



HRRMC Direct Access Laboratory Testing Consent

REQUEST FOR LABORATORY EVALUATION TO BE REPORTED TO PATIENT ONLY (PATIENT SELF-REFERRAL FOR TESTING)

To be completed by patient for Direct Access Laboratory Testing (DALT).

The laboratory results of the Direct Access Laboratory Testing (DALT) require additional expert interpretation and do not substitute for medical advice, diagnosis or treatment, which should be based on your physician's professional judgment, including his/her review of your test results, the findings of physical examination, and the review of your personal and family medical history. ***DALT laboratory results are not sent to your physician.*** You are responsible for distribution of your reports to your physician and for scheduling a follow-up appointment to discuss your results with your physician.

Patient Name (Last, First, MI)

Cell phone

Home phone

Address

City, State

Zip

Birth date

Email

Emergency contact name

Emergency contact phone

I agree that this test is being requested for the purpose of providing information to myself, so I can compare my results with the laboratory's established reference ranges (so-called normal ranges). I understand that no medical interpretation, medical advice, or medical expertise will be provided by HRRMC, its Laboratory Director, its staff or employees. No doctor-patient relationship exists between the Laboratory Director and myself, the requestor of the tests. No doctor-patient relationship exists between the HRRMC staff physicians and myself, unless I have specifically scheduled a consultation with a physician who has agreed to accept the responsibility of a formal physician/patient relationship with myself.

We urge all patients requesting tests for themselves to seek, without delay, the expertise of a health care professional skilled in the interpretation and treatment of diagnostic tests and medical conditions. It is your responsibility to seek a physician and distribute your test results to your physician.

I have read, understand and agree to the above provisions:

Date: _____

Patient Signature: _____

This form will be completed and returned to the hospital lab before any requested tests are performed.

Check box below to indicate which test is desired:

Test Name	Price
Annual Wellness Panel (CMP, Blood Count, Lipid Panel, TSH, Iron, Uric Acid) <i>fasting recommended*</i>	\$65.00
Blood Chemistry (Comprehensive Metabolic Panel [CMP], Lipid, TSH, Iron, Uric Acid) <i>fasting recommended*</i>	\$40.00
Blood Count (Included in Men's and Women's Health Panels)	\$25.00
Ferritin (Included in Iron Panel)	\$20.00
Folate/B12 Profile	\$40.00
Free Thyroxine (Free T4, FT4) (Included in Thyroid Panel)	\$25.00
Free Triiodothyronine (Free T3, FT3) (Included in Thyroid Panel)	\$25.00
Glucose <i>fasting recommended* **</i>	\$10.00
Hemoglobin A1c (HgA1c)	\$35.00
Iron (Serum Iron)** (Included in Iron Panel)	\$10.00
Iron Panel (Iron, Total Iron Binding Capacity (TIBC), Ferritin Transferrin Saturation)	\$30.00
Lipid Panel <i>fasting recommended* **</i>	\$25.00
Magnesium	\$10.00
Prostate Specific Antigen (PSA) (Included in Men's Panel) <i>Men only</i>	\$35.00
Serum Pregnancy Test	\$25.00
Testosterone <i>For Men & Women</i>	\$45.00
Thyroid Stimulating Hormone (TSH)** (Included in Thyroid Panel)	\$25.00
Thyroid Panel (TSH, FT4, FT3)	\$60.00
Uric Acid**	\$10.00
Urinalysis	\$20.00
Vitamin D	\$55.00

**Diabetics should not fast. **Included in Blood Chemistry, Men's & Women's Health Panels*



HEART OF THE ROCKIES
REGIONAL MEDICAL CENTER

HRRMC Direct Access Laboratory Testing Legal Information / Disclaimer and Waiver

INFORMATIONAL NATURE OF THE TESTS: The HRRMC Laboratory provides Direct Access Laboratory Testing (DALT), including accompanying reference ranges (expected normal ranges), for your informational purposes only. **Direct Access Laboratory Testing cannot substitute for medical advice, diagnosis or treatment. Diagnosis and treatment of human illness should be based on your medical history, including your family's medical history, and a physical examination, along with your doctor's professional judgment and review of test results.**

It is therefore important for you to discuss your test results with your personal physician/health care provider. Physician judgment must remain central to the selection of diagnostic tests and therapy options of a specific patient's medical condition. **Always seek the advice of your doctor if you have any questions, and before you stop, start or change any treatment plan, including the use of medication. If you do not have a personal physician, the HRRMC Laboratory Manager (719-530-2261 or 719-530-2262) will provide you with the list and phone numbers of local licensed health care providers,** so you can contact a provider for medical advice, diagnosis and treatment.

