Revlimid®
(lenalidomide) capsules
2.5 · 5 · 10 · 15 · 20 · 25 mg

Lab results tracker

Your guide to understanding and keeping track of multiple myeloma blood tests.

REVLIMID® (lenalidomide) is a prescription medicine, used to treat adults with multiple myeloma (MM) in combination with the medicine dexamethasone, or as maintenance treatment after autologous hematopoietic stem cell transplantation (a type of stem cell transplant that uses your own stem cells). REVLIMID should not be used to treat people who have chronic lymphocytic leukemia (CLL) unless they are participants in a controlled clinical trial. It is not known if REVLIMID is safe and effective in children. REVLIMID is only available through a restricted distribution program, REVLIMID REMS®.

WARNING: REVLIMID can cause harm to an unborn baby, blood clots, and low blood cell counts.

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Blood tests help your doctor monitor your multiple myeloma.

With multiple myeloma, it's easy to become overwhelmed with the many terms, tests, and procedures, some of which you may have never heard before. The Lab Results Tracker is a brochure designed to help you understand – and keep track of – many of the blood tests you may be asked to undergo.

Inside, we will review some of the common blood tests your doctor may have you take. We'll go over some possible symptoms of multiple myeloma and discuss what abnormal lab values may mean to you. You will also find a chart where you can write down the results of your blood tests and compare them with the results from the same tests at other times during your treatment. Finally, we will include a glossary to help you understand some of the terms in your lab results reports and what your doctor may be keeping a close eye on.

As always, it's important to speak to your doctor about your test results and ask any questions that may arise.

Common blood tests for patients with multiple myeloma.

Throughout treatment, your doctor may administer several important blood tests in order to help monitor how multiple myeloma is affecting you and how well you are responding to treatment. Common tests include:

CBC or complete blood count
Measures the number of red blood cells, white blood cells, and platelets in the blood

Chemistry/metabolic panel
Checks the level of certain substances such as calcium, serum creatinine, and liver enzymes. The results may show how multiple myeloma is affecting your bones, heart, kidneys, and liver

Immunoglobulin levels
Helps to monitor multiple myeloma by counting abnormal antibodies

Serum protein electrophoresis (SPEP)
Helps to monitor multiple myeloma by measuring the abnormal monoclonal protein (M protein) in the blood

Immunofixation
Helps to monitor multiple myeloma by identifying the types of M protein in the blood

Freelite™ Serum free light chain assay
Helps to monitor multiple myeloma by measuring immunoglobulin light chains

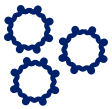
Understanding your lab results.

Your test results can help your doctor understand why you might be experiencing certain multiple myeloma symptoms. Your doctor can use blood tests to tell if you have enough red blood cells, white blood cells, platelets, and other components of your blood. Blood tests are also used to monitor your M protein levels—an important indicator of multiple myeloma. Your doctor may also check your blood calcium levels, which are an indicator of bone health.

Below are some of things your doctor will be looking out for and the symptoms that may be associated with them.

Low red blood cells
Fatigue or exhaustion, sometimes with weakness, pale skin, and dizziness

Low white blood cells
More infections than normal



Low platelets
Easily bruised, more bleeding than normal when cut or scraped

High blood calcium
Increased thirst and frequent urination, loss of appetite and constipation, sleepy and sometimes confused

Increased monoclonal protein (M protein)
The blood thickens and becomes sticky, which causes shortness of breath, chest pain, and confusion

Blood tests may help explain your symptoms.

Tracking your lab results.

Use this chart to keep track of your lab test appointments and results.

