio (83789/82570)

ENDOTHELIAL FUNCTION
- ☐ ADMA/SDMA (83789)

LIPIDS
- ☐ Standard Lipid Panel *(Includes non-HDL cholesterol)* (80061)
  - ☐ If TGs >400 mg/dL, reflex to a Direct LDL (83721)
- ☐ ApoB (82172)
- ☐ ApoA1 (82172)
- ☐ sdLDL (83701)
- ☐ Lp(a) (83695)
- ☐ HDL2b (82664)
- ☐ The VAP® Test (83701/84478)
- ☐ The VAP®+ Test (VAP® with VLP) (83704/84478)
- ☐ *NMR LipoProfile®* with Lipids (83704/80061)*
- ☐ *NMR LipoProfile®* without Lipids (83704)*

METABOLIC
- ☐ Glucose (82947)
- ☐ Insulin (83525)
  - ☐ Reflex to Adiponectin if indicated (83516)
- ☐ OGTT (82951)
- ☐ GLYCOMARK® (84378)
- ☐ HbA1c (83036)
  - ☐ Reflex to GLYCOMARK® if indicated (84378)
- ☐ Adiponectin (83516)
- ☐ Fructosamine (82985)
- ☐ C-Peptide (84681)
- ☐ Cystatin C (82610)
- ☐ Homocysteine (83090)

HYPERTENSION/HEART FAILURE
- ☐ Galectin-3 (82777)
- ☐ NT-proBNP (83880)*

VITAMINS/SUPPLEMENTS
- ☐ Coenzyme Q10 (83789)**
- ☐ Vitamin D, 25 OH (82306)
- ☐ Vitamin D2/D3 (82306)
- ☐ Folate (82746)
- ☐ RBC Folate (82747)
- ☐ Vitamin B12 (82607)

FATTY ACIDS
- ☐ OmegaCheck™ (82541)

HORMONES
- ☐ Testosterone, Total (84403)
- ☐ Estradiol (82670)
- ☐ FSH (83001)
- ☐ Luteinizing Hormone (83002)
- ☐ Progesterone (84144)

THYROID FUNCTION
- ☐ T4, Free (84439)
- ☐ T4, Total (84436)
- ☐ T3, Free (84481)
- ☐ T3, Total (84480)
- ☐ TSH (84443)
  - ☐ Reflex to T4, Free if indicated (84439)
  - ☐ Reflex to T3, Free if indicated (84481)

ANEMIA/IRON METABOLISM
- ☐ Ferritin (82728)
- ☐ Iron (83540)
- ☐ Serum Iron & IBC (83540/83550)

CANCER
- ☐ PSA, Total (84153)
  - ☐ Reflex to PSA, Free if indictated (84154)
- ☐ PSA, Total (G0103; Medicare)
  - ☐ Reflex to PSA, Free if indicated (84154)

COAGULATION/PLATELET FUNCTION
- ☐ AspirinWorks® (84431/82570)
- ☐ Fibrinogen Mass (85385)

GENETICS
- ☐ CYP2C19 (81225)
- ☐ ApoE (81401)
- ☐ MTHFR (81291)

ROUTINE PANELS
- ☐ Basic Metabolic Panel (80048)
- ☐ Comprehensive Metabolic Panel (80053)
- ☐ Hepatic Function Panel (80076)
- ☐ Renal Function Panel (80069)
- ☐ Electrolyte Panel (80051)

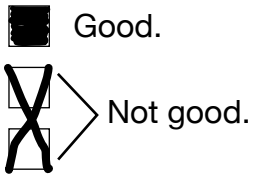
STANDARD LABORATORY TESTS
- ☐ CBC/Auto Diff (85025)*
- ☐ CBC (85027)*
- ☐ Urinalysis (81001)*
- ☐ Uric Acid (84550)
- ☐ Creatine Kinase (82550)

CLEVELAND CLINIC WELLNESS PROGRAMS
- ☐ Go!® Foods for You
- ☐ Stress Free Now
- ☐ Go!® to Sleep

OTHER
- ☐ _____ _____
- ☐ _____ _____
- ☐ _____ _____
- ☐ _____ _____
- ☐ _____ _____
- ☐ _____ _____
- ☐ _____ _____
- ☐ _____ _____
- ☐ _____ _____
- ☐ _____ _____
- ☐ _____ _____
- ☐ _____ _____
- ☐ _____ _____
- ☐ _____ _____

* Sample must be shipped the same day collected.
** Sample must be protected from light.

- Please clearly mark the test(s) wanted for each patient. It is important to fill in the box completely so that the appropriate tests are performed.
- For a complete list of testing available please refer to the back of a current requisition form or go to www.clevelandheartlab.com/our-lab-services/tests-menu.
- Write in any additional tests under the OTHER category and make sure to fill in the box.



Section 6 Complete the Billing Information and Attach a Copy of the Insurance or Medicare Card

BILLING INFORMATION (Check only one billing option)

☐ **Insurance:** Please attach a copy of **BOTH** sides of patient's insurance card.

☐ **Medicare#** _____
Please attach a copy of **BOTH** sides of patient's Medicare card.

Note: *A patient approved Medicare ABN Form required for all genetic tests and all general adult medical examination diagnostic codes; otherwise testing will not be performed.*

☐ **Self-Pay:** CHL, Inc. will bill the patient.

Please complete the billing information section on the requisition form indicating your patient's coverage, and attach a copy of both sides of the patient's insurance card and/or demographics page.

Historical Reporting

Please Note: Historical reporting is a feature that we offer on our results report. Historical reporting allows you to see the results of your patient's last visit alongside the current results. In order for this feature to appear on your report, you must provide the following information about your patient and it must match from visit to visit:

1. **First and Last Name**
2. **Date of Birth**
3. **Last Four Digits of Social Security Number**
4. **Practitioner's Name**

As a quality measure we will not match patients with any mismatched information. Please see a few examples of what would be considered mismatched information:

	Patient Name	DOB	Last 4 SSN	Practitioner
Visit 1	Thomas Smith	8/15/1955	5589	Dr. Jones
Visit 2	Tommy Smith	8/15/1955	5589	Dr. Jones

The patient's name is a mismatch and cannot be merged.

Visit 1	Thomas Smith	8/15/1955	5589	Dr. Jones
Visit 2	Thomas Smith	8/15/1955	55589	Dr. Jones

Typo on SSN will result in a mismatch.

Visit 1	Thomas Smith	8/15/1955	5589	Dr. Jones
Visit 2	Thomas Smith	MISSING	5589	Dr. Jones

Missing information will result in a mismatch.

If you have any questions regarding historical reporting, please contact customer support at **866.358.9828**.

The Following is Our Test Menu

Please visit www.clevelandheartlab.com/our-lab-services/tests-menu for a complete listing of available tests.

The back is the test menu broken down by sample type.

Cleveland HeartLab Test Menu

For a complete listing of available tests, please visit our website at **www.clevelandheartlab.com**.

Individual Tests

Order Code	Test	CPT Code	Sample Type	Tube Color
C314	Adiponectin	83516	Serum	
C561	ADMA/SDMA	83789	Serum	
C109	Albumin	82040	Serum	
C111	Alkaline Phosphatase	84075	Serum	
C112	ALT	84460	Serum	
C127	Amylase	82150	Serum	
C604	ApoE Genotype	81401	EDTA Whole Blood*	
C123	ApoB	82172	Serum	
C122	ApoA1	82172	Serum	
C922	AspirinWorks®	84431/82570	Urine	and
C113	AST	84450	Serum	
C115	Bilirubin, Direct	82248	Serum	
C114	Bilirubin, Total	82247	Serum	
C107	BUN	84520	Serum	
C130	CA 125	86304	Serum	
C131	CA 15-3	86300	Serum	
C132	CA 19-9	86301	Serum	
C102	Calcium	82310	Serum	
C135	Carcinoembryonic Antigen (CEA)	82378	Serum	
C106	Chloride	82435	Serum	
C117	Cholesterol, Total	82465	Serum	
C2138	CK-MB	82553	Serum	
C105	CO_2	82374	Serum	
C311	Coenzyme Q10	83789	Serum or EDTA Plasma	or
C915	Complete Blood Count w/ Differential	85025	EDTA Whole Blood	
C917	Complete Blood Count w/o Differential	85027	EDTA Whole Blood	
C136	C-Peptide	84681	Serum	
C137	Creatine Kinase (CK)	82550	Serum	
C108	Creatinine	82565	Serum	
C603	CYP2C19 Genotype	81225	EDTA Whole Blood*	
C307	Cystatin C	82610	Serum	
C316	Estradiol	82670	Serum	
C918	F_2-Isoprostanes/Creat ratio	83789/82570	Urine	
C140	Ferritin	82728	Serum	
C334	Fibrinogen Mass	85385	NaCit Plasma	
C258	Folate	82746	Serum	
C317	Follicle Stimulating Hormone	83001	Serum	
C2164	Fructosamine	82985	Serum	
C315	Galectin-3	82777	Serum or EDTA Plasma	or
C165	GGT	82977	Serum	
C101	Glucose	82947	Serum	
C155	GlycoMark®	84378	Serum or EDTA Plasma	or
C145	HbA1c	83036	EDTA Whole Blood	
C118	HDL Cholesterol, Direct	83718	Serum	
C324	HDL2b	82664	Serum	
C308	Homocysteine	83090	Serum or EDTA Plasma	or
C121	hsCRP	86141	Serum or EDTA Plasma	or
C146	Insulin, Total	83525	Serum	
C147	Iron	83540	Serum	
C273	Iron Binding Capacity	83550/83540	Serum	
C148	Lactate Dehydrogenase	83615	Serum	
C120	LDL Cholesterol, Direct	83721	Serum	
C292	Lipase	83690	Serum	
C124	Lp(a)	83695	Serum	
C167	Lp-PLA$_2$ (The PLAC® Test)	83698	Serum or EDTA Plasma	or
C149	Luteinizing Hormone	83002	Serum	

Individual Tests (Continue)

Order Code	Test	CPT Code	Sample Type	Tube Color
C150	Magnesium	83735	Serum	
C605	MTHFR	81291	EDTA Whole Blood*	
C133	Myeloperoxidase (MPO)	83876	EDTA Plasma	
C2152	Myoglobin	83874	Serum	
C907	*NMR LipoProfile®* with Lipids	83704/80061	Serum	
C944	*NMR LipoProfile®* without Lipids	83704	Serum	
C125	NT-proBNP	83880	Serum	
C505	OGTT	82951	Serum	
C402	OmegaCheck™	82541	EDTA Whole Blood	
C335	Oxidized LDL	83516	Serum or EDTA Plasma	or
C309	Parathyroid Hormone (PTH), Intact	83970	Serum	
C104	Potassium	84132	Serum	
C320	Progesterone	84144	Serum	
C556	PSA, Total and Free	84154/84153	Serum	
C154	PSA, Total	84153	Serum	
C110	Protein, Total	84155	Serum	
C1259	RBC Folate	82747	EDTA Whole Blood	
C281	sdLDL	83701	Serum	
C103	Sodium	84295	Serum	
C156	Testosterone, Total	84403	Serum	
C942	Testosterone, Total and Free	82040/84270/84403	Serum	
C943	Testosterone, Total, Bio and Free	82040/84270/84403	Serum	
C157	Thyroid Stimulating Hormone	84443	Serum	
C142	Thyroxine (T4), Free	84439	Serum	
C158	Thyroxine (T4), Total	84436	Serum	
C119	Triglycerides	84478	Serum	
C143	Triiodothyronine (T3), Free	84481	Serum	
C144	Triiodothyronine (T3), Total	84480	Serum	
C2159	Troponin T	84484	Serum	
C161	Uric Acid	84550	Serum	
C916	Urinalysis	81001	Urine	
C919	Urinary Microalbumin/Creat ratio	82043/82570	Urine	
C913	The VAP® Test	83701/84478	Serum	
C900	The VAP®+ Test (VAP® with VLP)	83704/84478	Serum	
C260	Vitamin B12	82607	Serum	
C339	Vitamin D, 25 OH	82306	Serum	
C277	Vitamin D2/D3	82306	Serum or EDTA Plasma	or

Standard Panels

Order Code	Panel	CPT Code	Sample Type	Tube Color
C906	Standard Lipid Panel (includes non-HDL cholesterol)	80061	Serum	
C902	Basic Metabolic Panel	80048	Serum	
C901	Comprehensive Metabolic Panel	80053	Serum	
C903	Hepatic Function Panel	80076	Serum	
C904	Renal Function Panel	80069	Serum	
C905	Electrolyte Panel	80051	Serum	

Cleveland Clinic Wellness Programs

Order Code	Program
C207	Go!® Foods for You
C208	Stress Free Now
C333	Go!® to Sleep

A single separate tube is required for genetic tests.

EDTA Plasma | Transport Tube | Serum | Urine (without preservative) | Urine (with preservative) | NaCit Plasma | EDTA Whole Blood | NMR

ClevelandHeartLab®
Know your risk.

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CHL-D026h

Serum (Tiger Top)

Sample Handling
1. Draw.
2. Gently invert 5x (DO NOT SHAKE!).
3. Let blood clot for 30 min. at room temperature
4. Centrifuge at 1300 rcf for 10 min.
5. Store and transport refrigerated.

Note: A minimum of 0.5 mL of serum is required

Tests
- Adiponectin
- ADMA/SDMA
- Albumin
- Alkaline Phosphatase
- ALT
- Amylase
- ApoB
- ApoA1
- AST
- Bilirubin, Direct
- Bilirubin, Total
- BUN
- CA 125
- CA 15-3
- CA 19-9
- Calcium
- Carcinoembryonic Antigen (CEA)
- Chloride
- Cholesterol, Total
- CK-MB
- CO_2
- Coenzyme Q10
- C-Peptide
- Creatine Kinase (CK)
- Creatinine
- Cystatin C
- Estradiol
- Ferritin
- Folate
- Follicle Stimulating Hormone
- Fructosamine
- Galectin-3
- GGT
- Glucose
- GlycoMark®
- HDL Cholesterol, Dir
- HDL2b
- Homocysteine
- hsCRP
- Insulin, Total
- Iron
- Iron Binding Capacity
- Lactate Dehydrogena
- LDL Cholesterol, Dire
- Lipase
- Lp(a)
- Lp-PLA$_2$ (The PLAC® Test)
- Luteinizing Hormone
- Magnesium
- Myoglobin
- NT-proBNP
- OGTT
- Oxidized LDL
- Parthyroid Hormone (PTH), Intact
- Potassium
- Progesterone
- PSA, Total and Free
- PSA, Total
- Protein, Total
- sdLDL

In place of step 5 above – Immediately aliquot and freeze serum at

Sodium Citrate (Light Blue Top and Transport Tube)

Sample Handling
1. Draw. Must fill the tube to maximum capacity.
2. Gently invert 3-4x (DO NOT SHAKE!).
3. Centrifuge immediately at 1300 rcf for 10 min.
4. Pre-squeeze transfer pipet bulb and draw off a upper plasma layer. Aliquot plasma into labele tightly. Discard original tube. Label the transpo and ship to Cleveland HeartLab.
5. For same day shipping, store and transport re
6. For next-day shipping, freeze the sample and

Note: A minimum of 0.5 mL of plasma is require

Tests
- Fibrinogen Mass

NMR Lipo Tube (Black)

Sample Handling
1. Draw.
2. Gently invert 5-10x (DO NOT SHAKE!).
3. Let blood clot for 30 min. in an upright position at room temperature.
4. Centrifuge at 1300 rcf for 15 min.
5. Store and transport refrigerated.

Tests
- *NMR LipoProfile®* with Lipids
- *NMR LipoProfile®* without Lipids

system.
2. Transfer urine sample into the yellow top tube using the vacutainer system.
3. Store and transport refrigerated. Please discard the vacutainer cup system and do not ship the cup.

Note: A minimum of 1.0 mL of urine is required per test.

Tests
- AspirinWorks®*
- F_2-Isoprostanes/Creat ratio
- Urinary Microalbumin/Creat ratio

**AspirinWorks® also requires a urine specimen in a cherry/yellow top tube.*

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Collecting Test Samples

The following pages provide detailed instructions on how to properly collect and store samples that you are sending to Cleveland HeartLab. We are committed to providing high quality results and a key component is receiving quality samples.

The following pages outline:

- Sample Handling
- Storage Instructions
- Tube Labeling Instructions

Please Note: Be sure that the name on the requisition form exactly matches the name on their insurance card or medicare card. Each sample must have the patient's full name (first and last), and date of birth. The collection date and time must also be included on the requisition form to ensure the quality and reliability of results.

Sample Handling/Storage Instructions

- Collect blood samples using aseptic venipuncture technique.
- Check that you have enough sample to perform each test ordered.
- Cap tightly and label sample tube. All samples should be properly identified. The sample label **must** include: FULL NAME (First and Last), and DATE OF BIRTH. Specify specimen type when using a transport tube.
- Treat all samples with Universal and Standard precautions.
- Please contact Cleveland HeartLab if you have any questions related to sample stability or visit www.clevelandheartlab.com/our-lab-services/tests-menu.

Serum (Tiger Top)

Sample Handling

1. Draw.
2. Gently invert 5x (DO NOT SHAKE!).
3. Let blood clot for 30 min. at room temperature.
4. Centrifuge at 1300 rcf for 10 min.
5. Store and transport refrigerated.

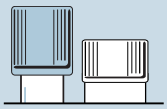
Note: A minimum of 0.5 mL of serum is required per test or panel.

Tests

- Adiponectin
- ADMA/SDMA
- Albumin
- Alkaline Phosphatase
- ALT
- Amylase
- ApoB
- ApoA1
- AST
- Bilirubin, Direct
- Bilirubin, Total
- BUN
- CA 125
- CA 15-3
- CA 19-9
- Calcium
- Carcinoembryonic Antigen (CEA)
- Chloride
- Cholesterol, Total
- CK-MB
- CO_2
- Coenzyme Q10
- C-Peptide
- Creatine Kinase (CK)
- Creatinine
- Cystatin C
- Estradiol
- Ferritin
- Folate
- Follicle Stimulating Hormone
- Fructosamine
- Galectin-3
- GGT
- Glucose
- GlycoMark®
- HDL Cholesterol, Direct
- HDL2b
- Homocysteine
- hsCRP
- Insulin, Total
- Iron
- Iron Binding Capacity
- Lactate Dehydrogenase
- LDL Cholesterol, Direct
- Lipase
- Lp(a)
- Lp-PLA_2 (The PLAC® Test)
- Luteinizing Hormone
- Magnesium
- Myoglobin
- NT-proBNP
- OGTT
- Oxidized LDL
- Parthyroid Hormone (PTH), Intact
- Potassium
- Progesterone
- PSA, Total and Free
- PSA, Total
- Protein, Total
- sdLDL
- Sodium
- Testosterone, Total
- Testosterone, Free
- Testosterone, Total, Bio and Free
- Thyroid Stimulating Hormone
- Thyroxine (T4), Free
- Thyroxine (T4) Total
- Triglycerides
- Triiodothyronine (T3), Free
- Triiodothyronine (T3), Total
- Troponin T*
- Uric Acid
- The VAP® Test
- The VAP®+ Test (VAP® with VLP)
- Vitamin B12
- Vitamin D, 25 OH
- Vitamin D2/D3
- Standard Lipid Panel
- Basic Metabolic Panel
- Comprehensive Metabolic Panel
- Hepatic Function Panel
- Renal Function Panel
- Electrolyte Panel

**In place of step 5 above – Immediately aliquot and freeze serum at -20° C. Ship the same day on dry ice.*

Sodium Citrate (Light Blue Top and Transport Tube)



Sample Handling

1. Draw. Must fill the tube to maximum capacity.
2. Gently invert 3-4x (DO NOT SHAKE!).
3. Centrifuge immediately at 1300 rcf for 10 min.
4. Pre-squeeze transfer pipet bulb and draw off approximately 2/3 of the upper plasma layer. Aliquot plasma into labeled transport tube and cap tightly. Discard original tube. Label the transport tube as NaCit Plasma and ship to Cleveland HeartLab.
5. For same day shipping, store and transport refrigerated.
6. For next-day shipping, freeze the sample and ship on dry ice.

Note: A minimum of 0.5 mL of plasma is required per test.

Tests

- Fibrinogen Mass

NMR Lipo Tube (Black)

Sample Handling

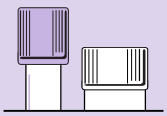
1. Draw.
2. Gently invert 5-10x (DO NOT SHAKE!).
3. Let blood clot for 30 min. in an upright position at room temperature.
4. Centrifuge at 1300 rcf for 15 min.
5. Store and transport refrigerated.

Tests

- *NMR LipoProfile®* with Lipids
- *NMR LipoProfile®* without Lipids

EDTA Plasma (Lavender Top, 6mL and Transport Tube)

(TALL)



Sample Handling

1. Draw.
2. Gently invert 8-10x (DO NOT SHAKE!).
3. Centrifuge immediately at 1300 rcf for 10 min.
4. Pre-squeeze transfer pipet bulb and draw off approximately 2/3 of the upper plasma layer. Aliquot plasma into labeled transport tube and cap tightly. Discard original tube. Label the transport tube as EDTA Plasma and ship to Cleveland HeartLab.
5. Store and transport refrigerated.

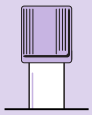
Note: A minimum of 0.5 mL of plasma is required per test.

Tests

- Myeloperoxidase (MPO)
- Lp-PLA_2 (The PLAC® Test)
- hsCRP
- Oxidized LDL
- Coenzyme Q10
- Homocysteine
- Galectin-3
- GlycoMark®
- Vitamin D2/D3

EDTA Whole Blood (Lavender Top, 4mL)

(SHORT)



Sample Handling

1. Draw.
2. Gently invert 8-10x (DO NOT SHAKE!).
3. Do not centrifuge
4. Store and transport refrigerated.

Note: A single separate tube is required for genetic tests. A minimum of 1.0 mL of whole blood is required per genetic test.

Tests

- ApoE Genotype
- Complete Blood Count w/ Differential
- Complete Blood Count w/o Differential
- CYP2C19 Genotype
- HbA1c
- MTHFR
- OmegaCheck™
- RBC Folate

Sample Handling/Storage Instructions (continued)

Urine Specimen Tube (Cherry Red/Yellow Top)

Sample Handling

1. Collect random urine into the vacutainer cup system.
2. Transfer urine sample into the cherry/yellow top tube using the vacutainer system.
3. Gently invert 8-10x (DO NOT SHAKE!).
4. Store and transport refrigerated. Please discard the vacutainer cup system and do not ship the cup.

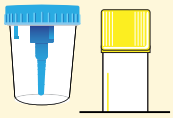
Note: A minimum of 3.0 mL of urine is required per test.