URGENT/EMERGENT RESULTS: The client purchasing DAT services understands that DAT services are not appropriate for urgent or emergent medical conditions or needs. Clients experiencing urgent or emergent medical conditions should call their medical provider to obtain a medical provider's order for obtaining urgent or emergent laboratory reporting of the results to the provider for his or her immediate interpretation.

DAT results of which do not fall into a pre-defined, life-threatening category are not intended to be reported to a client in an urgent or emergent manner. DAT results are typically reported within four (4) working days of collection. In addition, holidays and weekends may delay the timing of results.

LIMITATIONS OF LABORATORY TESTING: Your laboratory tests are completed in a CLIA-certified laboratory, utilizing stringent quality-control standards. However, no guarantees are made with respect to accuracy, completeness, errors or omissions of content. In no event will HRRMC, its Laboratory Director, or HRRMC personnel be liable for any decision made, action taken, or action omitted, based upon the information provided through this Direct Access Laboratory Testing program. The tests provided are known to have a certain percentage of false-negative results (disease is present, but lab value is normal), and false-positive results (no disease is present, but lab value is abnormal). Therefore, whether your lab results are normal or abnormal, you should consult with your physician/health care provider to determine the significance of your laboratory values.

NORMAL RESULTS: A normal laboratory result does not exclude the presence of serious disease, such as cancer. People with cancer and other serious diseases can have normal laboratory values. Pregnant women can have negative pregnancy tests if the test is performed early in pregnancy. Up to one in four men with prostate cancer will have a normal PSA result. PSA testing should always be accompanied by a digital rectal examination, which is part of a regular examination by your personal physician.

ABNORMAL RESULTS: Abnormal laboratory results do not necessarily mean that disease is present. Many variables, including diet, exercise, medications/supplements, and inflammatory conditions can affect laboratory values. In addition, the conditions to which blood or urine is subjected during and after collection (before being tested in the laboratory) can affect laboratory values.

LEGEND FOR INTERPRETING RESULTS ON REPORTS: I understand that results outside the expected “normal” reference range will be indicated as letters next to the numerical value result. “H” means high value, “L” means low value, “HC” means “high critical” value, “LC” means “low critical” value.

ROLE OF LABORATORY DIRECTOR AND LABORATORY PERSONNEL IN DIRECT ACCESS LABORATORY TESTING:

With Direct Access Laboratory Testing, the HRRMC Laboratory Director does not receive your results and does not review your results. There is no doctor-patient relationship between the Laboratory Director and the Test Subject/Consumer requesting the tests. **The Laboratory Director will not be interpreting your results, acting on your results, or giving medical advice concerning the significance of your lab values.** Likewise, Laboratory personnel will not be interpreting your results. Results must be interpreted by your personal physician/health care provider.

Your test results will only be sent to you, not to your physician. It is your responsibility to share the lab results with your physician/health care provider, and to schedule an appointment to discuss your results with your physician/health care provider.

CRITICAL VALUE RESULTS: Certain laboratory values are considered “critical values” (or alert values). Critical value results are lab results which are considered life threatening and require urgent medical attention by a health care provider, such as your personal physician or an emergency room physician. If your test shows a “critical value,” the laboratory staff will call you to give you the critical value result, and will recommend that you contact a physician/health care provider immediately.

It is your responsibility to immediately report any critical value to your health care provider, or to a nearby emergency room doctor, if you do not have a provider. The Laboratory will not be calling your doctor with any critical values obtained.

For purposes of communicating to you any “critical results,” you are agreeing that HRRMC Laboratory may leave a voicemail message on your telephone answering machine (or cell phone), asking you to call the Lab immediately to obtain a critical result. In the event that the Lab cannot reach you by leaving voicemail for you, you are also agreeing that HRRMC Lab can call your listed “Emergency contact,” to ask them to help us notify you to call the HRRMC Lab immediately.