***Lab values are ranges based on individual labs; values may vary from lab to lab.**

Lab Assessment	Normal Range*	Appt. Date	Lab Result
Serum Protein Electrophoresis			
Protein	6-8 g/dL		
Albumin	3.3-5.7 g/dL		
α_1-Globulin	0.1-0.4 g/dL		
α_2-Globulin	0.3-0.9 g/dL		
β-Globulin	0.7-1.5 g/dL		
γ-Globulin	0.5-1.4 g/dL		
Monoclonal spike (M spike)	-		
Immunoglobulin, Serum			
IgA	61-356 mg/dL		
IgG	767-1590 mg/dL		
IgM	37-286 mg/dL		
IgD	≤10 mg/dL		
IgE	≤214 mg/dL		
Complete Metabolic Profile			
Sodium	135-145 mEq/L		
Potassium	3.7-5.2 mEq/L		
Chloride	96-106 mEq/L		
Blood urea nitrogen (BUN)	6-20 mg/dL		
Creatinine	0.6-1.3 mg/dL		
Calcium	8.5-10.2 mg/dL		
Creatinine clearance	Males: 97-137 mL/min Females: 88-128 mL/min		
Alkaline phosphatase (ALP)	20-130 U/L		
Alanine aminotransferase (ALT)	4-36 U/L		
Aspartate aminotransferase (AST)	8-33 U/L		
Bilirubin, total	0.1-1.2 mg/dL		
Glucose, fasting	70-100 mg/dL		
Lactate dehydrogenase (LDH)	105-333 IU/L		

Tracking your lab results.

Use this chart to keep track of your lab test appointments and results.

***Lab values are ranges based on individual labs; values may vary from lab to lab.**

Lab Assessment	Normal Range*	Appt. Date	Lab Result
Serum Free Light Chains			
Serum kappa	3.3-19.4 mg/L		
Serum lambda	5.71-26.3 mg/L		
Kappa/lambda, free	0.26-1.65		
Kappa/lambda, free (renal impairment)	0.37-3.1		
β_2-Microglobulin (B2M)	0.70-1.80 mg/L		
Complete Blood Count (CBC) with Differential			
Red blood cell count (RBC)	Males: 4.32-5.72 x 10^{12}/L Females: 3.90-5.03 x 10^{12}/L		
Hemoglobin (Hgb)	Males: 13.5-17.5 g/dL Females: 12.0-15.5 g/dL		
Hematocrit (HCT)	Males: 38.8-50.0% Females: 34.9-44.5%		
Platelets	150-450 x 10^9/L		
White blood cell count (WBC)	3.5-10.5 x 10^9/L		
Lymphocytes	24.0-44.0%		
Monocytes	1.0-10.0%		
Neutrophils	1.7-7.0 x 10^9/L		

Units of measure are also important to understand. For example, grams per liter (g/L) can sometimes be represented as grams per deciliter (g/dL), which will give a value that appears 10 times greater, but that is actually the same value.

These may not be all the lab values your doctor will review. Be sure to tell your doctor if you have any questions about your results.

Tracking your lab results.

Use this chart to keep track of your lab test appointments and results.

***Lab values are ranges based on individual labs; values may vary from lab to lab.**

Lab Assessment	Normal Range*	Appt. Date	Lab Result
Urine Protein Electrophoresis			
Total Protein	<167 mg/24 hours		
Urine Albumin	<5 mg/dL		
α_1-Globulin	0%		
α_2-Globulin	0%		
β-Globulin	0%		
γ-Globulin	0%		

References:

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Quest Diagnostics. Protein, total and albumin (7577). https://testdirectory.questdiagnostics.com/test/test-detail/7577/?cc=TMP. Accessed August 12, 2019.

These may not be all the lab values your doctor will review.
Be sure to tell your doctor if you have any questions about your results.

Glossary.

Below is a brief glossary of common terms to help you understand each of the tests so that you can be better prepared to discuss your results with your doctor.

Absolute neutrophil count (ANC)

The number of neutrophils (a type of white blood cell) in a sample of your blood. Neutrophils play an important role in your immune system by destroying bacteria. If you have a low ANC, this could be a sign of a condition called neutropenia, which can be a side effect of some multiple myeloma treatments and may put you at a higher risk for infection. If this happens, your doctor may make adjustments to your treatment plan to help increase your neutrophils.