Tests

- AspirinWorks®*
- Urinalysis

**AspirinWorks® also requires a urine specimen in a yellow top tube.*

Urine Specimen Tube (Yellow Top)



Sample Handling

1. Collect random urine into the vacutainer cup system.
2. Transfer urine sample into the yellow top tube using the vacutainer system.
3. Store and transport refrigerated. Please discard the vacutainer cup system and do not ship the cup.

Note: A minimum of 1.0 mL of urine is required per test.

Tests

- AspirinWorks®*
- F_2-Isoprostanes/Creat ratio
- Urinary Microalbumin/Creat ratio

**AspirinWorks® also requires a urine specimen in a cherry/yellow top tube.*

Did you remember to:

- ☑ Check that you have collected the proper specimen types for the tests ordered.
- ☑ Check that you have collected enough sample to perform the tests ordered.
- ☑ Cap tightly and label each tube with full name, first and last and date of birth.
- ☑ Specify specimen type on each transport tube.

Sample Rejection Policy

Samples will be rejected for any of the following reasons:

- Samples were shipped on Saturday.
- Friday blood draws arrived on Monday.
- Sample types were incorrect or samples were received in damaged condition (i.e. tube open or cracked, sample not at correct temperature).
- Sample tube is not properly labeled with first and last name and date of birth.
- Requisition form is not completely filled out. First and last name, date of birth and gender are required.
- Physician signature is missing.

Preventing Sample Handling Errors

Cleveland HeartLab is a CAP-accredited and CLIA-certified clinical reference laboratory dedicated to providing high quality cardiovascular disease testing.

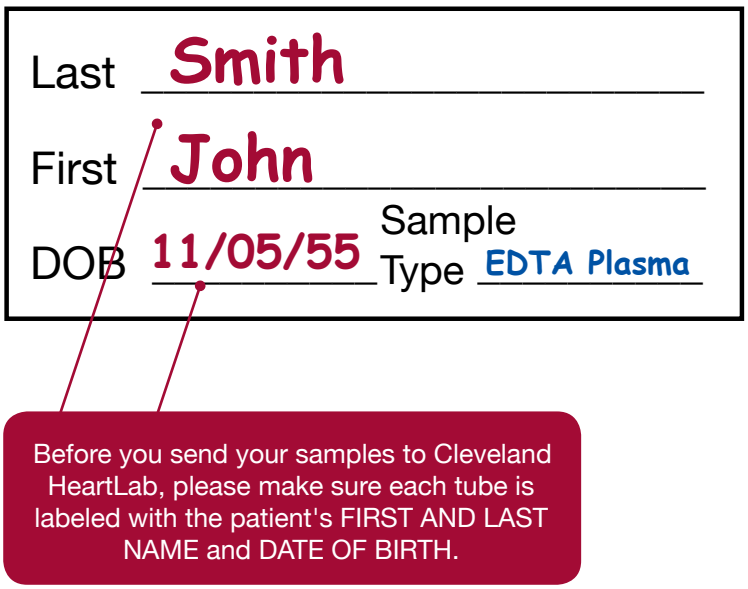
Filling out complete and accurate patient information will help ensure that you receive patient results in a timely manner.

The table below provides examples of commonly encountered sample handling errors that can result in an invalid test result or delays in reporting.

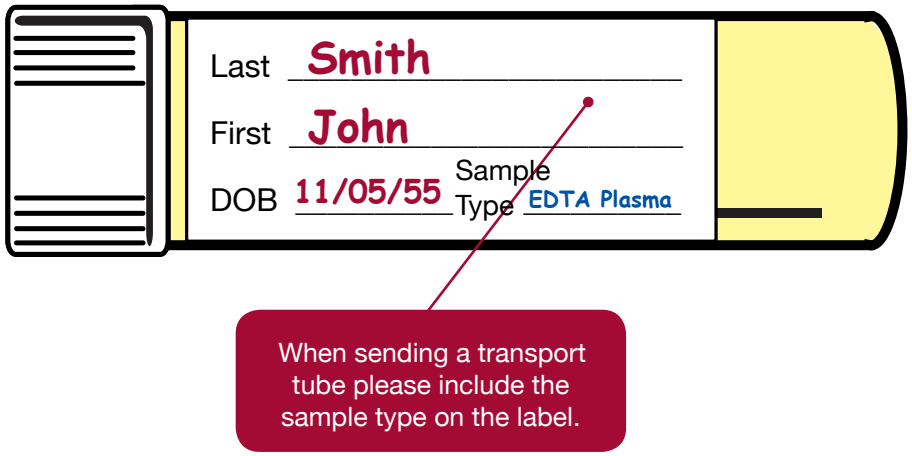
Sample Handling Error	Effects of the Sample Handling Error
No date of birth	Some reference ranges are based on age. If no date of birth is given we are unable to result these tests.
No gender marked on requisition form	Some reference ranges are gender-specific. If no gender is given we are unable to result these tests.
Incomplete name	A complete name on the requisition form and tubes are critical for patient and specimen identification. A complete name is also needed to file the insurance claim.
No draw date	The draw date is required per CAP/CLIA regulation; this will ensure both the quality of your samples and reliability of your results. There is a place for the draw date on the left hand side of the requisition.
Improper labeling or no label on tubes	Before you send your samples to Cleveland HeartLab, please make sure each tube is labeled with the patient's FIRST AND LAST NAME and DATE OF BIRTH. When sending a transport tube, please include the sample type on the label. Incorrect specimen type will result in erroneous results for your patients and significantly impact patient care.
No test checked off or ordered on requisition form	If a requisition form is received without a test ordered, it will be put aside and the office will be contacted to send in a new requisition form. This may result in delayed or expired samples.
Incorrect whole blood sample handling	For whole blood, draw the patient and gently invert the sample 8-10 times. **Do not shake or centrifuge the sample.** **Do not spin down the sample and remove the plasma.** Failure to follow these whole blood sample guidelines will result in erroneous results.
Not allowing the SST tube to clot for 30 minutes	The SST tube needs to sit for 30 minutes at room temperature in order for the chemical activator in the tube to initiate clot formation. Inadequate clot formation could result in: • Invalid results due to poor serum/cell separation

It is important to properly label your tubes before sending them to Cleveland HeartLab for testing.

Tube Labeling

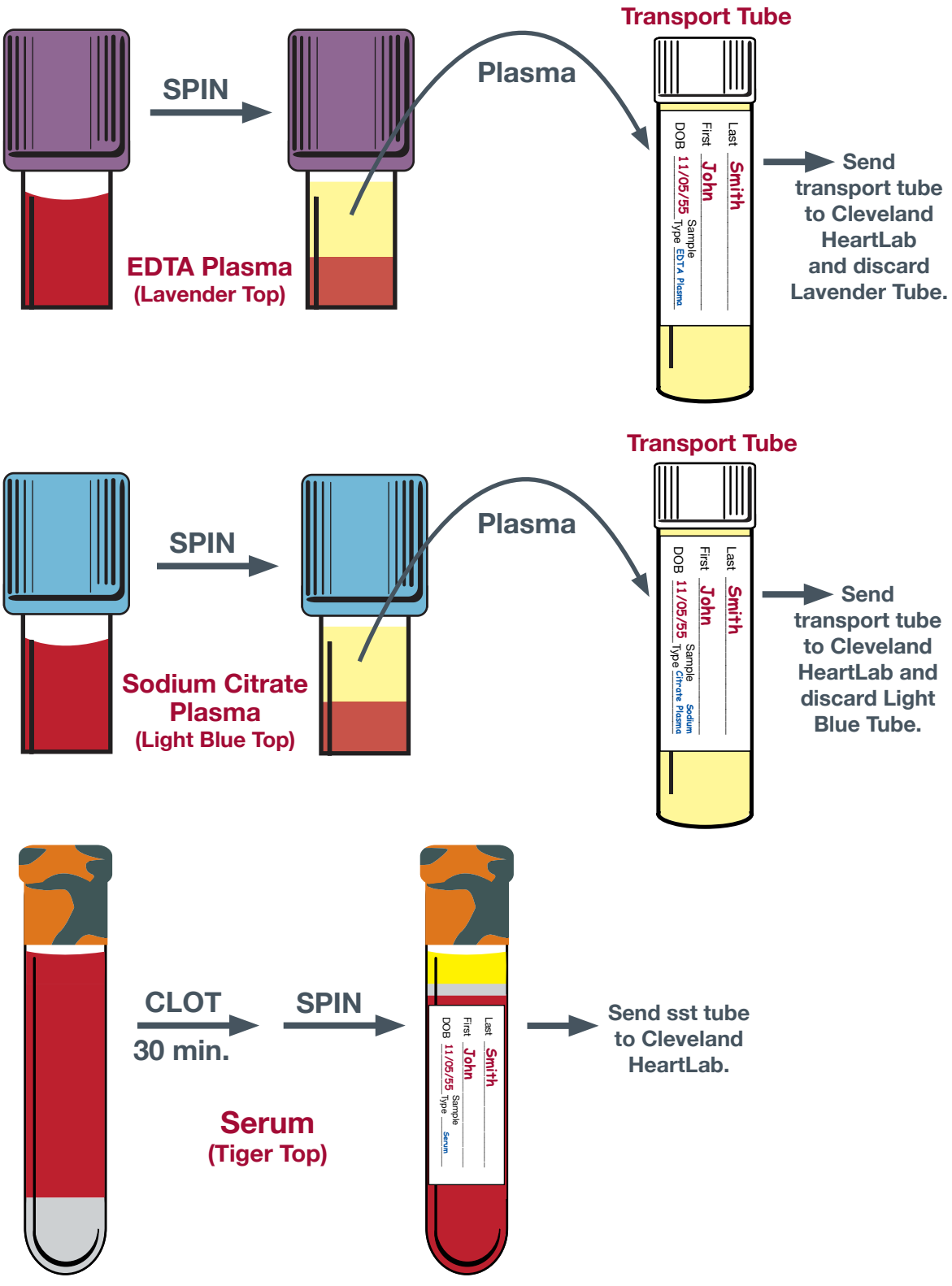


Transport Tube



Tube Labeling (continued)

For samples that require separation into a transport tube, you must label the transport tube with the sample type.

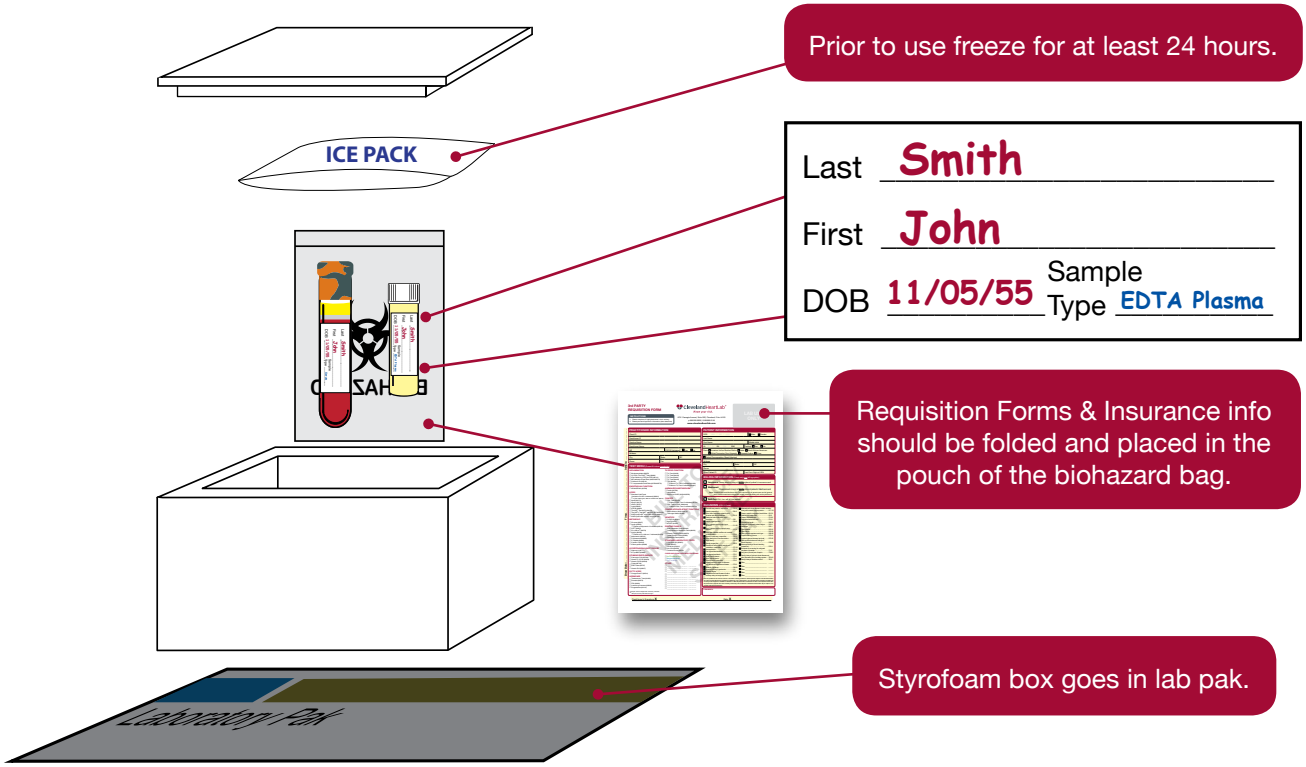


Shipping Samples and Requisition Forms

Packaging Diagram

The following outlines instructions on how to:

- Package samples for shipment
- Schedule a UPS pick-up



Months with no 'R' - double the ice bricks to insure stability!
[May - August]

Office Packing

Samples should be stored at 2-8º C immediately after they are collected and processed.

1) Place cold or frozen sample(s) in the biohazard bags.
2) Place completed requisition (and insurance information if applicable) for each sample in the pouch of the biohazard bag.
3) Place biohazard bag (with sample(s) and requisition form) in the Styrofoam box.
4) Place a frozen ice pack on top of the samples in the Styrofoam box.
5) Place Styrofoam box into UPS Laboratory Shipping Pak.

UPS/FEDEX Pick-Up

Folllowing these instructions will ensure that your samples arrive at Cleveland HeartLab in a timely manner.

	UPS	FedEx
Phone Number	**(800) 742-5877**	**(800) 463-3339**
Request Instructions	Ask to schedule a "RETURN SERVICE LABELED PICK-UP"	Ask to schedule a "PRE-PAY AIRBILL PICK-UP"
Have your shipping label available when calling for a pick-up.		
Ship for next day delivery (with provided label) to: Cleveland HeartLab, Inc. 6701 Carnegie Ave, Suite 500, Cleveland, OH 44103, Phone: 866-358-9828. Samples can be shipped Monday through Friday.		

- A UPS scheduled pick-up can be arranged by calling Cleveland HeartLab Customer Support at 866.358.9828.
- We recommend that you make photocopies of your shipping label or record the tracking number before shipping. This will be helpful in case there is a delay in transit and we need to try and locate your package.

Cleveland HeartLab offers three options for receiving your patients results. Your sales representative will discuss these with you during the start-up process and work with you to determine the best option and set you up accordingly. The following are the 3 options:

On-line results

- Retrieve results directly from our web portal.
- You will have real time access to your results as they are completed and released.
- You will be assigned an initial user name and password to access the system. This will be provided to you by your sales representative or customer support.

The following section of the Resource Book outlines:

» Instructions on how to access test reports
» Understanding the Patient Test Report
» Example of Patient Test Report
» Critical Results Notification

Fax Results

- Receive your patient reports via your fax machine or electronic fax once all results have been completed and released.

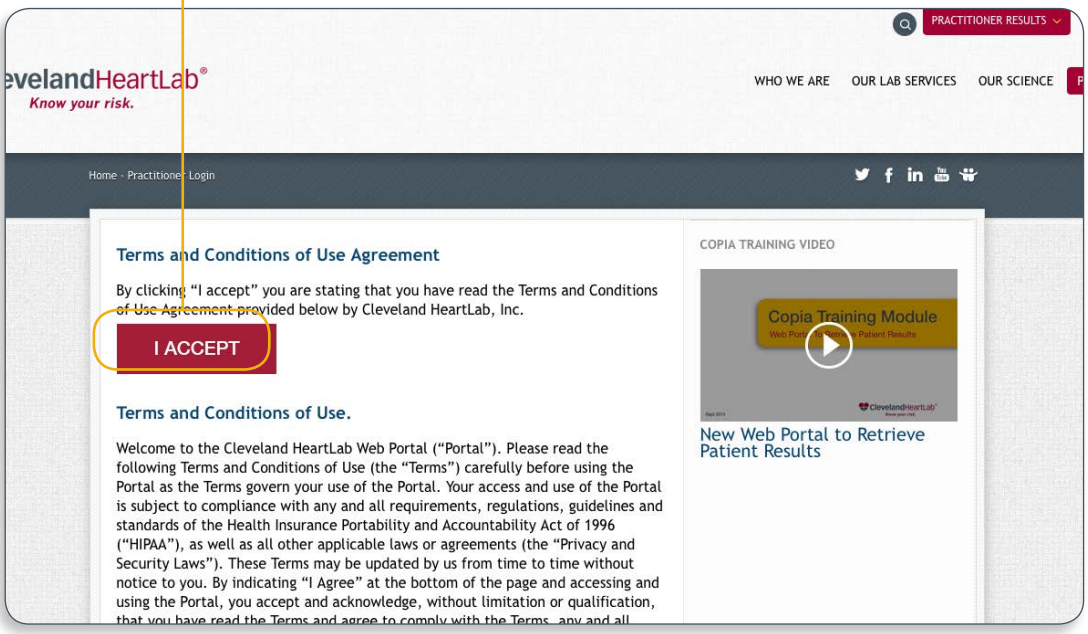
Interface/Electronic Medical Record

- Your sales representative will be able to provide you additional information and guidelines on this option.

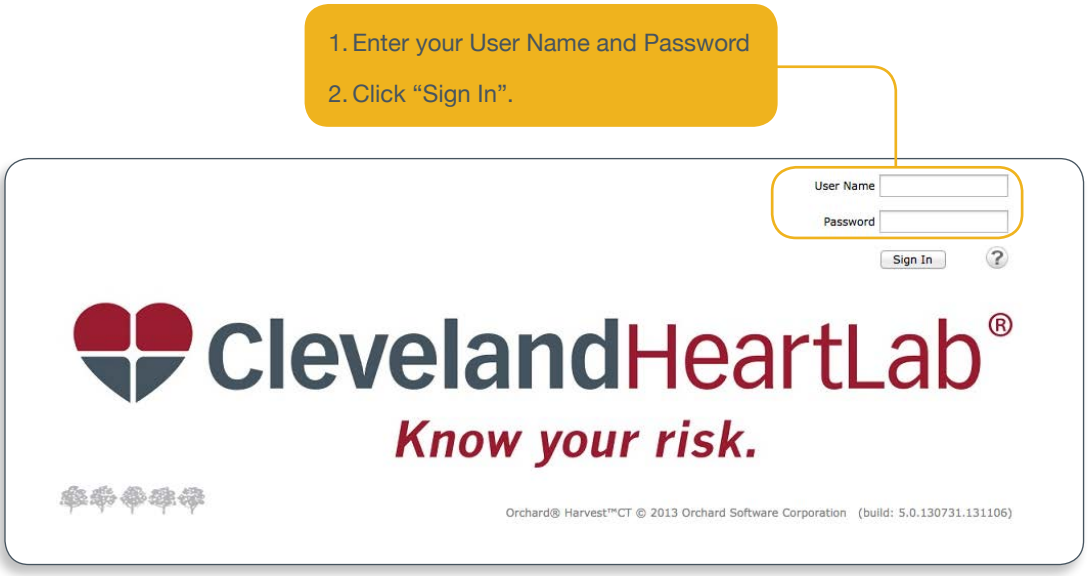
I. Log in to Copia to view Patient Results

1. Go to: www.clevelandheartlab.com
2. Click on “Practitioner Results”.

1. Read the Terms and Conditions.
2. Click “I ACCEPT”.

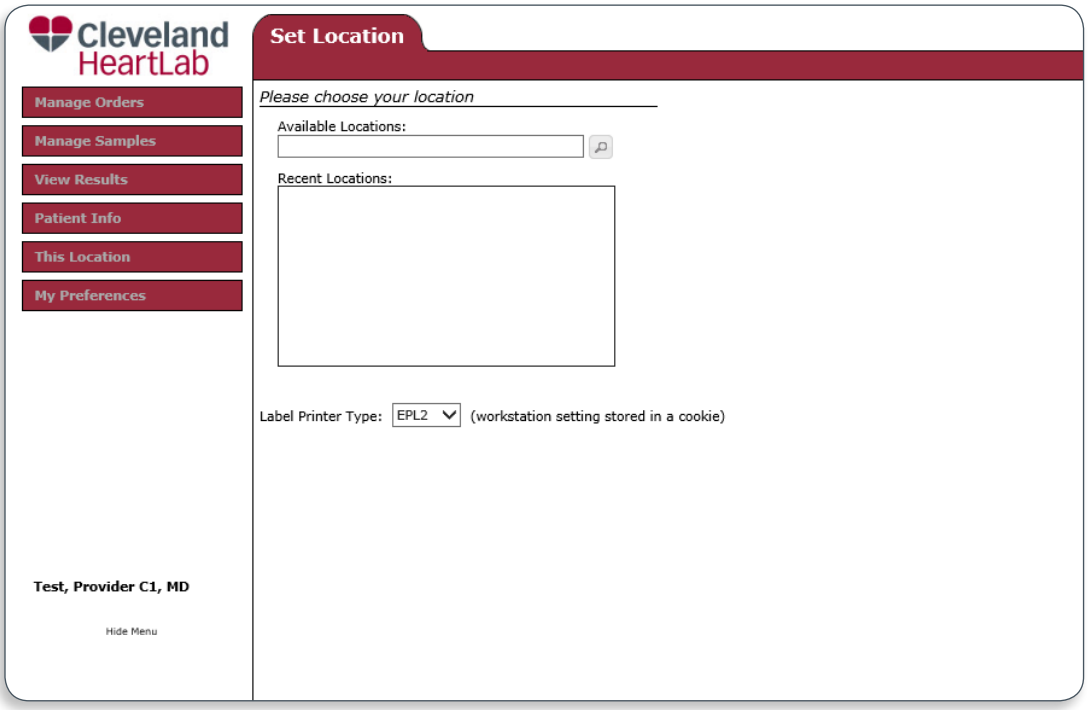


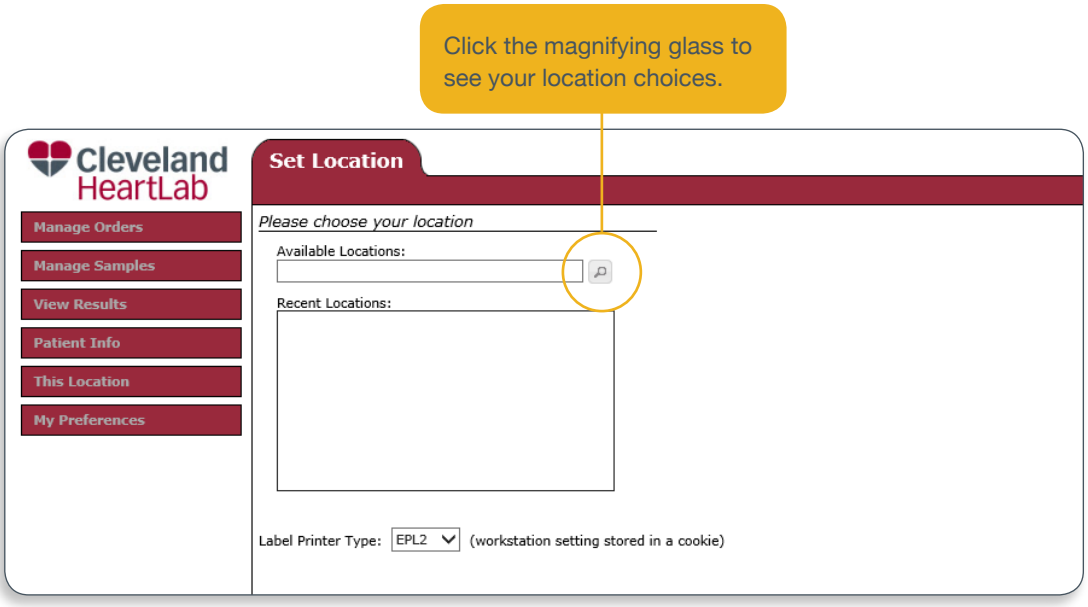
This will bring you to the Copia login screen.