MAILING OF RESULTS: Otherwise, laboratory results will be mailed to you within four days of specimen collection. **Since results will be mailed to you at your address, you accept responsibility should someone else at that address access these results. If you do not receive your results within one week, it is your responsibility to call the Laboratory Manager at 719-530-2261 or 719-530-2262 to obtain your results.**

PRIVACY: HRRMC respects your privacy. Personal information collected from customers will not, unless required by law, be shared with any third party. The primary reason we collect personal information is for identification purposes and to enable you to obtain your test results. We do not distribute unsolicited e-mails, nor, unless required by law, do we share the names of customers with any third party.

FOR PARTICIPANTS OF EMPLOYER WELLNESS GROUP PROGRAM: In the Aggregate Group Report, your individual results will be de-identified and then compiled into an Aggregate Group Report comprising all participating members of the Employer Wellness Group Program. The purposes of this Aggregate Group Report include, but are not limited to, providing a snapshot of an Employer Group's current health status, and providing direction for which health initiatives may be appropriate for an Employer Wellness Group. The Employer Wellness Group will not be provided with individual lab results of its employees; individual participant results are de-identified when the Aggregate report is compiled. The individual participants within the Employer Wellness Group Program will be mailed their own confidential reports, which they can discuss with their own personal physicians.

HRRMC EMPLOYEE EXPOSURE POLICY: You understand that the HRRMC Laboratory has a policy to test for viral Hepatitis and HIV (AIDS) in the event that a Lab employee sustains an accidental exposure to your blood. You are consenting to viral Hepatitis testing and HIV (AIDS) testing of your blood sample in the event of employee exposure to your blood. The results of any such testing will be shared with you.

THIRD PARTY PAYMENT OR REIMBURSEMENT: Direct Access Laboratory Testing may or may not be reimbursed by a health insurance company or by Medicare, Medicaid, or any other city, state or federal program. Please check with your health insurance company or with Medicare, Medicaid, or any other city, state or federal program.

PAYMENTS: I understand that full payment is expected at the time of specimen collection. No other billing will occur, and there is no refund option available.

Patient Name (printed)

Date

Patient Signature

Date

Witness Signature

Date

Legal Guardian/Parent Name (printed)
required for test subjects less than 18 years old

Date

Legal Guardian/Parent Signature
required for test subjects less than 18 years old

Date



HEART OF THE ROCKIES
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HRRMC Direct Access Laboratory Testing Health Screenings

1. Annual Wellness Panel: This blood panel includes CMP, Lipid Panel, TSH, Iron, Uric Acid (see descriptions under Test #1); Blood Count (see description under Test #2). **Fasting for 10-12 hours prior to the blood draw is recommended but not required. However, people with diabetes should not fast.** Check with your medical provider for specific recommendations. You are encouraged to drink plenty of water and continue to take prescription medications. For a complete men's health panel, patients can add on a PSA test. (see description under Test #14)

2. Blood Chemistry: This test requires a blood draw. The Blood Chemistry screening panel can help you and your doctor monitor your health and catch health issues (such as kidney or liver disease) earlier.

Fasting for 10-12 hours prior to the blood draw is recommended but not required. However, people with diabetes should not fast. Check with your medical provider for specific recommendations. You are encouraged to drink plenty of water and continue to take prescription medications.

The **Blood Chemistry** screening includes:

- **Comprehensive Metabolic Panel (CMP):** This tests for liver function, kidney function, electrolytes, acid/base balance, blood proteins, blood glucose (also known as blood sugar, which tests for diabetes).
- **Lipid Panel (Cardiac Risk Assessment):** The Lipid Panel screens for blood findings associated with cardiovascular risk. It tests for total cholesterol, triglycerides, HDL cholesterol, LDL cholesterol, and VLDL cholesterol. Studies have shown important cardiac risk factors include age, smoking status, hypertension (high blood pressure), diabetes, blood total cholesterol levels, and blood HDL cholesterol levels. **Fasting for 10-12 hours prior to the blood draw is recommended but not required. However, people with diabetes should not fast.** Check with your medical provider for specific recommendations. You are encouraged to drink plenty of water and continue to take prescription medications.
- **Thyroid Stimulating Hormone (TSH):** This test is used to screen for thyroid function, and to detect mild and overt hypothyroidism (underactive thyroid) or hyperthyroidism (overactive thyroid). It is also used to monitor therapy with thyroid hormone/Synthroid/Levothyroxine medication. It is often used together with Free Thyroxine (Free T4) levels to detect thyroid dysfunction.
- **Iron (Serum Iron):** This test is used to monitor the amount of iron (serum iron) circulating in the bloodstream. The Serum Iron test is often used with the Serum Ferritin test to monitor for iron deficiency (anemia) or iron-overload diseases.
- **Uric Acid:** This screens for gout and monitors gout therapy. It also helps with diagnosis and treatment of kidney stone disease; monitoring patients receiving cytotoxic drugs/chemotherapy; and monitoring other disorders, including leukemia, psoriasis, starvation and other wasting conditions.