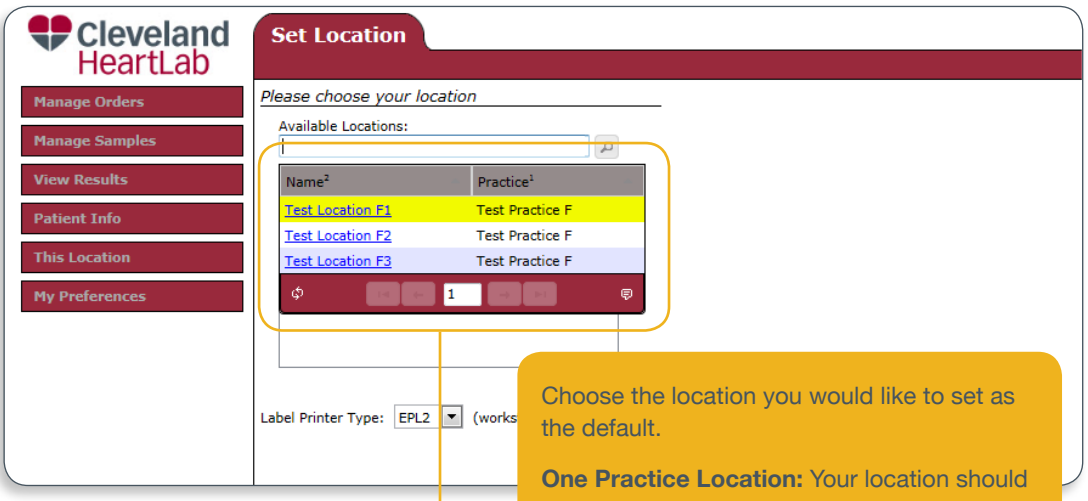


If you need your username and password please call customer support at **1-866-358-9828**.

The first time you log in, you will see this screen. You only need to choose a default location one time.







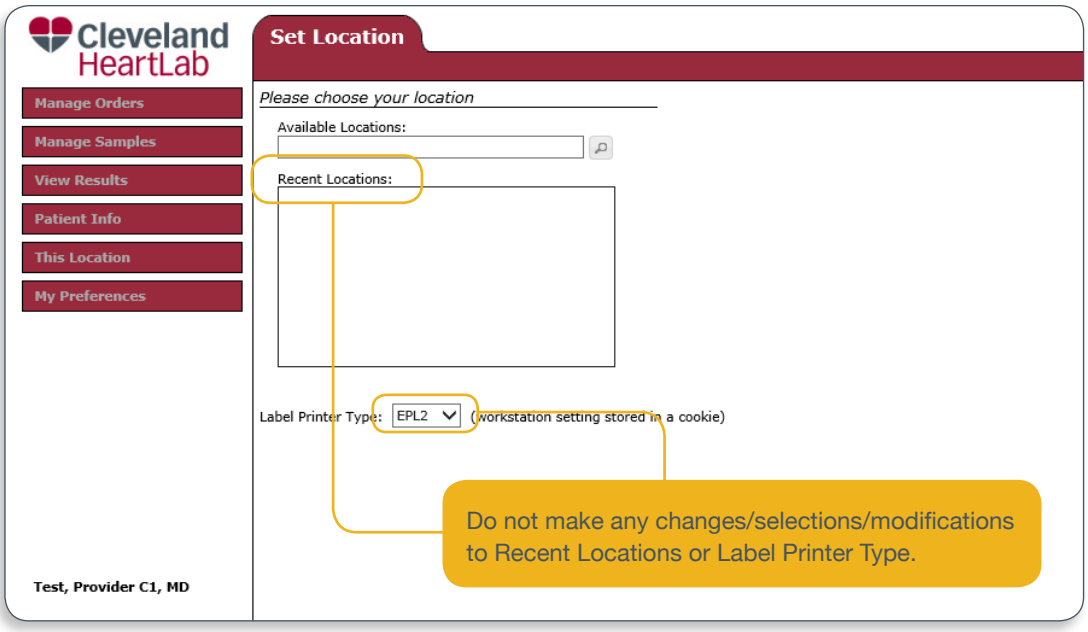
Choose the location you would like to set as the default.

One Practice Location: Your location should appear and you will need to choose it.

Multiple Practice Locations: Choose one location to set as your default location.

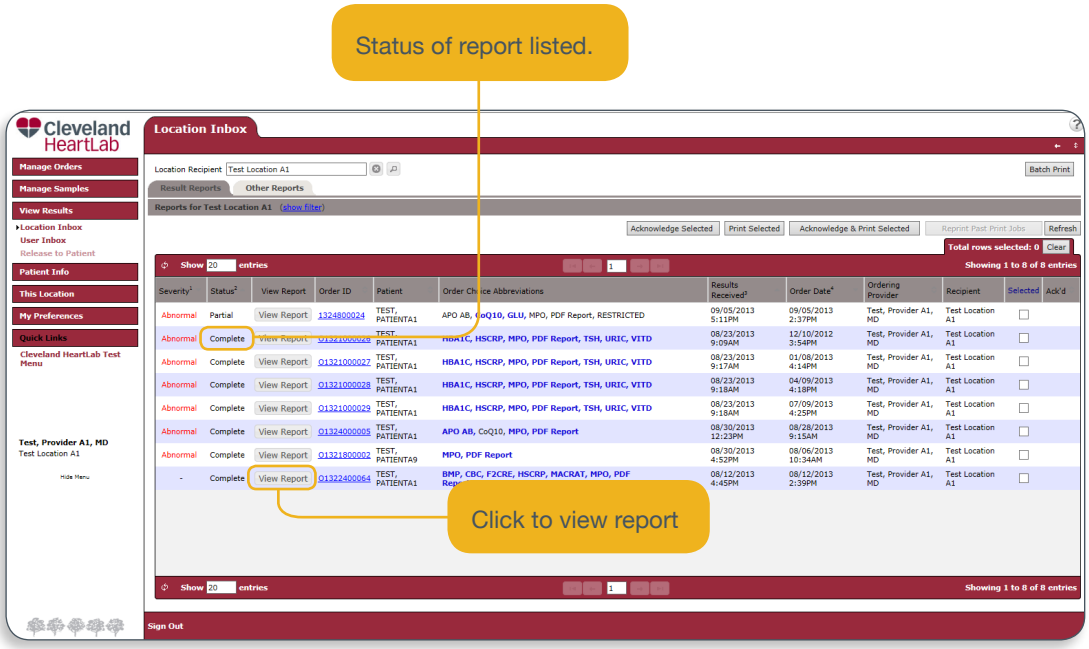
Please Note: You will be able to view any location at any time once you are logged into the system.

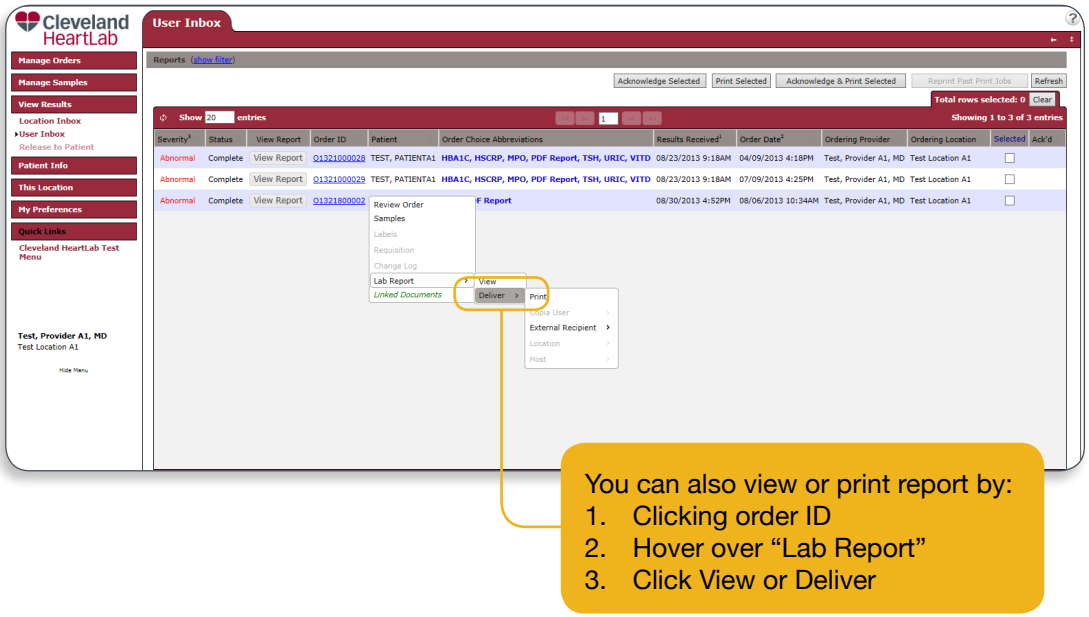
If you do not see an ordering location that you think should be listed please let your Cleveland HeartLab representative know or call Customer Support (866) 358-9828.

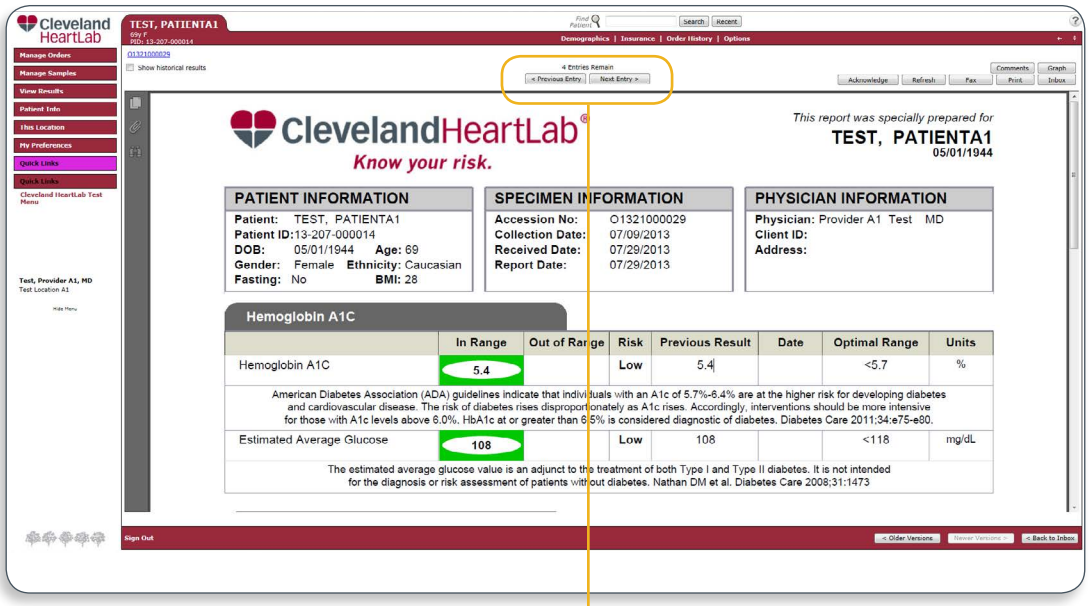

Cleveland HeartLab
Manage Orders
Manage Samples
View Results
Patient Info
This Location
My Preferences
Test, Provider C1, MD
Set Location
Please choose your location
Available Locations:
Recent Locations:
Label Printer Type: EPL2 (workstation setting stored in a cookie)
Do not make any changes/selections/modifications to Recent Locations or Label Printer Type.

II. User Inbox: Quick Glance

The user inbox lists your most recently accessioned patients. The view is defaulted to sort by SEVERITY and then STATUS.

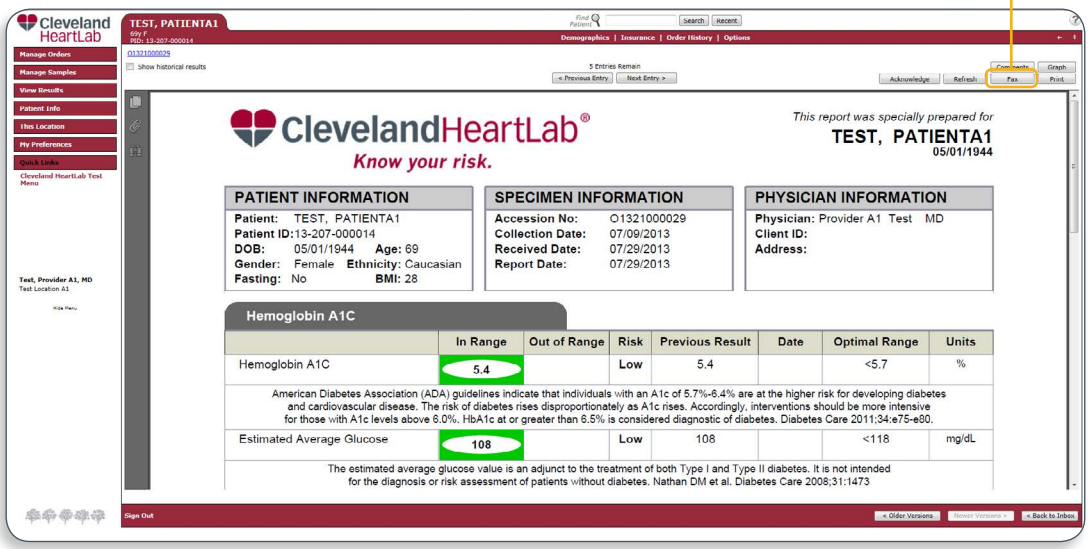


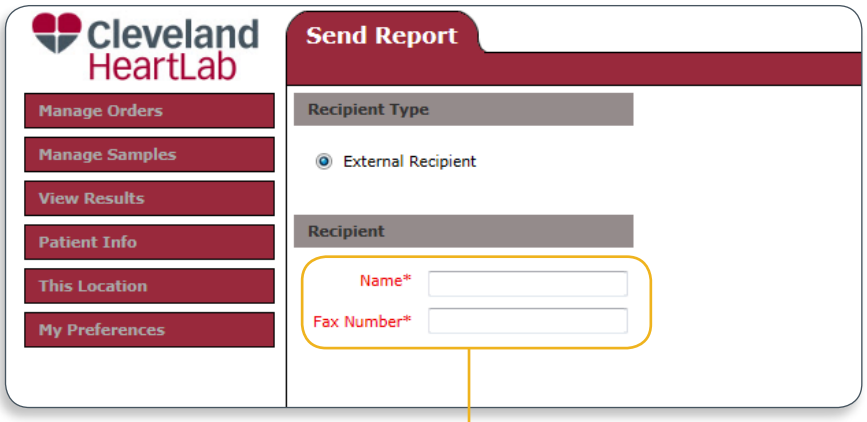




The **Previous Entry** and **Next Entry** buttons allow you to scroll through your inbox easily.

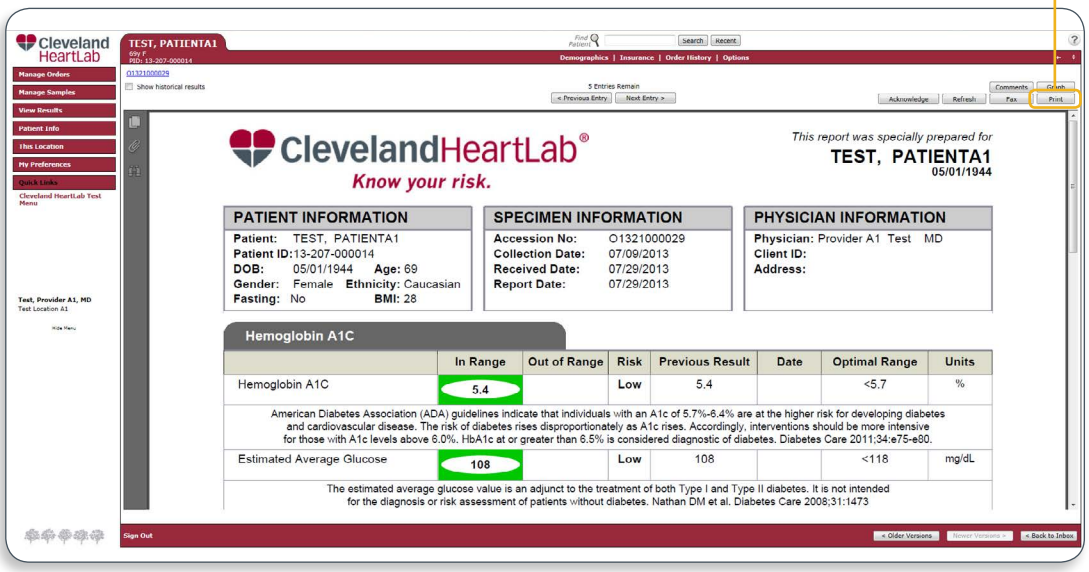
The Fax button allows you to fax a patient's result to an external recipient.

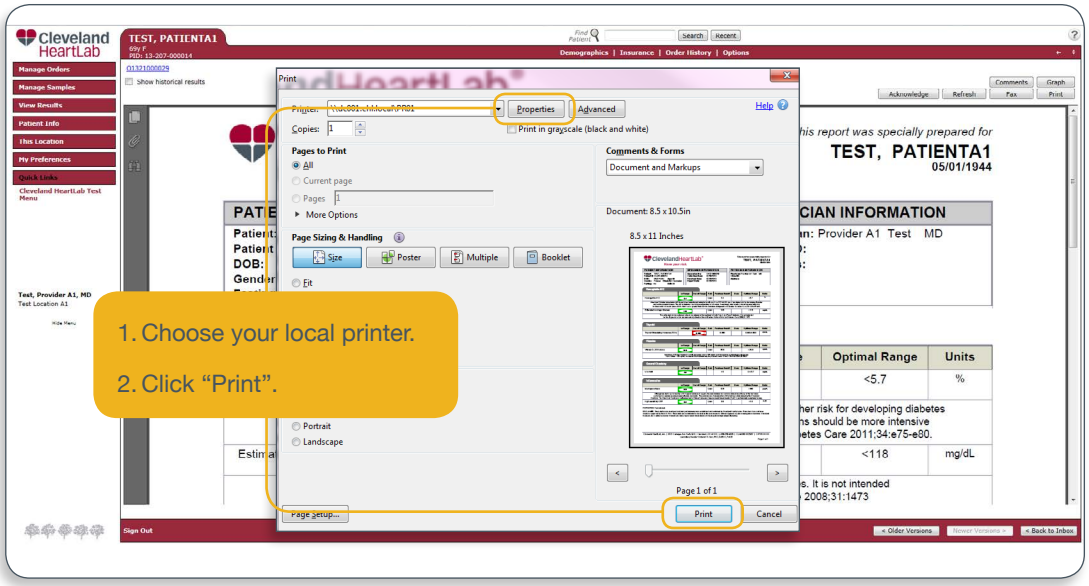




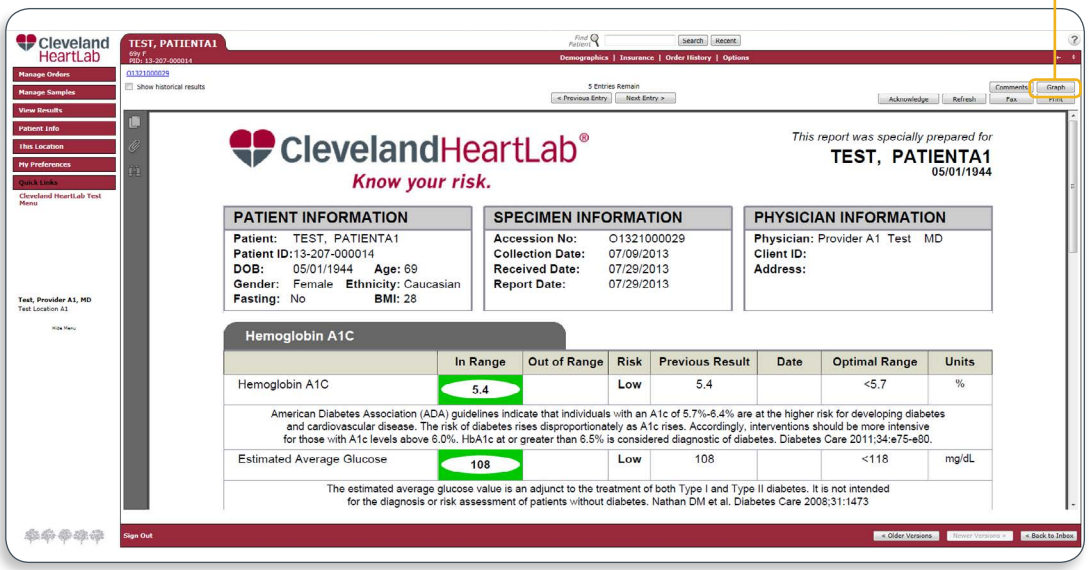
1. Type the name of the recipient.
2. Type the recipient's fax number. (The fax will work with or without the 1 preceding the area code.)

The Print button allows you to print your result to a local printer.

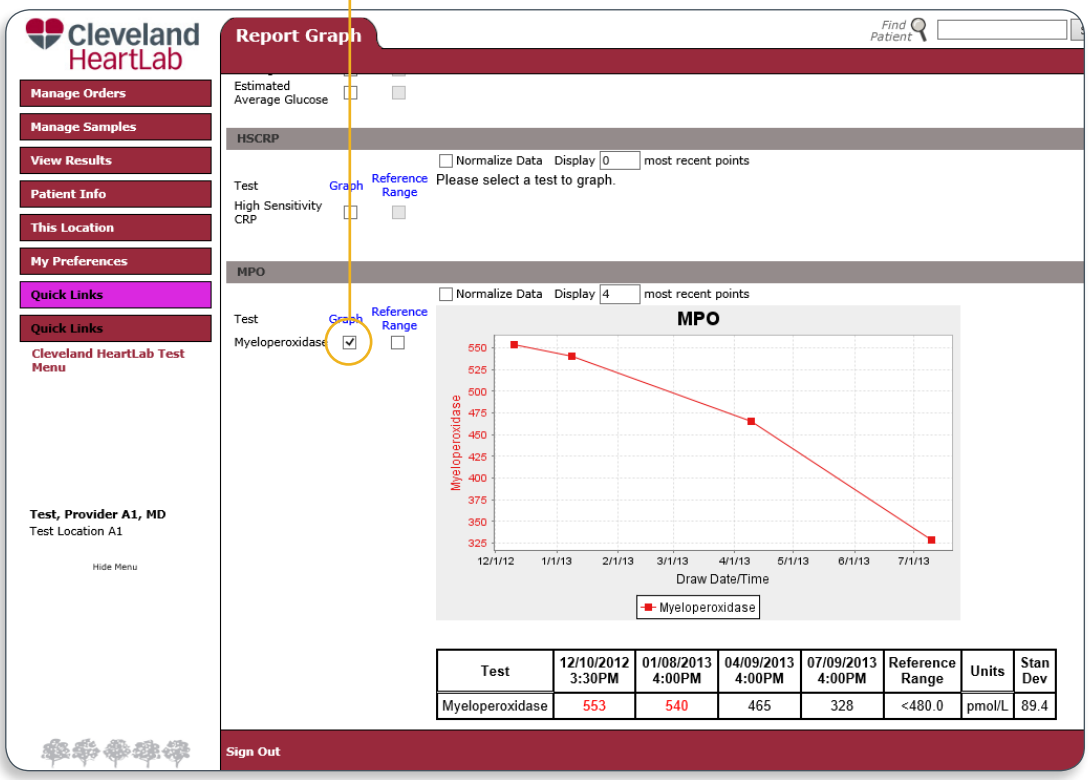




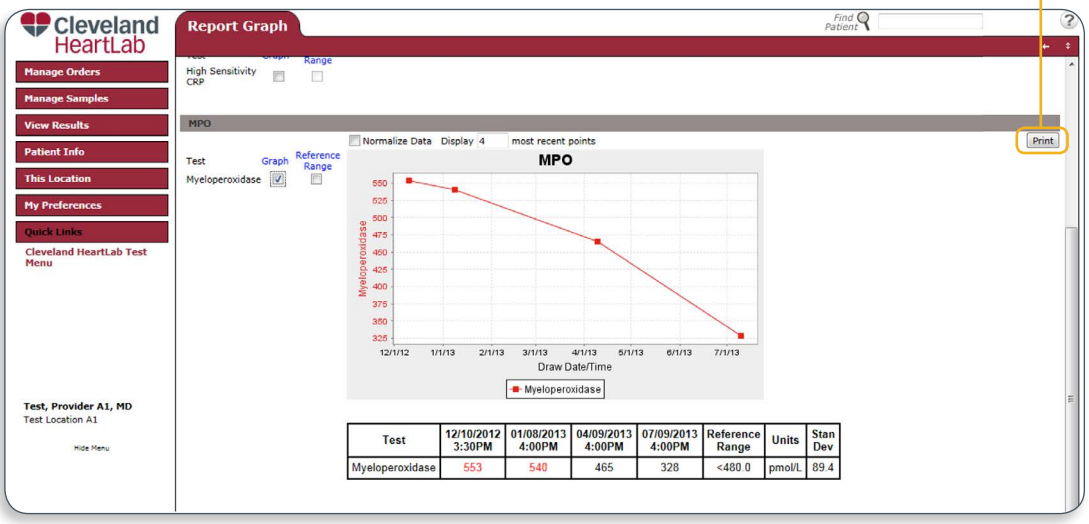
The **Graph** button allows you to view historical reporting in a line graph format (by patient and test).



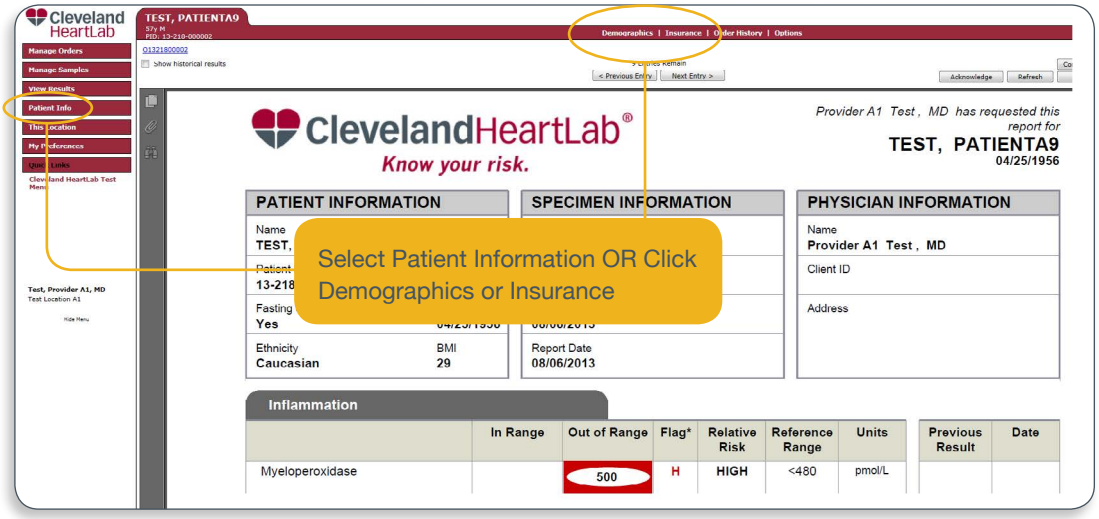
Click the Graph check box to select which test you wish to view as a graph.



Click the “Print” button to print a hard copy.

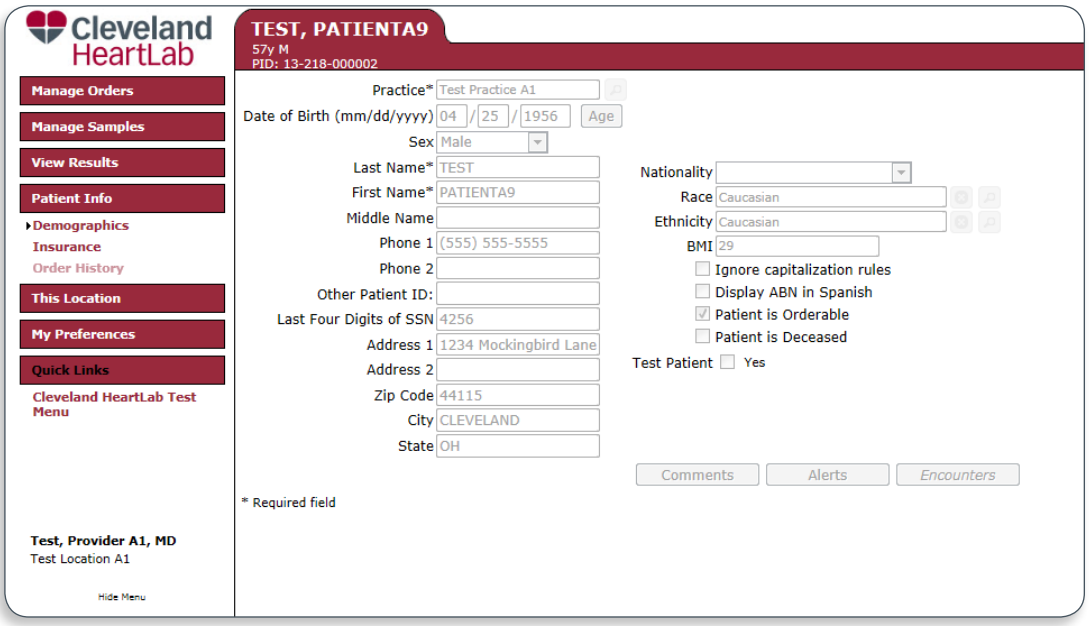


While you are in the patient's lab report, you have the option to view the demographics and insurance information that we have on file. You can do this by selecting Patient Info from the sidebar menu or selecting Demographics or Insurance from the top menu. Both choices will take you to the same screen.



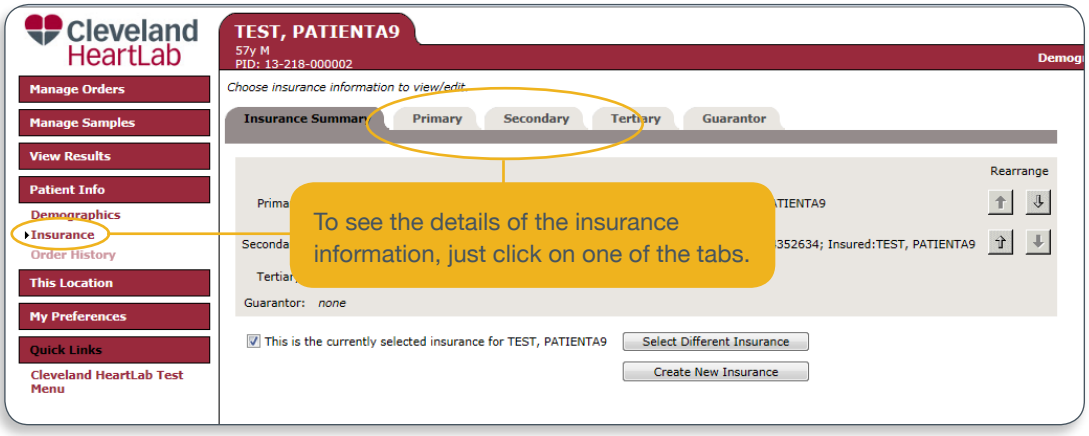
Patient Demographics

Patient Demographic information is available to view, but no changes can be made. If you see anything that needs to be changed or missing information, please call customer support and they can update this information for you.

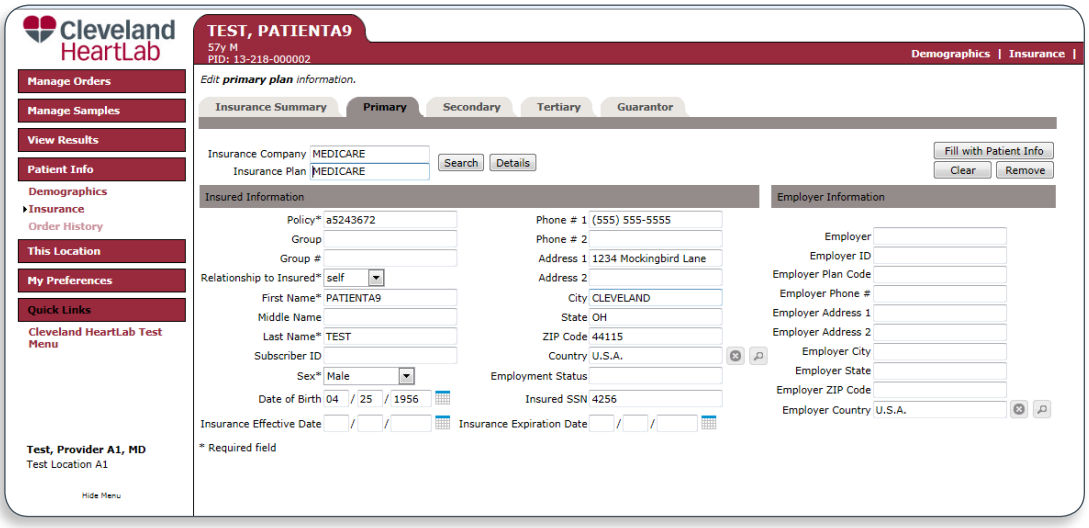


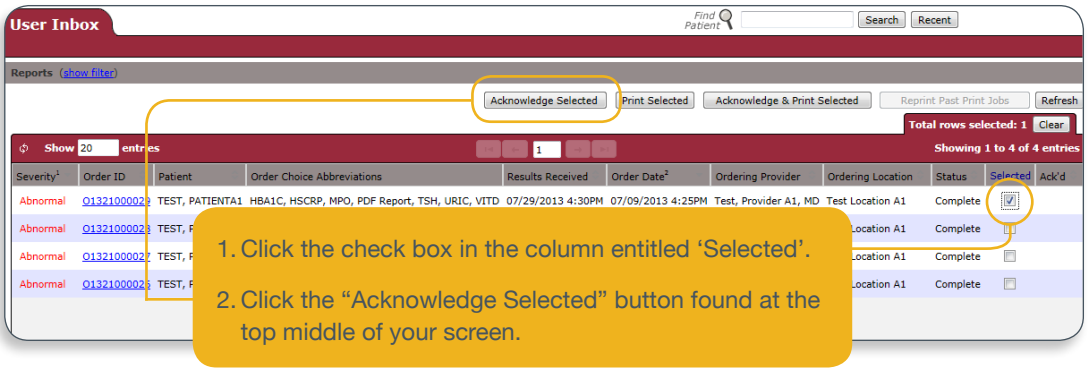
Patient Insurance

The Insurance tab on the right menu bar brings you to the main insurance page which provides a summary.



Looking at the primary insurance tab you can see the detailed information we have on file for your patient's primary insurance. Again, if anything is missing or incorrect please call customer support.



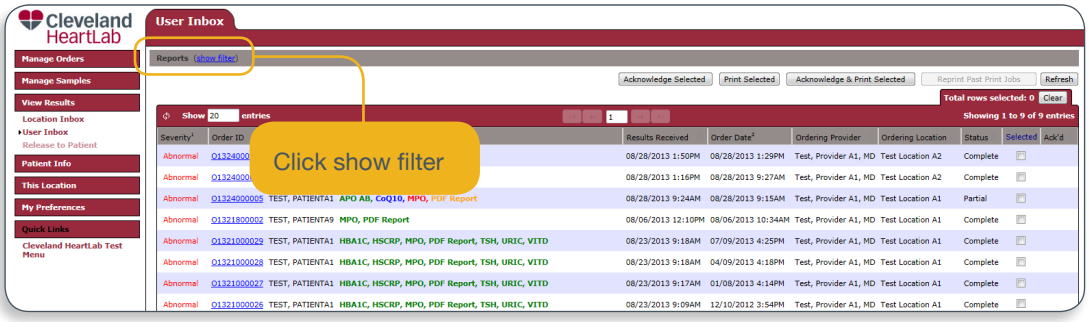


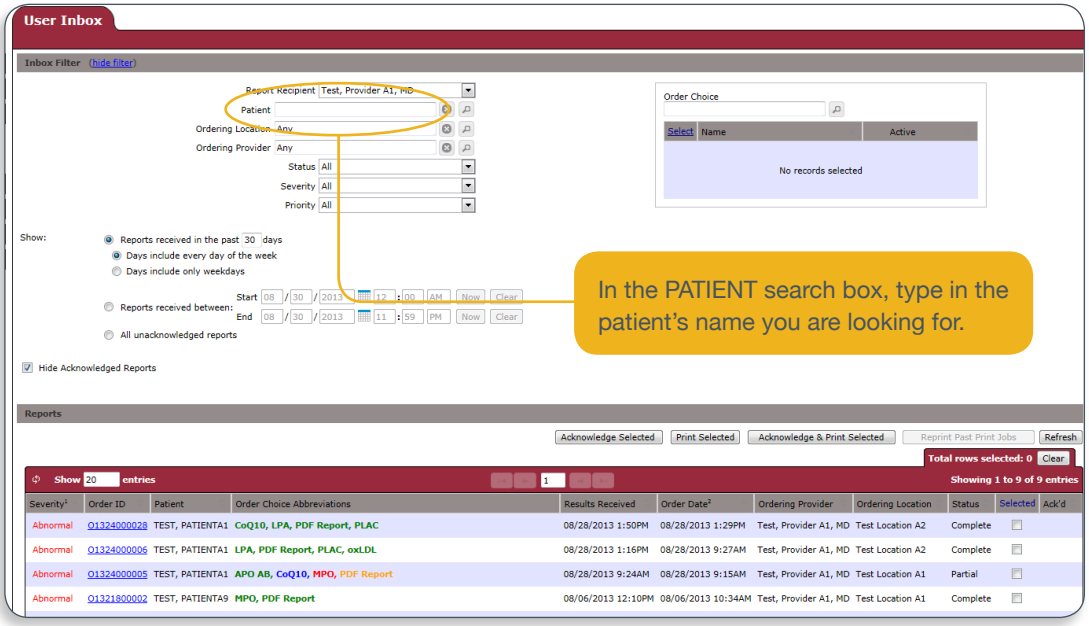
To archive a report and remove it from your inbox, check the selected column and acknowledge selected on top of the screen.

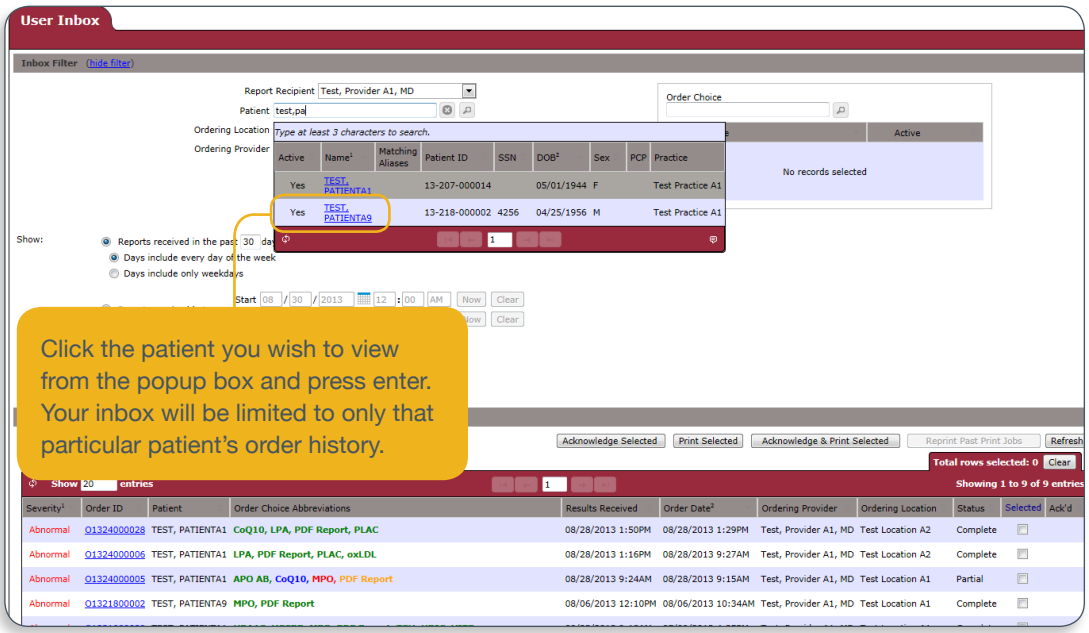
Please Note: Archived patients are available via the search function.

III. Search for Patient

A. Search from inbox

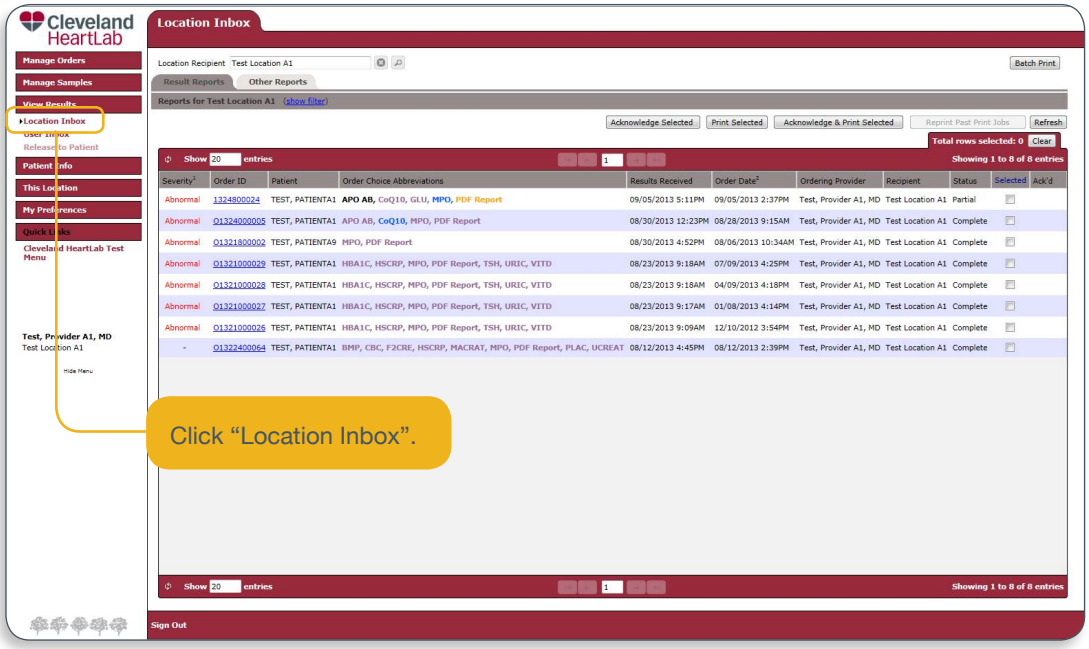


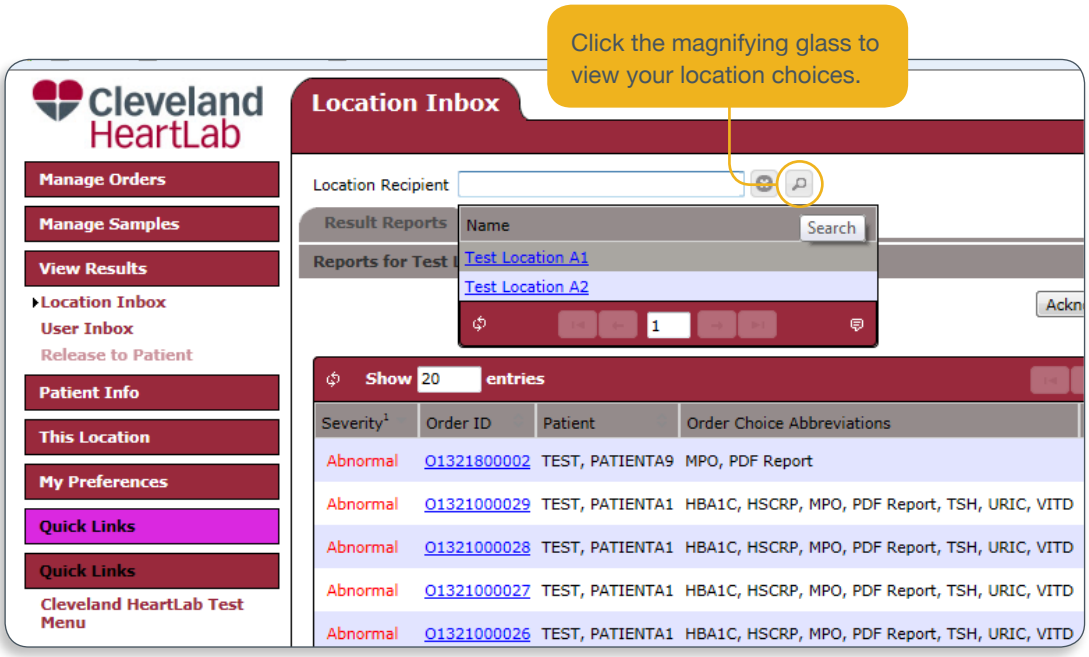


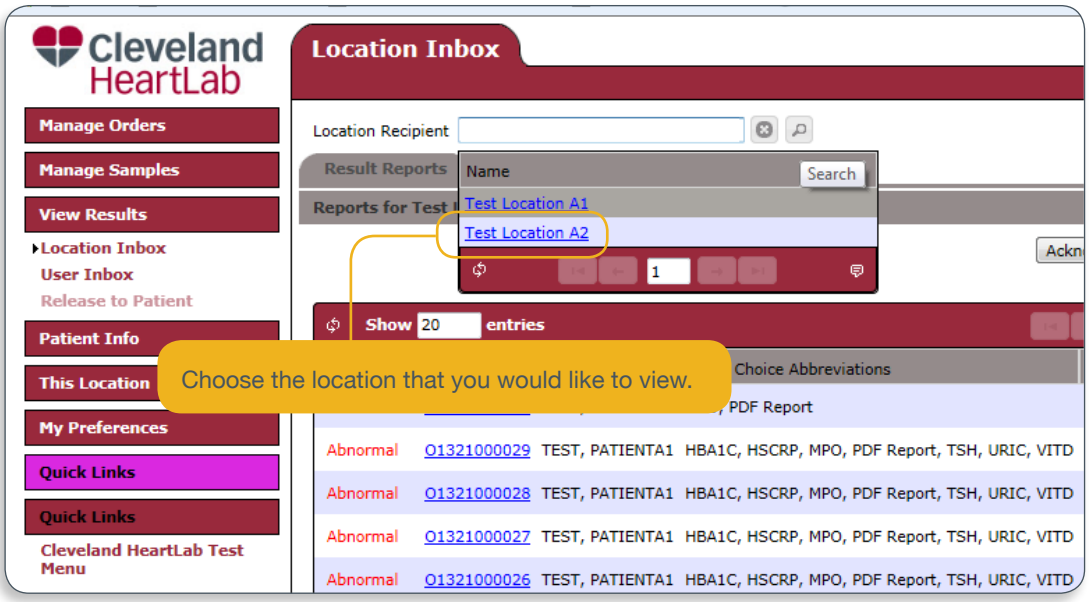


B. Search by Practice Location

If your office has more than one ordering location you can take advantage of this feature. Our system separates the patient results by ordering location for ease of viewing. If you are logged in at one location and need to switch to a different location click LOCATION INBOX on the menu on the left hand side under VIEW RESULTS. The screen now contains a Location Recipient search box at the top.