All Direct Access Laboratory Tests with the exception of #21 (Vitamin D) require a blood draw.

3. Blood Count: This screening measures the total number of white blood cells, red blood cells (with hematocrit and hemoglobin levels), and platelets. The white blood cell number is used as an indicator of possible infection, immune status and some leukemias; the red blood cell number (and hemoglobin/hematocrit) is a possible indicator of anemia or polycythemia; the platelet number may indicate bleeding disorders.

4. Ferritin (Serum Ferritin): Ferritin is an iron-containing protein which is the primary form of iron stored inside of cells. The small quantity of ferritin that is released into the bloodstream is a reflection of the amount of total iron stored in the body. However, ferritin is an acute-phase reactant in the blood, which means that circulating ferritin levels increase with infection, inflammation and cancer. Therefore, circulating ferritin levels must be interpreted by your doctor together with other laboratory values (such as Serum Iron and other lab values).

5. Folate (Folic Acid)/B12 Panel: Folate is one of the B vitamins which the body uses for growth and development as well as the production of red blood cells, white blood cells and platelets. A Folate Test can help determine the cause for anemia or aid in the diagnosis of malnutrition or malabsorption. This test is typically ordered when someone has symptoms of anemia or vitamin deficiency. It may also be ordered as a follow-up to irregular results from a CBC test or to monitor someone who is being treated for folate deficiency.

Vitamin B12 is an essential vitamin which is needed for the formation of healthy red blood cells and proper nerve function. A deficiency in B12 can cause a condition known as Macrocytic Anemia in which red blood cells are larger than normal. Common causes for Vitamin B12 deficiency are malnutrition, liver disease, alcoholism and malabsorption disorders such as Celiac Disease, Cystic Fibrosis and Inflammatory Bowel Disease. A Vitamin B12 test is typically ordered when a person is experiencing symptoms such as diarrhea, dizziness, fatigue, pale skin, loss of appetite, rapid heart beat, shortness of breath, tingling or numbness in the extremities, and a sore mouth or tongue. B12 is often ordered as a follow-up to a Complete Blood Count (CBC), which shows abnormal results for red blood cells and Mean Corpuscular Volume (MCV).

6. Free Thyroxine (Free T4, FT4): Also included in Thyroid Panel. See description under #18. Free Thyroxine (FT4) is generally measured together with Thyroid-Stimulating Hormone (TSH) when disorders of the thyroid are suspected. Elevations in FT4 can indicate hyperthyroidism (overactive thyroid); decreases can indicate hypothyroidism (underactive thyroid).

7. Free Triiodothyronine (Free T3, FT3): Also included in Thyroid Panel (see #18). Free T3 is used to assess thyroid function and may be ordered to help monitor a known thyroid disorder. Elevated levels of FT3 may indicate hyperthyroidism (overactive thyroid).

8. Glucose (Blood Sugar): This is useful for detecting and managing diabetes mellitus (high blood sugar) and other carbohydrate metabolism disorders, such as low blood sugar (hypoglycemia). **Fasting for 10-12 hours prior to the blood draw is recommended but not required. However, people with diabetes should not fast.** Check with your medical provider for specific recommendations. You are encouraged to drink plenty of water and continue to take prescription medications.

9. Hemoglobin A1c (HgA1c, HbA1c): This test screens for diabetes by measuring your average blood sugar control for the past 2 to 3 months. For people with known diabetes, it indicates how well your diabetes treatment plan is working.

10. Iron (Serum Iron): Also included in Blood Chemistry. See description under Test #1.

11. Iron Panel: This blood panel includes Iron (Serum Iron, #10), Ferritin (#4), Total Iron Binding Capacity (TIBC), and Transferrin Saturation (also known as % Saturation or % Saturation of Transferrin with Iron). Iron is an essential mineral and an important component of hemoglobin, the substance in red blood cells that carries oxygen from your lungs and transports it throughout your body. If you don't have enough iron, your body can't make enough healthy oxygen-carrying red blood cells, which can result in a condition called iron-deficiency anemia.