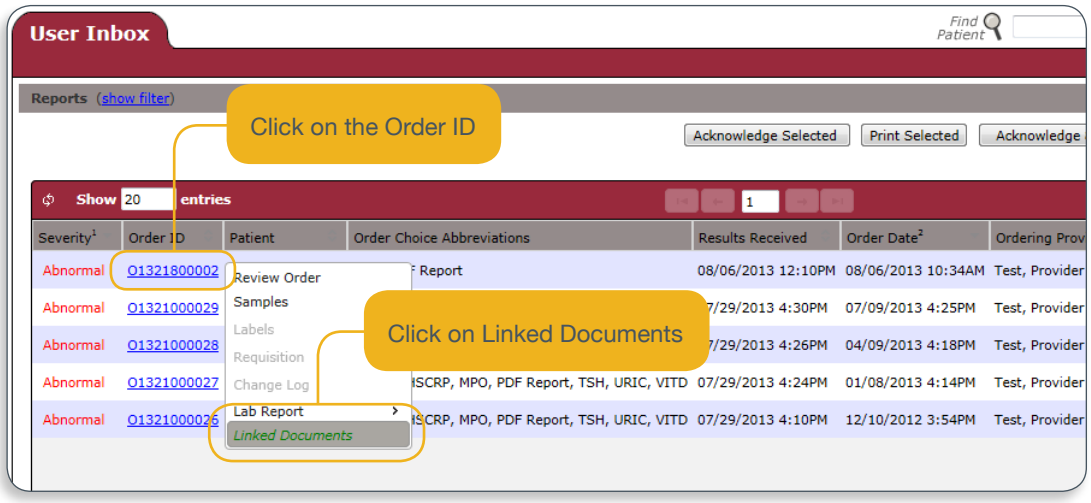


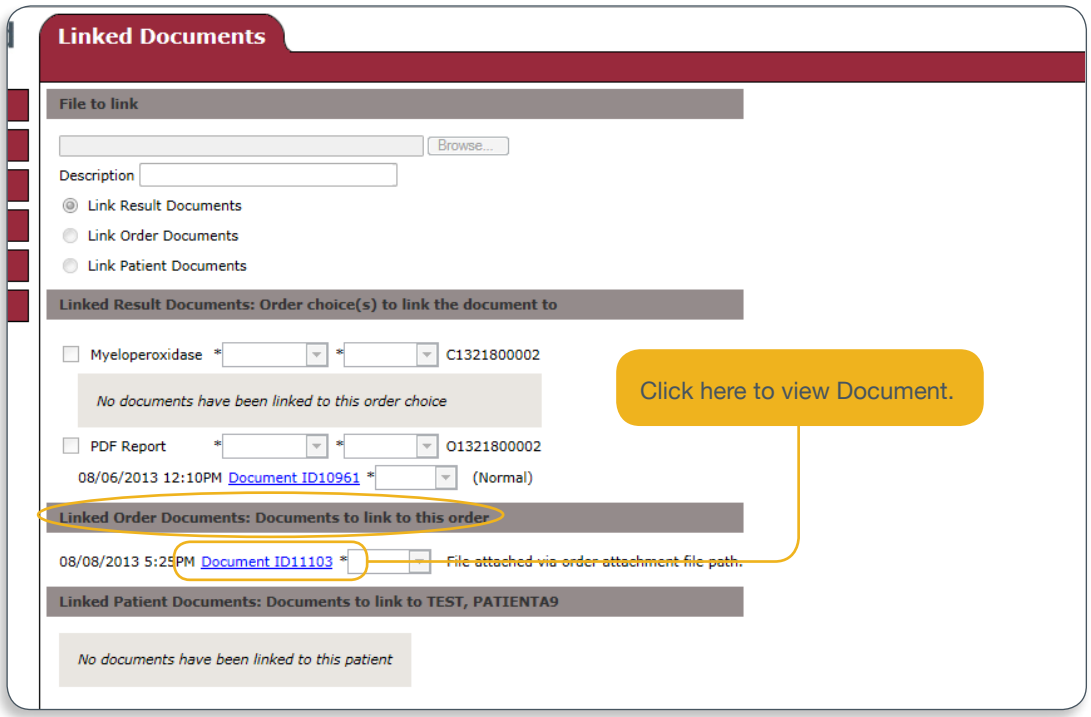



Cleveland HeartLab
Location Inbox
Manage Orders
Manage Samples
View Results
Location Inbox
User Inbox
Release to Patient
Patient Info
This Location
My Preferences
Quick Links
Quick Links
Cleveland HeartLab Test Menu
Location Recipient
Result Reports
Name
Search
Reports for Test
Test Location A1
Test Location A2
Show 20 entries
Choose the location that you would like to view.
Choice Abbreviations
PDF Report
Abnormal O1321000029 TEST, PATIENTA1 HBA1C, HSCRP, MPO, PDF Report, TSH, URIC, VITD
Abnormal O1321000028 TEST, PATIENTA1 HBA1C, HSCRP, MPO, PDF Report, TSH, URIC, VITD
Abnormal O1321000027 TEST, PATIENTA1 HBA1C, HSCRP, MPO, PDF Report, TSH, URIC, VITD
Abnormal O1321000026 TEST, PATIENTA1 HBA1C, HSCRP, MPO, PDF Report, TSH, URIC, VITD

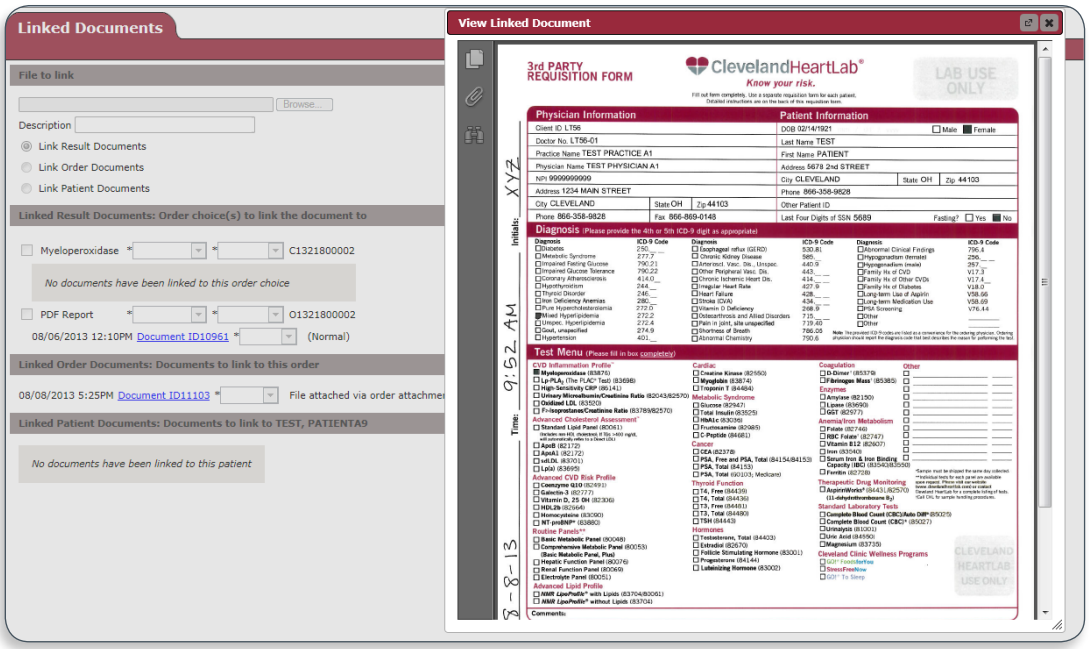
IV. Linked Documents

Documents can be attached to each patient order or your user account. Completed requisitions, and accompanying documents, such as insurance information will be linked to your patient's order. This will allow you to have access to view your requisition forms online once they are attached, should you need to refer back to them. From your User Inbox click on the patient that you wish to view and then select Linked Documents.





This will take you to any documents that were linked to this patient order.


Linked Documents
File to link
Browse...
Description
Link Result Documents
Link Order Documents
Link Patient Documents
Linked Result Documents: Order choice(s) to link the document to
Myeloperoxidase * * C1321800002
No documents have been linked to this order choice
PDF Report * * O1321800002
08/06/2013 12:10PM Document ID10961 * (Normal)
Linked Order Documents: Documents to link to this order
08/08/2013 5:25PM Document ID11103 * File attached via order attachme
Linked Patient Documents: Documents to link to TEST, PATIENTA9
No documents have been linked to this patient
View Linked Document
3rd PARTY REQUISITION FORM
ClevelandHeartLab®
Know your risk.
LAB USE ONLY
Physician Information
Patient Information
Diagnosis (Please provide the 4th or 5th ICD-9 digit as appropriate)
Test Menu (Please fill in box completely)
Initials: XYZ
Time: 9:52 AM
8-8-13

Understanding the Patient Test Report

Demographic/Specimen Information
- An extensive demographics section will be provided on the first page of each report.
- In order to ensure these sections are populated appropriately, please fill out the requisition form in its entirety.

Report Status
- The report status will appear at the top of all pages within the report
- There are 4 types of reports:
  1. **Complete**: Final results
  2. **Complete (Amended)**: Final results that have one or more amendments
  3. **Partial**: Incomplete results due to one or more test results pending
  4. **Partial (Amended)**: Same as "Partial", but one of more results have been amended

Test Headers
- All tests offered by CHL will be placed under unique headers associated with the type of test.
- For example:
  1. Inflammation
  2. Lipids
  3. Metabolic
  4. Genetics

In Range/Out of Range Reporting
- All test results will fall under an In Range or Out of Range category.
- Tests reported as Out of Range will either be colored yellow (for tests associated with a moderate relative risk) or red (for tests that are associated with a high relative risk or simply to denote that they are Out of Range).

Test Result Comments
- Some test results may have educational comments associated with the results.

Report Customization
- This is an added feature that adds more personalization to the test report and provides easy identification of the patient.

Relative Risk
- Tests associated with a relative risk will have the word "LOW", "MOD" or "HIGH".

(Note: "MOD" is short for moderate)

Flags
- Tests associated with a reference range will be flagged as "H" for Out of Range High, or "L" for Out of Range Low.

Critical Results
- Critical results will be identified with a CL (Critical Low) or CH (Critical High)
- A statement will appear below the test result that confirms that the result was verified by repeat testing, and a designee from the office was notified by CHL.

Flags Key
- A key is provided at the base of each report page to distinguish the different types of Flags you may see within the report.

Historical Results
- Historical results are reported as a convenience so long as the following are provided:
  1. The patient's **first and last name**
  2. The patient's **DOB**
  3. The last 4 digits of the patient's **SSN**
  4. The ordering **practitioner's name**
- All information must be matching. For example, the same patient entered into our system as Tom Smith and Tommy Smith will not match, and therefore historical results will not be provided.

ClevelandHeartLab®
Know your risk.

COMPLETE REPORT

DOCTOR TEST, M.D. has requested this report for
TEST, PATIENT
04/07/1967

PATIENT INFORMATION		SPECIMEN INFORMATION	PRACTITIONER INFORMATION
Name: TEST, PATIENT	Age: 47	Order ID: 1411100041	Name: DOCTOR TEST, M.D.
Patient ID	Gender: Male	Collection Date/Time: 04/21/2014, 1:40 PM	Client ID: 10001 CLEVELAND HEARTLAB
Fasting Status: Fasting	DOB: 04/07/1967	Received Date/Time: 04/21/2014, 1:39 PM	Address: 6701 CARNEGIE AVE, SUITE 500 CLEVELAND, OH , 44103
Ethnicity: Caucasian	BMI: 26	Report Date/Time: 04/21/2014, 1:48 PM	

INFLAMMATION

	In Range	Out of Range	Flag**	Relative Risk	Reference Range	Units	Previous Result	Date
Myeloperoxidase (2)		520		HIGH	<420	pmol/L	472	04/21/2013
Based on a recent study of a high risk population, defined as stable patients without acute coronary syndrome who underwent elective diagnostic coronary angiography1, Cleveland HeartLab has defined the following cut-offs for MPO: A cut-off of <420 pmol/L defines an "apparently healthy" population at low risk for a cardiovascular event. 420–479 pmol/L defines a population at intermediate risk for a cardiovascular event. and >=480 pmol/L defines a high risk population based on the 97.5%ile." (Reference: 1Tang et al. Am J Cardiol. 111:465-70, 2013).								
Lp-PLA$_2$ (The PLAC® Test)	185			LOW	≤ 200	ng/mL	180	04/21/2013
High-sensitivity CRP		1.5		MOD	<1.0	mg/L	1.2	04/21/2013
Microalbumin/Creatinine ratio	4.5			LOW	<30.0	mg/g	12.9	04/21/2013
Persistent Microalbumin/Creatinine ratios of 30-300 mg/g has been shown to be an early indicator of diabetic nephropathy (1). A 3-fold increase in CVD has been found in men with Microalbumin/Creatinine ratios >=3.9 mg/g and in women with values >=7.5 mg/g in the Framingham Heart Study (2). (References: 1. Diabetes Care 2011;34:S33A; 2. Arnlov et al. Circulation 2005;112:969).								
Microalbumin	4.2					mg/L	12.1	04/21/2013
Creatinine, Urine	94.1				20.0-300.0	mg/dL	94.1	04/21/2013
OxLDL (4)	34			LOW	<60	U/L	45	04/21/2013
Please note new Reference Range of <60 U/L, effective 1/7/2014. This Reference Range to replace <45 U/L. Based on a recent study of an 'apparently healthy' and non-metabolic syndrome population-1, the following cut-offs have been defined for OxLDL: A cut-off of <60 U/L defines a population with a low relative risk of developing metabolic syndrome, a range of 60 to 69 U/L defines a population with a moderate relative risk (2.8 fold) and >=70 U/L defines a population with a high relative risk (3.5-fold).# (Reference: 1-Holvoet et al. JAMA. 2008; 299: 2287-2293.)								
F_2-Isoprostane/Creatinine Ratio (1)	0.58			LOW	<0.86	ng/mg	0.62	04/21/2013
F_2-Isoprostane	0.55					ng/mL	0.58	04/21/2013
Creatinine, Urine	94.1				20.0-300.0	mg/dL	94.1	04/21/2013

LIPIDS

	In Range	Out of Range	Flag**	Relative Risk	Reference Range	Units	Previous Result	Date
Total Cholesterol	170			LOW	<200	mg/dL		
LDL-Calculated	82			LOW	<100	mg/dL		
Direct HDL Cholesterol	60			LOW	≥40	mg/dL		

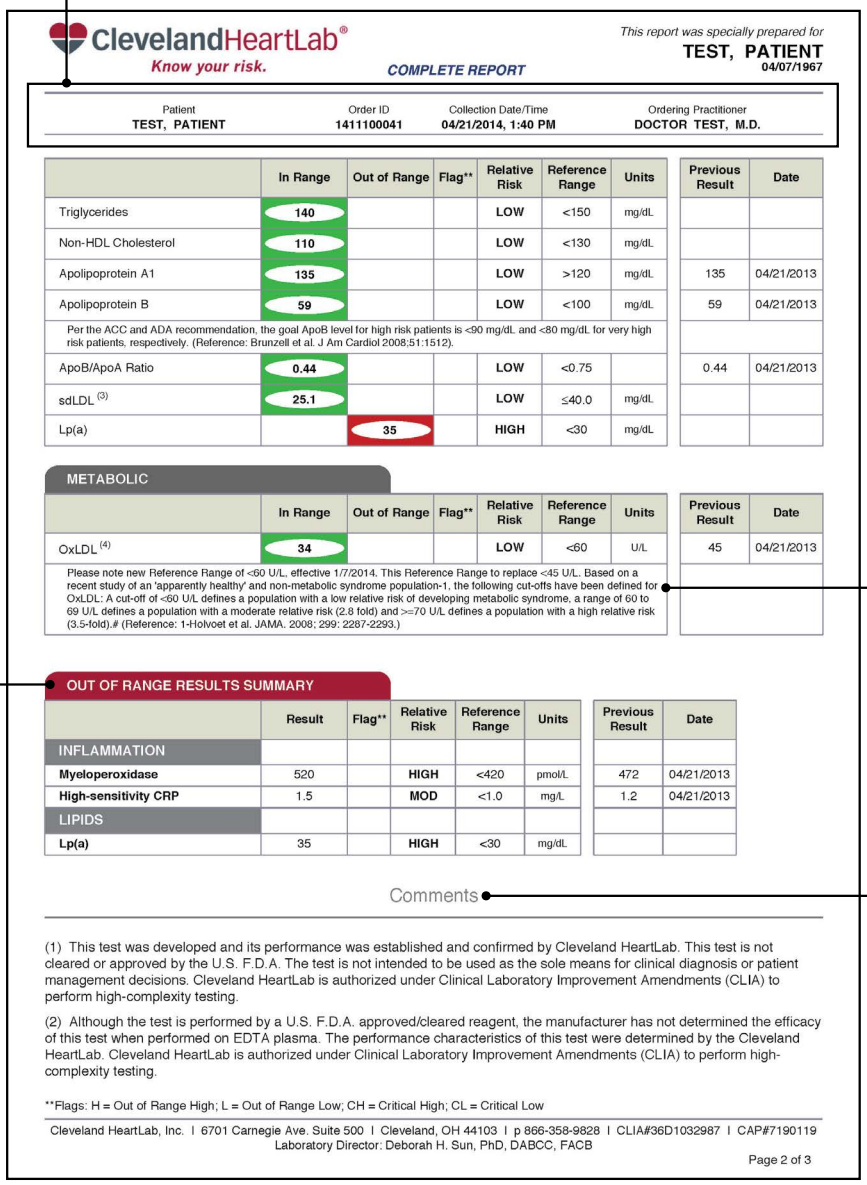
**Flags: H = Out of Range High; L = Out of Range Low; CH = Critical High; CL = Critical Low

Cleveland HeartLab, Inc. I 6701 Carnegie Ave. Suite 500 I Cleveland, OH 44103 I p 866-358-9828 I CLIA#36D1032987 I CAP#7190119
Laboratory Director: Deborah H. Sun, PhD, DABCC, FACB

Page 1 of 3

Understanding the Patient Test Report (continued)

Demographic/Specimen Information
- An abbreviated demographics section will be provided on all subsequent pages of a report.



ClevelandHeartLab®
Know your risk.

COMPLETE REPORT

This report was specially prepared for
TEST, PATIENT
04/07/1967

Patient	Order ID	Collection Date/Time	Ordering Practitioner
TEST, PATIENT	1411100041	04/21/2014, 1:40 PM	DOCTOR TEST, M.D.

	In Range	Out of Range	Flag**	Relative Risk	Reference Range	Units	Previous Result	Date
Triglycerides	140			LOW	<150	mg/dL		
Non-HDL Cholesterol	110			LOW	<130	mg/dL		
Apolipoprotein A1	135			LOW	>120	mg/dL	135	04/21/2013
Apolipoprotein B	59			LOW	<100	mg/dL	59	04/21/2013
Per the ACC and ADA recommendation, the goal ApoB level for high risk patients is <90 mg/dL and <80 mg/dL for very high risk patients, respectively. (Reference: Brunzell et al. J Am Cardiol 2008;51:1512).								
ApoB/ApoA Ratio	0.44			LOW	<0.75		0.44	04/21/2013
sdLDL (3)	25.1			LOW	≤40.0	mg/dL		
Lp(a)		35		HIGH	<30	mg/dL		

METABOLIC

	In Range	Out of Range	Flag**	Relative Risk	Reference Range	Units	Previous Result	Date
OxLDL (4)	34			LOW	<60	U/L	45	04/21/2013
Please note new Reference Range of <60 U/L, effective 1/7/2014. This Reference Range to replace <45 U/L. Based on a recent study of an 'apparently healthy' and non-metabolic syndrome population-1, the following cut-offs have been defined for OxLDL: A cut-off of <60 U/L defines a population with a low relative risk of developing metabolic syndrome, a range of 60 to 69 U/L defines a population with a moderate relative risk (2.8 fold) and >=70 U/L defines a population with a high relative risk (3.5-fold).# (Reference: 1-Holvoet et al. JAMA. 2008; 299: 2287-2293.)								

OUT OF RANGE RESULTS SUMMARY

	Result	Flag**	Relative Risk	Reference Range	Units	Previous Result	Date
INFLAMMATION							
Myeloperoxidase	520		HIGH	<420	pmol/L	472	04/21/2013
High-sensitivity CRP	1.5		MOD	<1.0	mg/L	1.2	04/21/2013
LIPIDS							
Lp(a)	35		HIGH	<30	mg/dL		

Comments

(1) This test was developed and its performance was established and confirmed by Cleveland HeartLab. This test is not cleared or approved by the U.S. F.D.A. The test is not intended to be used as the sole means for clinical diagnosis or patient management decisions. Cleveland HeartLab is authorized under Clinical Laboratory Improvement Amendments (CLIA) to perform high-complexity testing.

(2) Although the test is performed by a U.S. F.D.A. approved/cleared reagent, the manufacturer has not determined the efficacy of this test when performed on EDTA plasma. The performance characteristics of this test were determined by the Cleveland HeartLab. Cleveland HeartLab is authorized under Clinical Laboratory Improvement Amendments (CLIA) to perform high-complexity testing.

**Flags: H = Out of Range High; L = Out of Range Low; CH = Critical High; CL = Critical Low

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Page 2 of 3

Out of Range Results Summary
- This section is provided as a convenience and the header is colored red in order to stand out from the test result sections
- This section provides a comprehensive overview of all abnormal results outside of an In Range or Out of Range grouping.

Reference Range Changes
- Notifications of a reference range change will appear below the test result, and will remain there for approximately 3-6 months from date of the change.

Comments
- When necessary, comments will appear at the very end of the test report (the last page of the report).
- Comments include any educational statements or information about how a test is performed.

Patient Test Report (Example of a patient test report)

ClevelandHeartLab®
Know your risk.

Provider A1 Test, MD has requested this report for
TEST, PATIENTA1
05/01/1944

PATIENT INFORMATION		SPECIMEN INFORMATION	PRACTITIONER INFORMATION
Name **TEST, PATIENTA1**	Age **68**	Order ID **O1321000028**	Name **Provider A1 Test, MD**
Patient ID	Gender **Female**	Collection Date **04/09/2013**	Client ID
Fasting Status **No**	DOB **05/01/1944**	Received Date **07/29/2013**	Address
Ethnicity **Caucasian**	BMI **30**	Report Date **07/29/2013**	

INFLAMMATION

	In Range	Out of Range	Flag**	Relative Risk	Reference Range	Units	Previous Result	Date
Myeloperoxidase	465			LOW	<480	pmol/L	540	01/08/2013
Although the test is performed by a FDA approved/cleared reagent, the manufacturer has not determined the efficacy of this test when performed on certain specimen type/collection device/etc. The performance characteristics of this test were determined by the Cleveland HeartLab. The Cleveland HeartLab is authorized under Clinical Laboratory Improvement Amendments (CLIA) to perform high-complexity testing.								
High-sensitivity CRP		2.3	H	MOD	<1.0	mg/L	3.1	01/08/2013

METABOLIC

	In Range	Out of Range	Flag**	Relative Risk	Reference Range	Units	Previous Result	Date
HbA1c		5.7	H	MOD	<5.7	%	5.7	01/08/2013
American Diabetes Association (ADA) guidelines indicate that individuals with an A1c of 5.7%-6.4% are at the higher risk for developing diabetes and cardiovascular disease. The risk of diabetes rises disproportionately as A1c rises. Accordingly, interventions should be more intensive for those with A1c levels above 6.0%. HbA1c at or greater than 6.5% is considered diagnostic of diabetes. Diabetes Care 2011;34:e75-e80.								
Estimated Average Glucose	117			LOW	<118	mg/dL	117	01/08/2013
The estimated average glucose value is an adjunct to the treatment of both Type I and Type II diabetes. It is not intended for the diagnosis or risk assessment of patients without diabetes. Nathan DM et al. Diabetes Care 2008;31:1473								

VITAMINS/SUPPLEMENTS

	In Range	Out of Range	Flag**	Relative Risk	Reference Range	Units	Previous Result	Date
Vitamin D, 25 Hydroxy		22.8	L	MOD	>29.9	ng/mL	6.2	01/08/2013
Incidence of 25-OH Vitamin D toxicity increases above 100 ng/mL and the majority of individuals with toxicity have values >150 ng/mL. Increased total calcium may be present. Jones G Am J Clin Nutr 2008;88:582S								

GENERAL CHEMISTRY

	In Range	Out of Range	Flag**	Relative Risk	Reference Range	Units	Previous Result	Date
Uric Acid	4.8				2.4-5.7	mg/dL	5.4	01/08/2013

**Flags: H = Out of Range High; L = Out of Range Low; CH = Critical High; CL = Critical Low

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Laboratory Director: Deborah H. Sun, PhD, DABCC, FACB

Patient Test Report (continued)

ClevelandHeartLab®
Know your risk.

This report was specially prepared for
TEST, PATIENTA1
05/01/1944

Patient	Order ID	Collection Date	Ordering Practitioner
TEST, PATIENTA1	**O1321000028**	**04/09/2013**	**Provider A1 Test, MD**

ABNORMAL RESULTS SUMMARY

	Result	Flag**	Relative Risk	Reference Range	Units	Previous Result	Date
INFLAMMATION							
High-sensitivity CRP	2.3	**H**	**MOD**	<1.0	mg/L	3.1	01/08/2013
METABOLIC							
HbA1c	5.7	**H**	**MOD**	<5.7	%	5.7	01/08/2013
VITAMINS/SUPPLEMENTS							
Vitamin D, 25 Hydroxy	22.8	**L**	**MOD**	>29.9	ng/mL	6.2	01/08/2013
THYROID FUNCTION							
Thyroid Stimulating Hormone (TSH)	7.454	**H**		0.400-4.500	uU/mL	8.310	01/08/2013

Comments

**Flags: H = Out of Range High; L = Out of Range Low; CH = Critical High; CL = Critical Low

Critical Results

A critical result is defined as a test result that represents a patient status at such variance with normal (expected values) as to be life threatening unless something is done promptly and for which some corrective action could be taken.

Please contact customer support at **866.358.9828** or send an e-mail inquiry to **customersupport@clevelandheartlab.com** for information on our critical values.

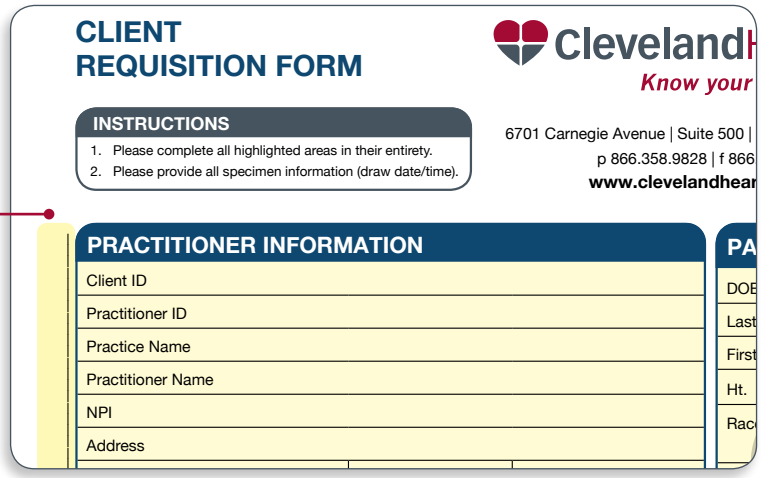
We understand that billing can be a complex and confusing process and may generate some questions. We are committed to helping you and your patients through the billing process and to assist with answering any questions. Patient Advocates, that are experts in our billing process as well as navigating the claims process, are available to assist you and your patients. Do not hesitate to contact us or have your patients contact our Patient Advocates at 866.358.9828, option 2.

The billing section of the Resource Book provides guidelines and information on our billing policies in the following areas:

- **Client Billing** – Client billing is implemented when a Client Requisiton form is used to order testing. The cost of testing is billed directly to the ordering practitioner.
- **Third Party Billing** – Third party billing is implemented when a 3rd party requistion form is used to order testing. Medicare and/or insurance information is required on the requistion form. We will use this information to file a claim on behalf of the patient to their respective coverage carrier. The patient will also receive an easy pay (co-payment) invoice from Cleveland HeartLab that is their financial responsiblity.
- **Patient Self-Pay Billing** – If the requisition form indicates the patient is responsible for the cost of testing, the patient will be billed directly.
- **Methods of Payment** – We outline the different payment options for both clients and patients.

Client Billing

This requisition form is for physician offices that would like to be billed directly (i.e. the physician is billed for services provided)


CLIENT
REQUISITION FORM

Cleveland

Know your

INSTRUCTIONS
1. Please complete all highlighted areas in their entirety.
2. Please provide all specimen information (draw date/time).

6701 Carnegie Avenue | Suite 500 |
p 866.358.9828 | f 866
www.clevelandhear

PRACTITIONER INFORMATION
Client ID
Practitioner ID
Practice Name
Practitioner Name
NPI
Address

PA
DOB
Last
First
Ht.
Rac

If you are ordering tests on the **client requisition form,** this is the process we will follow to invoice your office:

1. Cleveland HeartLab will invoice your office once a month for all the tests that were performed that month.
2. The invoice will contain tests ordered through the 24th of each month.
   (Example 1)
3. You will also receive a detailed list of the patients who were tested that supports the invoice.
   (Example 1a)
4. If there is an outstanding balance, we will send you a statement indicating what is past due.
   (Example 2)

Note: Please see **Examples 1, 1a and 2** for a sample of the client bill.

Client Billing (continued)

Example 1: Sample Client Billing

ClevelandHeartLab
Know your risk.

Cleveland Heartlab Inc.
6701 Carnegie Ave., Suite 500
Cleveland, OH 44103
866-358-9828
866-449-0960 Fax

INVOICE

BILL TO:

Invoice Date: 04/30/2013
Invoice No:
Customer #
Payment Terms Net 30

Item #	Description	QTY	Unit Price US DOLLARS	Extd Price US DOLLARS
C108	CREATININE	86	XX.XX	XXXX.XX
C121	HSCRP	86	XX.XX	XXXX.XX
C133	MYELOPEROXIDASE	86	XXX.XX	XXXXX.XX
C139	D-DIMER	86	XX.XX	XXXX.XX
C145	HEMOGLOBIN A1C	86	XX.XX	XXXX.XX
C146	INSULIN	86	XX.XX	XXXX.XX
C334	FIBRINOGEN MASS	86	XX.XX	XXXX.XX
C906	LIPID PANEL	86	XX.XX	XXXX.XX
C918	F2-ISOPROSTANE/CREATININE RATIO	85	XX.XX	XXXX.XX

Remit Payment To:	Credit Card Payments	
Cleveland Heartlab Inc. - CHL B2B Dept. CH19534 Palatine, IL 60055-9534	Visa / Mastercard / Discover / American Express Visit: www.clevelandheartlab.com/paymybill	Sales Total: XX,XXX.XX Sales Tax: 0.00 Freight: 0.00 Less: 0.00 Other Charges: 0.00 Invoice Total (USD): XX,XXX.XX

Client Billing (continued)

Example 1a: Detailed Patient Information to Support Invoice

ClevelandHeartLab
Know your risk

Client:

Ordered Test: C133 Myeloperoxidase

Patient	Collection Date	DOB	Accession
Test Patient 1	4/9/2013	2/5/1969	LB3100509
Test Patient 2	3/27/2013	5/31/1957	LB3100501
Test Patient 3	4/11/2013	9/28/1956	LB3100483
Test Patient 4	4/4/2013	11/18/1945	LB3100484
Test Patient 5	4/5/2013	6/7/1986	LB3100475
Test Patient 6	4/10/2013	3/11/1952	LB3100471
Test Patient 7	4/4/2013	4/6/1954	LB3100478
Test Patient 8	3/27/2013	12/30/1971	LB3100502
Test Patient 9	4/3/2013	5/16/1947	LB3100500
Test Patient 10	4/4/2013	3/27/1956	LB3100473
Test Patient 11	3/28/2013	3/29/1960	LB3100499
Test Patient 12	4/3/2013	11/26/1955	LB3100498
Test Patient 13	4/3/2013	7/20/1958	LB3100493
Test Patient 14	4/4/2013	2/7/1977	LB3100479
Test Patient 15	4/4/2013	1/17/1991	LB3100469
Test Patient 16	3/29/2013	1/3/1955	LB3100497
Test Patient 17	4/10/2013	6/28/1979	LB3100486
Test Patient 18	3/29/2013	9/8/1967	LB3100492
Test Patient 19	4/4/2013	12/4/1959	LB3100472
Test Patient 20	4/10/2013	2/25/1981	LB3100474
Test Patient 21	4/5/2013	12/30/1956	LB3100470
Test Patient 22	4/4/2013	7/8/1987	LB3100476
Test Patient 23	4/11/2013	6/19/1952	LB3100485
Test Patient 24	3/27/2013	5/12/1988	LB3100494
Test Patient 25	4/11/2013	4/10/1983	LB3100490
Test Patient 26	4/11/2013	9/3/1971	LB3100482
Test Patient 27	4/11/2013	1/31/1978	LB3100489
Test Patient 28	4/10/2013	9/7/1960	LB3100481
Test Patient 29	4/10/2013	4/10/2013	LB3100477
Test Patient 30	3/27/2013	12/21/1974	LB3100495
Test Patient 31	3/27/2013	6/5/1986	LB3100491
Test Patient 32	4/11/2013	1/31/1978	LB3100488
Test Patient 33	3/29/2013	9/11/1977	LB3100496
Test Patient 34	4/5/2013	3/3/1958	LB3100468
Test Patient 35	4/12/2013	12/19/1951	LB3100480
Test Patient 36	4/12/2013	6/13/1956	LB3100487
Test Patient 37	3/22/2013	7/26/1954	LB3100445
Test Patient 38	3/6/2013	5/27/1961	LB3100463
Test Patient 39	3/5/2013	8/17/1958	LB3100464
Test Patient 40	3/25/2013	4/12/1976	LB3100446
Test Patient 41	3/11/2013	4/3/1954	LB3100466
Test Patient 42	4/15/2013	7/11/1960	LB3100507
Test Patient 43	3/25/2013	8/31/1957	LB3100443

Thursday, April 25, 2013

Client Billing (continued)

Example 2: Statement Outlining any Past Due Amount

CLEVELAND HEARTLAB
6701 CARNEGIE AVENUE
SUITE 500
CLEVELAND OH
44103 USA

Page: 1
Statement Date: 05/02/2013

STATEMENT
US DOLLARS

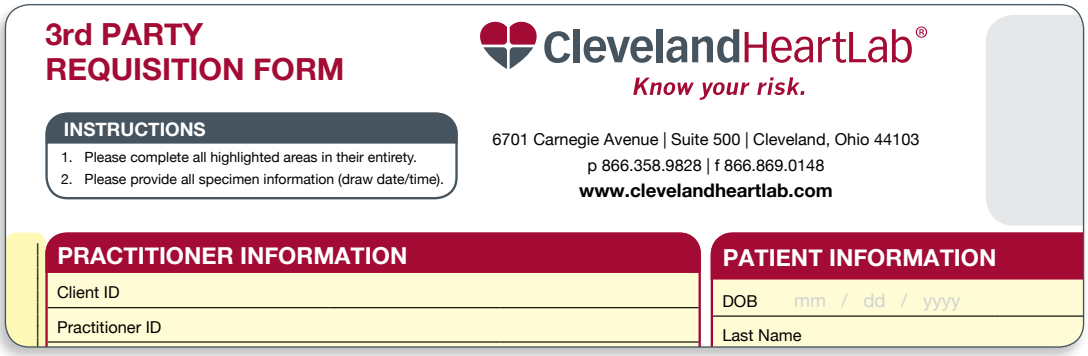
Bill To:

Customer ID:

Transaction Date	Due Date	Reference Number	Total Amount	Applied Amount	Remaining Balance
04/30/2013	05/30/2013	INV # 0000001161	XX,XXX.XX		XX,XXX.XX

Past Due -	1-30:	0.00	Current:	XX,XXX.XX
	31-60:	0.00	On Hold:	0.00
	OVER 60:	0.00	Unapplied Cash:	0.00
	Unapplied Cash/Credit:	0.00	Total Amount Past Due:	0.00
	YTD Service Charges:	0.00	Total Amount Due:	XX,XXX.XX

Third Party Billing



3rd PARTY
REQUISITION FORM

ClevelandHeartLab®
Know your risk.

INSTRUCTIONS
1. Please complete all highlighted areas in their entirety.
2. Please provide all specimen information (draw date/time).

6701 Carnegie Avenue | Suite 500 | Cleveland, Ohio 44103
p 866.358.9828 | f 866.869.0148
www.clevelandheartlab.com

PRACTITIONER INFORMATION
Client ID
Practitioner ID

PATIENT INFORMATION
DOB mm / dd / yyyy
Last Name

The **Third Party Requisition** form is used for ordering tests that will be reimbursed by Medicare, insurance or directly by the patient. Check the appropriate payer at the bottom of the requisition to indicate the responsible payer. Accurate and complete information are critical for a smooth and efficient process.

The following summary and examples are provided to insure that you and your patients understand Cleveland HeartLab's billing processes. Do not hesitate to contact our Patient Advocates with any questions, as they have ready access to both this requisition and the claim/invoice to the payer.

Medicare

Cleveland HeartLab is an approved provider to Medicare. Please qualify your patient's coverage. If the patient only has Part A coverage, then lab tests will not be reimbursed by Medicare and the patient will be responsible for payment. An ABN form may be requested for test that are not covered by Medicare and/or frequently denied for reimbursement. You will receive advance notification of any tests that require an ABN.

Insurance

The claim will be filed timely with the provided insurance company and Cleveland HeartLab will make every effort to ensure the payment process goes smoothly.

1. To address the patient's co-pay responsibility, Cleveland HeartLab designed the **EasyPay** to provide predictability and reflects our good faith estimate of the likely coinsurance after the insurance remittance. Your patient will receive an invoice for the EasyPay/co-pay amount ~30 days after testing date. Your sales representative or the Patient Advocate will provide you more information on EasyPay.

   Note: *Please see Example 3a for a sample EasyPay invoice.*

2. Process Exceptions:

   a. Payment to the Patient: Some insurance companies send payment to the patient vs. to Cleveland HeartLab. Given the high frequency of Blue Cross Blue Shield sending payment to the patients, Cleveland HeartLab proactively provides a letter to BCBS patients alerting them to the possibility that payment may be received by them and requesting their support to forward payment to Cleveland HeartLab.

Third Party Billing (continued)

Example 4 shows this letter.

b. Coverage Denied: When Cleveland HeartLab receives notification that the patient's coverage was denied, we first contact your office to obtain the missing and/or incorrect information. If unsuccessful, then we will send a letter to the patient. With new/additional information, Cleveland HeartLab will resubmit the insurance claim. See Example 5 – Missing Information Letter.

c. Final Step to Secure Payment: If after the above actions, there is no response and/or acceptance of the patient's coverage by the insurance company, then we consider the patient liable for payment. This step is taken after 30-45 days with no response. The patient will then receive a Patient Self-Pay Invoice, as noted in the Self-Pay Billing section, and shown in Example 6 on page 41.

Third Party Billing (continued)

Example 3a: Easy Pay Invoice

ClevelandHeartLab®
Know your risk.

Patient Statement

Account Number: LH16541

STATEMENT INFORMATION

Patient Name:	John Doe
Statement Date:	02/09/15
Amount Due:	$9.14

INSURANCE INFORMATION

Primary:	Easy Pay
Subscriber Name:	John Doe
CERT#-	0000
GRP#-	None On File
Secondary:	None On File

Cleveland HeartLab has filed a claim with the insurance provider which was included in your physician's order for lab testing. The statement represents our EasyPay Program which reflects an estimate of a patient's co-insurance or co-payment for the test. Cleveland HeartLab accepts the payment by your insurance company and your payment of this EasyPay statement amount as full settlement for the testing services that you received. Please contact our Patient Advocates at 866-358-9828, option 2 with any questions or concerns.

Date	Procedure	Description Of Service	Charges	Payments & Adjustments	Billed To Insurance	Patient Amount Due
16541		**Ordering Physician: James Smith**				
02/03/15	80053	Comprehensive Metabolic Panel	$4.49			
02/03/15	81001	Urinalysis	$1.34			
02/03/15	85025	Complete Blood Count W/ Diff	$3.31			
						$9.14
				PAY THIS AMOUNT		**$9.14**

PAYMENT OPTIONS

To pay by credit card, visit
www.knowyourrisk.com/patient-services
and use access code **LH16541**

To pay by check, return the lower portion with your payment.

QUESTIONS

For billing inquiries, call 866-358-9828 Option 2
8:30-5:30 PM EST.

For questions about tests and results, contact the **Ordering Physician** listed under Description of Service

PLEASE DETACH AND RETURN LOWER PORTION WITH YOUR PAYMENT TO ENSURE PROPER CREDIT

ClevelandHeartLab®
Know your risk.
6701 Carnegie Ave. Suite 500
Cleveland, OH 44103

ADDRESS SERVICE REQUESTED

☐ ***Check here if your address or insurance has changed, completing form on reverse side.***

Account Number:	**LH16541**
Due Date:	**03/02/15**
Amount Due:	**$9.14**
Amount Enclosed:	

Make Checks Payable To: Cleveland HeartLab, Inc,
Please include your account number on check.

To pay by credit card, visit
www.knowyourrisk.com/patient-services
and use access code **LH16541**

Do not send credit card information by mail.

To remit payment:
LH
CLEVELAND HEARTLAB INC.
PO BOX 8587
CAROL STREAM, IL 60197-8587

LH/E1503600865/00003354

Third Party Billing (continued)

Example 4: Payment to Patient Letter

ClevelandHeartLab®
Know your risk.

February 23, 2015

Patient Name: John Doe
Account Number/Access Code: LH-999999
Account Balance: $9.14

Place Of Service: Cleveland HeartLab Inc.
Referring Doctor: Dr. John Smith
Date of Service: 02/23/2015

Dear John Doe

Subject: Insurance Claim Process

Cleveland HeartLab (CHL) is a premier clinical reference laboratory committed to advancing cardiovasular risk assessment through novel diagnostic tests. We recently performed laboratory tests which were ordered by your physician. In addition to providing the lab results to your physician, we filed a claim on your behalf with the insurance information which was included in the order for lab testing. We have not received payment or a response from your insurance company. Frequently, your insurance company forwards payments directly to you, the patient, instead of Cleveland HeartLab.