TIBC is a blood test to see if you have too much or too little iron in your blood. Iron moves through the blood attached to a protein called transferrin, which is produced in the liver. TIBC measures the blood's capacity to bind iron with transferrin and helps your provider know how well the protein transferrin is carrying iron in your blood.

Taken together with Iron and Transferrin Saturation, clinicians usually perform a TIBC test when concerned about iron-deficiency anemia. Since the liver produces transferrin, alterations in liver function (such as cirrhosis, hepatitis, or liver failure) must also be considered when performing this test.

Transferrin Saturation (% Saturation or % Saturation of Transferrin with Iron): The optimal range is 25 – 35%. When it is less than 17%, a condition of iron-deficiency anemia is possible. When it is greater than 45%, a condition of iron overload is possible. In either case, further testing could be warranted.

12. Lipid Panel (Cardiac Risk Assessment): Also included in Blood Chemistry. See description under Test #1.

13. Magnesium: This test evaluates the level of magnesium in your blood to help determine the cause of abnormal levels of magnesium, calcium, and/or potassium. Magnesium is vital for energy production, muscle contraction, nerve function, and the maintenance of strong bones. It also regulates blood pressure, helps the heart to function normally, controls blood sugar level, and supports the immune system.

14. Prostate Specific Antigen (PSA): PSA is a blood-screening test for any person born with a prostate that measures a protein that is only produced by the prostate gland. Elevations of PSA may occur in persons with non-cancerous prostate diseases or prostate cancer. A normal PSA level does not exclude the possibility of prostate cancer. A physical/manual prostate exam, performed by a health care provider, is also necessary to evaluate for prostate disease and should be used along with a PSA test.

15. Serum Pregnancy Test (Qualitative HCG blood test): A basic pregnancy test that measures if human chorionic gonadotropin (HCG) is in your blood. HCG is a hormone produced in the body during pregnancy. Results are reported as positive or negative. This test is useful in detecting pregnancy at 10 days or so **after** the date a woman is due to start her menstrual period. However, a “false negative test” can occur early in pregnancy.

16. Testosterone: This test is used to detect low testosterone or high testosterone levels in the blood. Testosterone is the main sex hormone in men and is responsible for male physical characteristics. It is present in the blood of both men and women and is used to help diagnose low sex drive, erectile dysfunction, infertility or delayed or early puberty, for example.

17. Thyroid Panel: This panel includes TSH (see description under Test #19), FT3 (see description under Test #7), and FT4 (see description under Test #6).

18. Thyroid Stimulating Hormone (TSH): Also included in Blood Chemistry under Test #1, and the Thyroid Panel, Test #18.

19. Uric Acid: Also included in Blood Chemistry. See description under Test #1.

20. Urinalysis (UA): A urine sample is required. Urinalysis provides an overview of the function of the kidneys. The kidneys play a key role in the excretion of by-products of cellular metabolism and regulation water, acid-base and electrolyte balance. A urinalysis screens for protein or red blood cells in the urine (kidney disease/kidney function); and bacteria and white blood cells in the urine (urinary tract infection/bladder infection).

21. Vitamin D (25-Hydroxy Vitamin D): This screening can provide an initial baseline level of Vitamin D before starting Vitamin D therapy, or it can be used to monitor Vitamin D levels if you take a Vitamin D supplement. Vitamin D deficiency is now recognized as a worldwide problem. Your body requires Vitamin D to absorb calcium, and Vitamin D plays an important role in protecting your bone health (preventing and treating osteoporosis).

IMPORTANT NOTE TO DIRECT ACCESS LABORATORY TEST CONSUMERS:

Laboratory tests cannot be used alone to detect illness/disease/cancer or to exclude the presence of illness/disease/cancer. All laboratory tests should be interpreted by a licensed medical provider, who will use your personal medical history (symptoms), family medical history, a physical examination, and imaging studies (if indicated) to assess whether or not an illness/disease/cancer is likely, or not likely, in your specific situation.

It is your responsibility as a Direct Access Laboratory Test consumer to discuss your test results with your licensed medical provider. Further information on the usefulness of these tests is available on Internet websites such as “Lab Tests Online” (<https://labtestsonline.org>). The above descriptions are for your use as guidelines only. All laboratory screening tests are subject to “false positive results” and “false negative results.”