PLEASE COMPLETE ONE OF THE FOLLOWING:

1. **You HAVE RECEIVED payment from your Insurance Company**
   a. Endorse the check from the insurance company to Cleveland HeartLab Inc. and mail to the address provided below along with the Explanation of Benefits.
   b. Mail us a check along with a copy of the Explanation of Benefits showing the amount paid to you.
   c. Contact us to arrange payment by credit card with your Explanation of Benefits available for review at phone number 866-358-9828, (option 2).
2. **You HAVE NOT RECEIVED payment from your Insurance Company**
   Contact us to review the Explanation of Benefits you received from your insurance company so we can determine next steps. IF we do not hear from you or your insurance company, the services provided will be re-classified as "patient responsibility" and you will be invoiced the full amount of the Account Balance noted above.

If you have questions or need to review your Explanation of Benefits, please contact one of our Patient Advocates at 866-358-9828 (option 2) or by email at **patientadvocate@clevelandheartlab.com**

Thank you in advance for your timely response.

Cleveland HeartLab, Inc.
Billing Department

6701 Carnegie Ave. | Suite 500 | Cleveland, OH 44103 | p 866.358.9828 | f 866.869.0148 | **www.knowyourrisk.com** | **www.clevelandheartlab.com**

Third Party Billing (continued)

Example 5: Coverage Denied: Missing Information Letter

ClevelandHeartLab®
Know your risk.

February 23, 2015

Patient Name: John Doe
Account Number/Access Code: LH-999999
Account Balance: $9.14

Place Of Service: Cleveland HeartLab Inc.
Referring Doctor: Dr. John Smith
Date of Service: 02/23/2015

Dear John Doe

Cleveland HeartLab (CHL) is a premier clinical reference laboratory committed to advancing cardiovascular risk assessment through novel diagnostic tests. We recently performed laboratory tests which were ordered by your physician. We have filed a claim on your behalf with the insurance information included in your physician's order for lab testing. The claim was rejected due to missing or incorrect information.

IMPORTANT: You must provide your updated insurance information within 30 days so we are able to re-submit a claim on your behalf.

You have three convenient options to update your information:

1. Submit the corrected insurance information on line by going to **www.knowyourrisk.com/patient-services/pay-your-bill/.** You will need the access code noted above to access your account.
2. Contact a CHL patient advocate at 866-358-9828 (Option 2) or by email at **patientadvocate@clevelandheartlab.com**
3. Fill out the below section and mail back to us at the following address:

Cleveland HeartLab, Inc.
PO Box 8587
Carol Stream, IL 60197-8587

Please call our patient advocates with any questions. It is important that we receive the updated insurance information within 30 days. If you do not respond, we will be unable to re-file a claim which will result in your account being re-classified as "patient responsibility" and you will be invoiced the full amount of the Account Balance noted above.

Updated Insurance Information

Insurance Company Name: _____ Phone (_____)_____

Is your insurance part of the Multi-Plan Network? _____ (Y) Yes or (N) No

Address: _____ City: _____ State: _____ Zip: _____

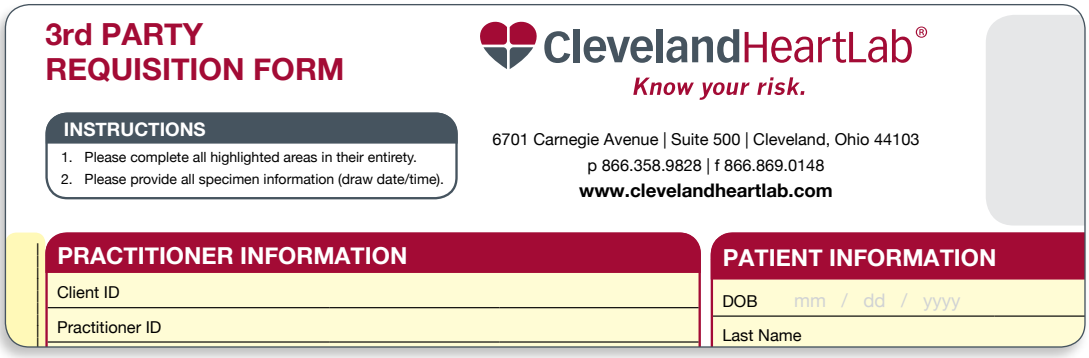
Insured's Name (as it appears on insurance card): _____

Relationship to Patient: _____ Policy/ID Number: _____

Group Number: _____ Other: _____

6701 Carnegie Ave. | Suite 500 | Cleveland, OH 44103 | p 866.358.9828 | f 866.869.0148 | **www.knowyourrisk.com** | **www.clevelandheartlab.com**

Self-Pay Billing



3rd PARTY
REQUISITION FORM

ClevelandHeartLab®
Know your risk.

INSTRUCTIONS
1. Please complete all highlighted areas in their entirety.
2. Please provide all specimen information (draw date/time).

6701 Carnegie Avenue | Suite 500 | Cleveland, Ohio 44103
p 866.358.9828 | f 866.869.0148
www.clevelandheartlab.com

PRACTITIONER INFORMATION
Client ID
Practitioner ID

PATIENT INFORMATION
DOB mm / dd / yyyy
Last Name

Patient Self-Pay

If the requisition indicates that the patient is responsible, then the patient will receive an invoice that reflects Cleveland HeartLab's standard test prices. Discounts are offered to reflect likely market pricing. We recognize the invoice prices may cause concerns so encourage your patients to contact Cleveland HeartLab's Patient Advocate with any questions and/or to discuss a discount. See Example 6 for Patient Self-Pay Invoice.

If you are ordering tests on the **third party requisition form and the patient is a self-pay patient**. Cleveland HeartLab will send an invoice to the patient for the testing performed. Discounts are offered for prompt payment.

Note: Please see **Example 6** for a sample invoice.

Important: *Make sure to include patient's address when submitting requisition form.*

Patient Assistance Program

For those patients with financial hardships, we provide a program to assist with medical expenses. Please call 1.866.358.9828, option 2 to speak with one of our Patient Advocates who can give you more information about this program or any other questions you may have about billing and payment options.

Self-Pay Billing (continued)

Example 6: Self-Pay Invoice

ACCOUNT NUMBER | DATE OF STATEMENT | PAYMENTS AFTER THIS DATE WILL APPEAR ON YOUR NEXT STATEMENT | 000001 | BALANCE | AMOUNT DUE

04/01/2013 $XXX.XX

PATIENT NAME

YOUR DOCTOR'S INSTRUCTIONS SHOW NO INSURANCE COVERAGE AND YOU ARE RESPONSIBLE FOR PAYMENT. THE AMOUNT DUE CAN BE REDUCED 50% FOR PROMPT PAYMENT.

Invoice for Laboratory Services: As ordered by your healthcare provider, Cleveland HeartLab performed the lab test(s) as detailed below and results were returned to your doctor. Timely resolution of payment is appreciated.

Place of Service: CLEVELAND HEARTLAB INC
Referring Doctor:

MAKE CHECKS PAYABLE TO:
CLEVELAND HEARTLAB,INC.
Dept. CH19545
Palatine, IL 60055 - 9545
866/358-9828

SEE REVERSE SIDE FOR IMPORTANT BILLING INFORMATION

Page 1 of 1

Date	Doctor	Qty	Code	Description	Amount
09/18/2012		1	83520	Galectin-3	XX.XX
09/18/2012		1	82491	Coenzyme Q10	XXX.XX
09/18/2012		1	83789	MASS/TANDEM SPECTROMETRY	XXX.XX
09/18/2012		1	82570	CREATININE; OTHER SOURCE	XX.XX
09/18/2012		1	82043	ALBUMIN; URINE, MICROALBUMIN,	XX.XX
09/18/2012		1	83698	LIPOPROTEIN-ASSOCIATED PHOSPHO	XXX.XX
09/18/2012		1	83876	MYELOPEROXIDASE MPO	XXX.XX

Pay or Access account at http://www.PerYourHealth.com ID:5065-00101675 Access Key:VYEEGJ

For questions call, 866/358-9828 and when prompted enter your identification number as follows
OPERATOR AVAILABLE 8:30AM - 7:00 PM EST

PLEASE DETACH AND RETURN THE BOTTOM PORTION WITH PAYMENT

ClevelandHeartLab®
Know your risk.

6701 CARNEGIE AVENUE, SUITE 500
CLEVELAND, OH 44103
Temp-Return Service Requested

ACCOUNT NUMBER | PATIENT NAME

STATEMENT DATE | AMOUNT DUE | AMOUNT ENCLOSED

04/01/2013 $XXX.XX

To make credit card payments:
www.peryourhealth.com (see statement detail for account number and password) or call 866/358-9828

MAKE CHECKS PAYABLE AND REMIT TO:

CLEVELAND HEARTLAB.INC.
Dept. CH19545
Palatine, IL 60055 - 9545

DS_MDIV

Methods of Payment

We always encourage you or your patient to contact Cleveland HeartLab's Patient Advocates with questions or concerns regarding payment; these specialists have ready access to the complete details of the Client and Third Party Requisition Forms, our lab's records and the Medicare/insurance claim history to review. You can reach our Patient Advocates by phone 1-866-358-9828, option 2 or e-mail chlpatient@clevelandheartlab.com.

Patients

1. **Online Credit Card Payment:** Your patients can make a secure online payment to Cleveland HeartLab by going to **www.knowyourrisk.com/pay-your-bill**.

   a. The patient name, account number, invoice number and payment amount will need to be entered to make on online payment.

   b. We accept VISA, MasterCard, Discover and American Express at no additional cost to the patient.

2. **By Phone Credit Card Payment:** Your patients can make a credit card payment by phone by speaking with one of our billing specialists at 1-866-358-9828, option 2. We accept VISA, MasterCard, Discover and American Express at no additional cost to the patient.

3. **Payment by Mail:** Your patients can make a payment by mail by sending a remittance advice with a check to the following address:

   Cleveland HeartLab Inc.
   Dept. CH19545
   Palatine, Il 60055-9545

Clients

1. **Online Credit Card Payment:** You can make a secure online payment to Cleveland HeartLab by going to **www.clevelandheartlab.com/paymybill**.
   a. The client name, account number, invoice number and payment amount will need to be entered to make on online payment.

   b. We accept VISA, MasterCard, Discover and American Express at no additional cost to you.

2. **By Phone Credit Card Payment:** You can make a credit card payment by phone by speaking with one of our billing specialists at 1-866-358-9828, option 2. We accept VISA, MasterCard, Discover and American Express at no additional cost to you.

3. **Payment by Mail:** You can make a payment by mail by sending a remittance advice with a check to the following address:

   Cleveland HeartLab Inc.
   Dept. CH19534
   Palatine, Il 60055-9534

Available Physician Education Materials

To support our committment to education we offer education materials on our key biomarkers. We also have a comprehensive practitioners guide and key resources to help you "get started" with Cleveland HeartLab. Reference materials are available to download on our website at www.clevelandheartlab.com/our-science/educational-materials

Physician Education Materials


F_2-Isoprostanes


Oxidized LDL


hsCRP


Urinary Microalbumin


MPO


The PLAC® Test


Adiponectin


Apolipoprotein E


CYP2C19


MTHFR


AspirinWorks®


Coenzyme Q10


GlycoMark®


Thyroid Stimulating Hormone


Vitamin D, 25 OH

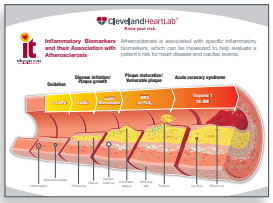

Galectin-3


HDL2b


OmegaCheck™

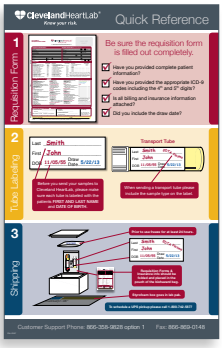
Practitioners Guide

Artery Wall

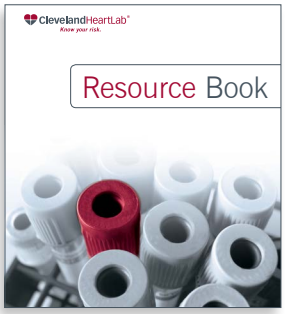


Wellness Program

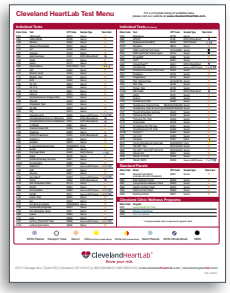
Customer Service Poster



Resource Book



Sample Quick Reference



Clinical References

The following is a summary of clinical references that support our key biomarkers. It should be noted that there are over 100+ published studies in support of the clinical utility of MPO testing.

Inflammation Testing ("it")

Myeloperoxidase

Karakas M et al. Myeloperoxidase is associated with incident coronary heart disease independently of traditional risk factors: Results from the MONICA/KORA Augsburg study. *J Intern Med*. 2012; 271:43-50.

- Population-Patients with CAD
- MPO levels in apparently healthy, middle-aged subjects predicted future coronary events independently of the lipid profile, traditional cardiovascular risk factors, markers of endothelial dysfunction, and other inflammatory markers.

Ndrepepa G et al. Impact of therapy with statins, beta-blockers and angiotensin-converting enzyme inhibitors on plasma myeloperoxidase in patients with coronary artery disease. *Clin Res Cardiol*. 2011; 100: 327-333.

- Population-Patients with CAD
- In subjects with angiographically confirmed CAD, lower plasma levels of MPO occurred at the time of hospital admission in subjects on either statin, BBs, or ACE inhibition therapies.
- The beneficial effect of these three classes of drugs on MPO levels occurred almost exclusively in subjects diagnosed with ACS.

Heslop et al. Myeloperoxidase and C-reactive protein have combined utility for long-term prediction of cardiovascular mortality after coronary angiography. *J Am Coll Cardiol*. 2010; 55: 1102-1109.

- Population-Patients with CAD
- This study was the first to demonstrate the benefit and value of MPO, compared to both traditional risk factors and CRP, for long-term prediction of cardiovascular mortality in subjects with stable CAD.
- Also for the first time, the complementary value of the addition of MPO to CRP for identifying patients at risk for future cardiovascular mortality was revealed. These subjects may well benefit from more aggressive cardiovascular risk reducing therapies in order to improve CAD outcomes.

Wong et al. Myeloperoxidase, subclinical atherosclerosis, and cardiovascular disease events. *J Am Coll Cardiol Img*. 2009; 2: 1093-1099.

- Population-Healthy individuals
- Using MPO and CAC measurements together may identify persons with vulnerable plaque who are at increased risk for CV events.
- In those with elevated CAC scores which imply a greater amount of plaque, adding MPO as a marker to help identify those with active vs. stable plaque may improve risk stratification and allow for earlier implementation of treatment to reduce the likelihood of CV events.

Tang et al. Usefulness of myeloperoxidase levels in healthy elderly subjects to predict risk of developing heart failure. *Am J Cardiol*. 2009; 103: 1269-1274.

- Population-Healthy individuals
- In apparently healthy elderly subjects, increased MPO levels were independently associated with the development of heart failure, beyond traditional risk factors and myocardial infarction.

Ndrepepa et al. Myeloperoxidase level in patients with stable coronary artery disease and acute coronary syndromes. *Eur J Clin Invest*. 2008; 38: 90-96.

- Population-Patients with CAD and/or ACS
- Subjects with CAD have higher levels of MPO than subjects without CAD.
- MPO levels increase with the progressive severity of CAD.
- Subjects with stable CAD have lower MPO levels compared to those with non-ST-segment acute coronary syndrome, while subjects with ST-segment myocardial infarction have the highest MPO levels.

Brevetti et al. Myeloperoxidase, but not C-reactive protein, predicts cardiovascular risk in peripheral arterial disease. *Eur Hear J*. 2008; 29: 224-230.

- Population-Patients with PAD
- MPO levels strongly predicted MI and stroke in subjects with PAD whereas CRP did not.
- MPO measures predicted MI and stroke independently from ABI, the most powerful marker currently used to predict risk in PAD.
- ABI and MPO together are better at predicting cardiovascular risk than ABI alone and may help to identify subjects who would benefit from more aggressive therapeutic interventions.

Clinical References (continued)

Mocatta et al. Plasma concentrations of myeloperoxidase predict mortality after myocardial infarction. *J Am Coll Cardiol*. 2007; 49: 1993-2000.

- Population-Patients post-MI
- Elevated MPO levels independently predict mortality in subjects post MI over a 5 year follow-up period.
- Measuring MPO levels post MI could assist in determining the prognosis and improve risk stratification of patients, especially if used in conjunction with LVEF and NT-proBNP.

Tang WHW et al. Prognostic value and echocardiographic determinants of plasma myeloperoxidase levels in chronic heart failure. *J Am Coll Cardiol*. 2007; 49: 2364-2370.

- Population-Patients with heart failure.
- Elevated MPO levels are associated with progression of heart failure in subjects with chronic systolic heart failure at baseline.
- MPO levels in subjects with chronic systolic heart failure can be used to predict future adverse clinical events after adjusting for traditional cardiovascular risks, BNP levels, and left ventricular ejection fraction.

Cavusoglu E et al. Usefulness of baseline plasma myeloperoxidase levels as an independent predictor of myocardial infarction at two years in patients presenting with acute coronary syndrome. *Am J Cardiol*. 2007; 99: 1364-1368.

- Population-Patients with ACS
- There is a strong, independent association between increased baseline levels of MPO and development of MI in the following 24 months in patients with ACS.
- The ability of MPO levels to predict future MI was independent of the extent of CAD.
- MPO was predictive for total MI, as well as nonfatal MI.
- MPO was a significant predictor of MI in patients with troponin-negative ACS.

Meuwese et al. Serum myeloperoxidase levels are associated with the future risk of coronary artery disease in apparently healthy individuals: the EPIC-Norfolk Prospective Population Study. *J Am Coll Cardiol*. 2007; 50: 159-165.

- Population-Healthy individuals
- MPO levels, in a primary prevention setting, were associated with future risk for CAD in an apparently healthy population.
- This study showed that elevations in both CRP and MPO precede the onset of CAD by years.

Exner M et al. Myeloperoxidase predicts progression of carotid stenosis in states of low high-density lipoprotein cholesterol. *J Am Coll Cardiol*. 2006; 47: 2212-2218.

- Population-Patients with CAD
- Elevated levels of MPO (i.e. above the median) were associated with increasing amounts of carotid atherosclerotic disease in subjects with HDL-C levels <49 mg/dL.

Vita et al. Serum myeloperoxidase levels independently predict endothelial dysfunction in humans. *Circulation*. 2004; 110: 1134-1139.

- Population-Patients with CAD
- This study in humans is consistent with previous animal model studies demonstrating that MPO consumes nitric oxide thereby inducing endothelial dysfunction.
- MPO levels strongly and independently predict endothelial dysfunction in humans.
- The impairment of endothelial function observed with increasing MPO levels is consistent with other studies that suggest a direct role of MPO in the pathogenesis of cardiovascular disease.
- These findings suggest that MPO induces endothelial dysfunction and may be a link between oxidation, inflammation, and cardiovascular disease.

Baldus S. et al. Myeloperoxidase serum levels predict risk in patients with acute coronary syndromes. *Circulation*. 2003; 108: 1440-1445.

- Population-Patients with ACS
- MPO is a powerful predictor of the risk of future cardiac events in subjects with ACS.
- In subjects with low CRP levels, elevated MPO levels can be used to identify those with unstable plaque prior to evidence of atherosclerotic occlusion.
- Results suggest that myocardial injury occurs after the release of MPO.

Brennan M-L et al. Prognostic value of myeloperoxidase in patients with chest pain. *N Engl J Med*. 2003; 349:1595-1604.

- Population-Patients with chest pain

Clinical References (continued)

- A single measurement of MPO can independently predict early risk of MI as well as the risk for MACE (e.g., MI, the need for revascularization, reinfarction, and death) in the 30 day and 6 month timeframes following admission for chest chain suspected from coronary etiology.
- In subjects admitted with chest pain who had no evidence of myocardial necrosis, CRP, CK-MB isoform, and troponin T levels did not identify future risk for MACE whereas elevated MPO levels suggested the presence of vulnerable plaque and imminent risk for MACE in these subjects.

Zhang R et al. Association between myeloperoxidase levels and risk of coronary artery disease. *JAMA*. 2001;286:2136-2142.

- Population-Patients with CAD
- Elevated levels of MPO, whether measured by leukocyte- or blood-MPO, are associated with the presence of CAD as determined by angiography.
- The authors suggest that this study supports a potential role for utilizing MPO as an inflammatory marker to help identify patients with CAD who may be missed by traditional risk assessment methodologies.

Lp-PLA$_2$

Ballantyne CM et al. Lipoprotein-associated phospholipase A$_2$, high sensitivity C-reactive protein, and risk for incident ischemic stroke in middle-aged men and women in the Atherosclerosis Risk in Communities (ARIC) study. *Arch Intern Med*. 2005; 165: 2479-2484.

- Population-Patients with ischemic stroke
- Increased Lp-PLA$_2$ and hsCRP levels are associated with an increased risk of ischemic stroke.
- The addition of Lp-PLA$_2$ and hsCRP levels to traditional risk factors may identify more middle-aged individuals at risk of ischemic stroke.

Ballantyne CM et al. Lipoprotein-associated phospholipase A$_2$, high-sensitivity C-reactive protein, and risk for incident coronary heart disease in middle-aged men and women in the Atherosclerosis Risk in Communities (ARIC) study. *Circulation*. 2004; 109: 837-842.

- Population-Healthy individuals
- The current study demonstrates that Lp-PLA$_2$ and hsCRP may be useful to identify individuals at increased CHD risk who have low LDL-C (<130 mg/dL) and who are not targeted for drug therapy by current guidelines.

Urinary Microalbumin

Arnlöv J et al. Low-grade albuminuria and incidence of cardiovascular disease events in nonhypertensive and nondiabetic individuals: The Framingham Heart Study. *Circulation*. 2005; 112: 969-975.

- Population-Non-diabetic, non-hypertensive individuals
- Low-grade urinary albumin excretion below the current diagnostic threshold is associated with increased risk of CVD and mortality in apparently healthy individuals, and may be a marker for subclinical vascular damage that predisposes to future CVD events

Gerstein HC et al. Albuminuria and risk of cardiovascular events, death, and heart failure in diabetic and nondiabetic individuals. *JAMA*. 2001; 286: 421-426.

- Population-Diabetic and non-diabetic individuals
- Microalbuminuria is a strong independent risk factor for cardiovascular events due to its ability to identify underlying vascular disease.
- The ACR may help estimate cardiovascular risk in individuals with or without DM, and the relationship between the ACR and cardiovascular disease extends to values well below the currently accepted screening threshold.

High-sensitivity C-reactive Protein

Ridker PM et al. Rosuvastatin to prevent vascular events in men and women with elevated C-reactive protein. *N Engl J Med*. 2008; 359: 2195-2207.

- Population-Healthy individuals
- Rosuvastatin reduced the rates of a first major cardiovascular event and death from any cause in apparently healthy men and women without hyperlipidemia but with elevated hsCRP levels.
- The study underscores the inflammatory hypothesis of atherothrombosis and warrants the development of targeted anti-inflammatory drugs for the reduction of vascular events.

Clinical References (continued)

Ridker PM. et al. Comparison of C-reactive protein and low-density lipoprotein cholesterol levels in the prediction of first cardiovascular events. *N Engl J Med*. 2002; 347: 1557-1565.

- Population-Healthy individuals
- C-reactive protein is a stronger biomarker of cardiovascular risk than LDL cholesterol levels, even after adjustment for other risk factors.

Ridker PM et al. Inflammation, aspirin, and the risk of cardiovascular disease in apparently healthy men. *N Engl J Med*. 1997; 336: 973-979.

- Population-Healthy individuals
- Baseline levels of CRP can predict risk of first MI and stroke in apparently healthy men.
- The efficacy of aspirin treatment in reducing the risk of MI declines with decreasing concentrations of CRP.

Oxidized LDL

Bays HE et al. Chitin-glucan fiber effects on oxidized low-density lipoprotein: A randomized controlled trial. *Eur J Clin Nutr*. epub ahead of print 5 September 2012.

- Population-Hypercholesterolemic individuals
- OxLDL levels can be significantly reduced by supplementation with CG. This reduction occurred without a concomitant reduction in F2-isoprostanes levels, suggesting that these markers can be modulated independently.

Rao VS et al. Association of inflammatory and oxidative stress markers with metabolic syndrome in Asian Indians in India. *Cardiol Res Pract*. 2010 Dec 28;2011:295976.

- Population-Individuals with metabolic syndrome
- The presence of metabolic syndrome is associated with an increase in inflammatory and oxidative stress biomarkers, indicating the presence of an atherogenic environment.
- OxLDL levels can predict the presence of metabolic syndrome independent of other inflammatory and oxidative stress biomarkers in Asian Indians.

Holvoet P et al. Association between circulating oxidized low-density lipoprotein and incidence of the metabolic syndrome. *JAMA*. 2008; 299: 2287-2293.

- Population-Individuals with metabolic syndrome
- Increased levels of OxLDL are associated with an increased risk of developing metabolic syndrome and also with various individual components of metabolic syndrome including high fasting glucose levels, high triglycerides and abdominal obesity.

F_2-Isoprostanes

Shishehbor MH et al. Systemic elevations of free radical oxidation products of arachidonic acid are associated with angiographic evidence of coronary artery disease. *Free Radic Biol Med*. 2006; 41: 1678-1683.

- Population-Patients with CAD
- Levels of F_2-Isoprostanes and 9-HETE correlated significantly with the presence of angiographically-defined CAD.
- The association remained significant even after adjustment for known cardiac risk factors.
- F_2-Isoprostanes appear to be superior to other lipid peroxidation products tested in determining CAD risk defined by angiography.

Schwedhelm E et al. Urinary 8-iso-prostaglandin F_{2a} as a risk marker in patients with coronary heart disease: A matched case-control study. *Circulation*. 2004; 109: 843-848.

- Population-Patients with CHD
- This study demonstrates that oxidative stress, as measured by urinary excretion of 8-iso-PGF_{2alpha}, is a cumulative risk factor for CHD.
- Additionally, increased urinary 8-iso-PGF_{2alpha} levels are a strong and independent risk factor for CHD.

Lipid Testing

Standard Lipid Panel

Third report of the National Cholesterol Education Program (NCEP). Expert panel on detection, evaluation and treatment of high blood cholesterol in adults (Adult Treatment Panel III). National Cholesterol Education Program. National Heart, Lung, and Blood Institute. National Institutes of Health. September 2002. *NIH Publication* No. 02-5215.

Clinical References (continued)

Apolipoprotein B (ApoB), Apolipoprotein A (ApoA1), and ApoB/ApoA1 ratio

Walldius G et al. High apolipoprotein B, low apolipoprotein A-1, and improvement in the prediction of fatal myocardial infarction (AMORIS study): A prospective study. *Lancet.* 2001: 358: 2026-2033.

- Population-Healthy individuals
- ApoB levels and the ApoB/ApoA ratio are strong and independent risk factors for fatal myocardial infarctions, while elevated ApoA levels were protective.
- Increasing ApoB and decreasing ApoA levels contribute to increased risk irrespective of total cholesterol and triglyceride levels.
- ApoB levels can be used to determine risk of a fatal myocardial infarction in individuals with low to normal levels of LDL cholesterol.

Yusuf S. et al. Effect of potentially modifiable risk factors associated with myocardial infarction in 52 countries (the INTERHEART Study): Case-control study. *Lancet*. 2004; 364: 937-952.

- Population-Patients with MI and matched controls
- An elevated ApoB/ApoA ratio is a strong and independent risk factor for acute myocardial infarction, with an impact similar to that of smoking.
- The relationship between the ApoB/ApoA ratio and the occurrence of an acute myocardial infarction was graded, without an apparent threshold.
- An elevated ApoB/ApoA ratio and smoking account for approximately 2/3 of the population attributable risk for acute myocardial infarction.

Walldius G et al. Stroke mortality and the ApoB/ApoA-1 ratio: Results of the AMORIS prospective study. *J Intern Med*. 2006; 259: 259-266.

- Population-Healthy individuals
- An elevated ApoB/ApoA ratio is associated with an increased risk of stroke, particularly ischemic stroke.
- Low ApoA levels were the strongest contributor to a low ApoB/ApoA ratio and risk of all stroke types.
- An abnormal cholesterol balance, as indicated by an elevated ApoB/ApoA ratio, is a strong marker of all ischemic events.

Small Dense LDL (sdLDL)

Rosensen RS et al. Relations of lipoprotein subclass levels and low-density lipoprotein size to progression of coronary artery disease in the Pravastatin Limitation of Atherosclerosis in the Coronary Arteries (PLAC-I) trial. *Am J Cardiol*. 2002; 90: 89-94.

- Population-Patients with CAD
- Baseline levels of sdLDL particles are associated with CAD progression, even after adjustment for traditional risk factors and lipid levels.
- Individuals with the highest levels of sdLDL particles had the greatest rates of disease progression.

Koba S et al. Significance of small dense low-density lipoproteins and other risk factors in patients with various types of coronary heart disease. *Am Heart J*. 2002; 144: 1026-1035.

- Population-Patients with CHD
- An LDL phenotype characterized by sdLDL particles was in independent risk factor for the development of CHD in both diabetic and non-diabetic individuals, but was unrelated to the severity and extent of coronary lesions.
- The findings suggest that sdLDL are involved in the initiation, but not progression, of CHD.

St-Pierre AC et al. Comparison of various electrophoretic characteristics of LDL particles and their relationship to the risk of ischemic heart disease. *Circulation*. 2001; 104: 2295-2299.

- Population-Patients with ischemic heart disease
- Increased levels of sdLDL particles, and the amount of cholesterol within the particles, are risk factors for the development of IHD in initially healthy men.
- Lipoprotein subclass determination can improve the prediction of cardiovascular disease risk beyond that provided by traditional risk factors.

Austin MA et al. Atherogenic lipoprotein phenotype. A proposed genetic marker for coronary heart disease risk. *Circulation*. 1990; 82: 495-506.

- Population-Healthy individuals
- Pattern B, with a predominance of small dense LDL particles, is associated with an atherogenic lipoprotein profile including elevated triglyceride and LDL-C levels and reduced HDL-C levels.

Clinical References (continued)

Lipoprotein(a) [Lp(a)]

Kamstrup PR et al. Genetically elevated lipoprotein(a) and increased risk of myocardial infarction. *JAMA*. 2009; 301: 2331-2339.

- Population-Healthy individuals
- Elevated levels of Lp(a), either measured in the plasma or determined by genotyping the KIV-2 repeat, are significantly associated with an increased risk of myocardial infarction.

Other Advanced Cardiovascular and Metabolic Tests

Coenzyme Q10

Toyama K et al. Rosuvastatin combined with regular exercise preserves coenzyme Q10 levels associated with a significant increase in high-density lipoprotein cholesterol in patients with coronary artery disease. *Atherosclerosis*. 2011; 217: 158-164.

- Population-Patients with CAD
- The combination of rosuvastatin and exercise significantly preserved CoQ10 levels with an increase in HDL-C levels in patient with CAD as compared to patients receiving atorvastatin.

Caso G et al. Effect of coenzyme Q10 on myopathic symptoms in patients treated with statins. *Am J Cardiol*. 2007; 99: 1409-1412.

- Population-Patients with myopathic symptoms
- CoQ10 supplementation may be beneficial in decreasing muscle pain associated with statin treatment and improving the interference of pain in daily living activities.

Mabuchi H et al. Effects of CoQ10 supplementation on plasma lipoprotein lipid, CoQ10 and liver and muscle enzyme levels in hypercholesterolemic patients treated with atorvastatin: A randomized double-blind study. *Atherosclerosis*. 2007; 195: e182-e189.

- Population-Hypercholesterolemic individuals
- CoQ10, HDL-C, and ApoA1 levels are reduced in individuals taking atorvastatin for management of hypercholesterolemia.
- CoQ10 supplementation restores CoQ10, HDL-C, and ApoA1 levels without affecting the lipid-lowering properties of atorvastatin.

AspirinWorks®

Eikelboom JW et al. Aspirin-resistant thromboxane biosynthesis and the risk of myocardial infarction, stroke, or cardiovascular death in patients at high risk for cardiovascular events. *Circulation*. 2002; 105:1650-1655.

- Population-Individuals at high risk of cardiovascular disease
- Aspirin resistance, as measured by the presence of elevated levels of 11-dehydrothromboxane B2 after aspirin consumption, is associated with an increased risk of myocardial infarction or cardiovascular death in individuals at high risk of cardiovascular events.
- A simple measurement of urinary 11-dehydrothromboxane B2 levels may identify at-risk individuals who require higher doses of aspirin or other anti-thrombotic medications.

Vitamin D, 25 OH

Wang TJ et al. Vitamin D deficiency and risk of cardiovascular disease. *Circulation*. 2008; 117: 503-511.

- Population-Healthy individuals
- Moderate to severe vitamin D deficiency is associated with an increased risk of cardiovascular disease, particularly among individuals with hypertension.

NT-proBNP

Bettencourt P et al. N-terminal-pro-brain natriuretic peptide predicts outcome after hospital discharge in heart failure patients. *Circulation*. 2004; 110: 2168-2174.

- Population-Patients with heart failure
- Elevated NT-proBNP levels at discharge in individuals hospitalized for heart failure are a strong and independent predictor of risk of hospital readmission and death within 6 months of discharge.

Available Patient Education Materials

To support our committment to education we provide patient information for our key biomarkers. These patient education materials are available to download on our website at www.clevelandheartlab.com/our-science/educational-materials

Patient Education Materials

F_2-Isoprostanes

Oxidized LDL

hsCRP

Urinary Microalbumin

MPO

The PLAC® Test

Adiponectin

Apolipoprotein E

CYP2C19

MTHFR

Coenzyme Q10

GlycoMark®

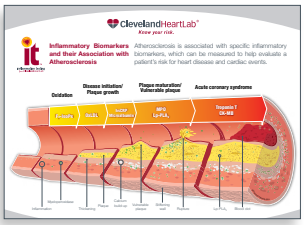
Galectin-3

AspirinWorks®

HDL2b

OmegaCheck™

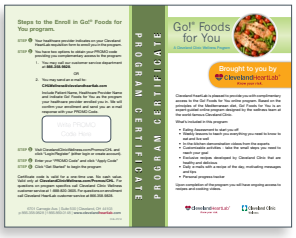
Additional Pieces



Artery Wall

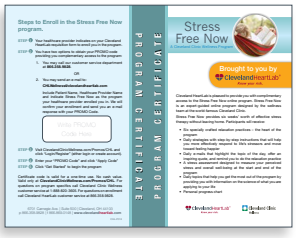
Patient "it" Brochure

Wellness Program



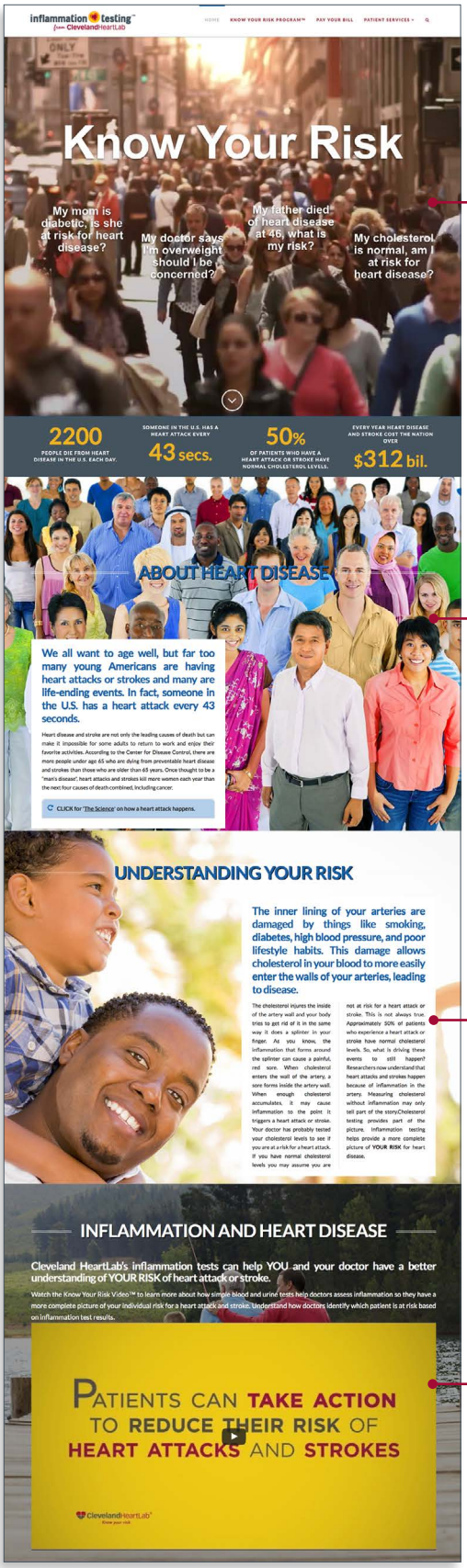
Go! Foods for You

Go! To Sleep



Stress Free Now

www.knowyourrisk.com



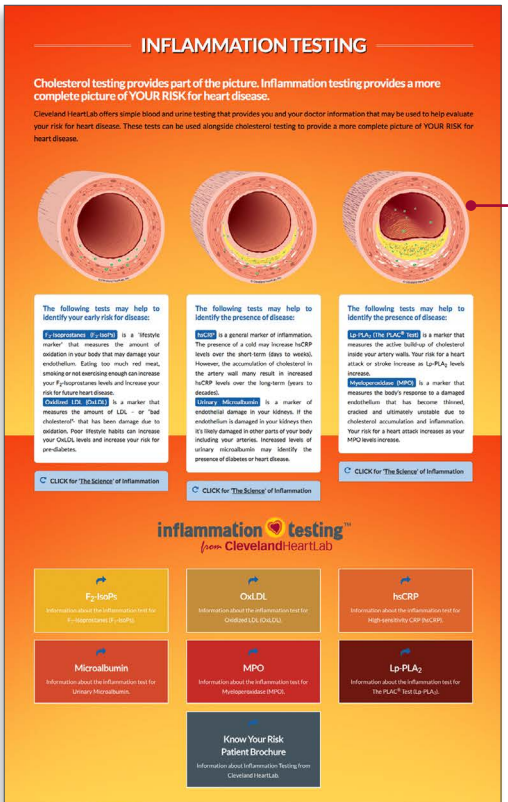
Home page:
Knowyourrisk.com is a resource which you can refer your patients to regarding CHL's inflammation tests. This site provides information on the link between heart disease and inflammation, CHL's inflammation testing and an overview of how to lower risk.

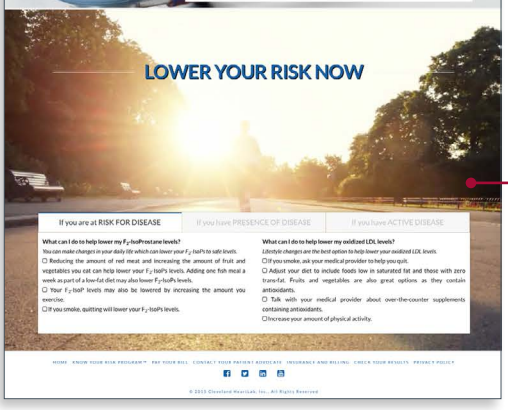
Slide 1 - About Heart Disease:
Provides a brief overview of heart disease and the "inside story" of how a heart attack happens.

Slide 2 - Understanding Your Risk:
Discusses why inflammation testing provides a more complete picture of an individual's risk for heart disease than cholesterol testing alone.

Slide 3 - Inflammation & Heart Disease:
Consumer video which will help your patients understand the link between inflammation and heart disease.

www.knowyourrisk.com (continued)





Slide 4 - Inflammation Testing: The artery wall represents a graphical depiction of the inside of an artery and provides insight of what the artery wall looks like at various stages of the inflammation risk spectrum. It also identifies which CHL tests can be used across the spectrum.

Slide 5 - Are You At Risk?: Discusses the importance of patients knowing if they are at risk so they are able to take steps to lower their risk.

Slide 6 - Lower Your Risk Now: Provides basic information on what can be done to help lower an individuals risk for heart attack and stroke. Refers them back to you for an individualized treatment plan.

General

How do I order supplies (sample collection kits, patient education, etc.)?

We have made ordering supplies very easy by offering them in an a la carte fashion. This allows you to receive only the items and amounts you need for your office. Visit our website at www.clevelandheartlab.com/our-lab-services/order-supplies to see a list of supplies available and place an order.

How can I schedule a reoccuring supply order?

To schedule reoccurring supplies, please contact our customer support department at 866.358.9828. They can help you determine the volume of supplies needed and will get you set up with an appropriate shipment schedule.

How do I schedule a UPS pick-up?

Call UPS at 1.800.742.5877 to schedule a "return service labeled" pick-up. You will then need to provide your contact information and the tracking number that is on your return label.

What should I do if UPS does not pick up our sample?

If you have a reoccurring UPS scheduled pick-up, or scheduled a one-time pick-up and UPS does not pick-up, please contact Cleveland HeartLab immediately at 866.358.9828.

How can I track my samples to make sure they arrived at Cleveland HeartLab?

To verify that your samples have made it to Cleveland HeartLab, please keep a copy of your shipping label which contains the tracking number. The tracking number will allow you to track your packages and see when they arrived at Cleveland HeartLab.

What should I do if I want to add a test that is not on the requisition form?

For a complete list of tests that we perform, visit www.clevelandheartlab.com/our-lab-services/tests-menu. Please write in the test you would like performed in the "other" section of the requisition form and mark the test as ordered.

How soon will I get test results back?

Our turnaround time varies by the type of test being ordered. For turn around time information please visit our test menu on www.clevelandheartlab.com/our-lab-services/tests-menu.

General (continued)

What will happen if my patient has a critical value show up on their report?

Federal statues require that Cleveland HeartLab notify the patient's care provider or referring laboratory when critical limits of specified test results are exceeded and/or critical results are obtained.

To assure that you recieve critical value results in a timely fashion, please complete the critical results notification form provided in this welcome kit and return to Cleveland HeartLab. Cleveland HeartLab will only call you if their is a critical value result on a test.

Please go to www.clevelandheartlab.com/our-lab-services/critical-values to view a list of reportable critical values or see the 'Results and Reporting' section of this book.

What if I have a question about my patient's results?

If you would like further explanation about a patient's results, please contact us at 866.358.9828 and we can assist you with better understanding, interpretation and treatment.

What should I do if I have trouble accessing my patient's results online?

Please refer to the web portal log-in instructions provided in this resource book if you are having difficulty accessing or viewing your patient's results on the web. For any additional questions please contact us at 866.358.9828.

Why are my results still pending?

Pending results will occur if the sample is still in the testing process. The turn-around time for receiving patient results varies depending on the test requested. If your test result is pending outside of the turn-around time, Cleveland HeartLab will contact you.

Billing

We understand that patients may come to you with billing questions. We therefore wanted to provide the most commonly asked questions and answers so that you can help assist them when necessary. For other additional questions or comments please have your patient contact us at 866.358.9828.

What insurance providers do you accept?

We accept most major insurance providers.

My insurance sent me a check. What should I do with it?

One option is to deposit that check from the insurance company and pay Cleveland HeartLab with a personal check or credit card. The second option is to endorse the check over to Cleveland HeartLab directly. Please be sure to keep a copy of all payments for personal records.

Patient Payments can be sent to:

Cleveland HeartLab
Dept. CH19545
Palatine, IL 60055-9545

Client Payments can be sent to:

Cleveland HeartLab
Dept. CH19534
Palatine, IL 60055-9534

Do you take payments over the phone?

Yes, to make a payment over the phone, please call 866.358.9828, option 2.

Can I make a payment online?

Yes, you can make a secure online payment to Cleveland HeartLab by going to www.clevelandheartlab.com.

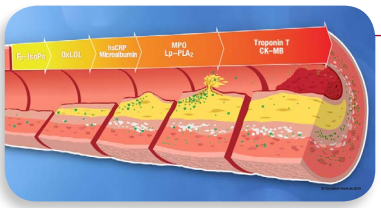
- Patients can make payments online by going to: **www.knowyourrisk.com/pay-your-bill/**
- Clients can make payments online by going to: **www.clevelandheartlab.com/paymybill**

www.clevelandheartlab.com

The Cleveland HeartLab website provides quick, easy access to the resources and tools you are looking for when working with Cleveland HeartLab. The website offers the following areas located on the tabs of the main menu:

Our Lab Services

- Services We Provide
- Getting Started
- Test Menu
- Requisition Form
- Order Supplies
- FAQs
- Critical Values
- Insurance and Billing
- Pay My Bill

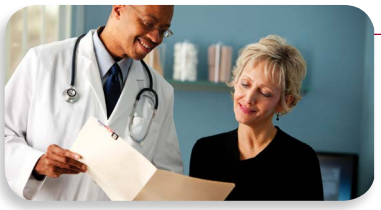


Our Science

- Our Story
- Inflammation Testing
- Advanced Lipid Testing
- Educational Materials
- Educational Videos
- Clinical References

Patients

- This tab links to our patient website located at www.knowyourrisk.com.



Practitoner Results - located on the right of the page

- This tab provides access to our online portal to retrieve patient results.

ClevelandHeartLab®

Know your risk.

6701 Carnegie Ave. | Suite 500 | Cleveland, OH 44103 | p 866.358.9828 | f 866.869.0148 | **www.clevelandheartlab.com**

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