Albumin

A protein made by your liver. Albumin is the largest protein component of the serum (the watery part of your blood that contains disease-fighting antibodies). Measuring the amount of albumin in your blood may help your doctor determine the stage of your MM and can provide information about your overall health.

Antibody (immunoglobulin)

A protein that is normally produced by the body's immune system to help fight infections. Antibodies are made of 2 heavy chains and 2 light chains of proteins. There are 5 different types of heavy chains: A, D, G, E, and M. There are 2 forms of light chains: kappa and lambda. The antibodies made by myeloma cells (monoclonal proteins) are not normal; they proliferate in excess and are not produced in response to an infection. Additionally, monoclonal proteins do not help to fight infections.

Blood urea nitrogen (BUN)

The amount of urea nitrogen (a byproduct that forms when protein breaks down) in your blood. Your doctor may look at your BUN to help monitor how well your kidneys are working. Higher levels of urea nitrogen in your blood may be a sign of decreased kidney function, which is common in people with multiple myeloma.

Calcium (blood serum)

An important mineral for the formation of bones. Higher levels of calcium in your blood may be a sign of bone damage, which can be caused by multiple myeloma. Calcium levels can be used to help diagnose multiple myeloma.

Creatinine clearance

A test that measures the rate at which creatinine, a waste product of muscle metabolism, is filtered out of the blood and into the urine. It is used to measure kidney function.

Free light chain

Plasma cells make immunoglobulins out of light and heavy chain components. (See antibody.) Plasma cells typically make more light than heavy chains. The excess light chains enter the bloodstream unattached to heavy chains and are called free light chains. The amount of free light chain production is linked to the activity of myeloma or plasma cell growth.

Immunoglobulin (antibody)

See antibody.

Hematocrit

The percentage of red blood cells found in the total amount of

whole blood. It can be used to check for different conditions such as anemia. Anemia can be a sign that the myeloma cells are taking up most of your bone marrow and not leaving enough space for your normal marrow cells to make red blood cells.

Hemoglobin

A protein in your red blood cells that carries oxygen from your lungs to the tissues in your body. Your doctor may use your hemoglobin level to help determine the stage of your multiple myeloma.

Lactate dehydrogenase (LDH)

A protein made by myeloma cells. High levels may indicate advanced disease.

Lymphocytes

Small white blood cells that make up the majority of your immune system and are found throughout your body, including in your lymph nodes, bone marrow, intestines, and blood. There are 2 major types of lymphocytes: T cells and B cells. When a healthy person gets an infection, his or her B cells mature into the plasma cells in the bone marrow that make antibodies (or immunoglobulins) to help the body fight the infection. But when you have multiple myeloma, your B cells become damaged and mature into malignant (or cancerous) multiple myeloma cells instead. This is why your lymphocyte levels may be low if you have multiple myeloma.

Mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC)

Measures involving your red blood cells (blood cells that carry oxygen through your body): MCV measures the average size (or volume) of your red blood cells; MCH measures how much hemoglobin (the substance in your red blood cells that carries oxygen) is in your red blood cells; and MCHC measures the amount of hemoglobin in your red blood cells relative to the size of the cell (called hemoglobin concentration). MCV is sometimes used, along with other lab test results, to help diagnose and monitor multiple myeloma. Your doctor may also use these tests to help diagnose types of anemia.

Monoclonal protein (M protein)

An antibody made by myeloma cells that is synthesized uncontrollably, as opposed to being produced in response to a germ. M proteins are found in excessive amounts in the blood or urine of patients with multiple myeloma.

Platelet

A type of blood cell that makes clots and stops bleeding.

Proteins

A chain of small chemical compounds that are vital to cells.

Red blood cell (RBC) count

A measure of the total number of red blood cells (the cells that carry oxygen through your body) in your blood. A low RBC count can be a sign of multiple myeloma and may be used to help diagnose the disease. Your doctor may also monitor your RBC count to check for anemia (low RBC count), which can be a side effect of some multiple myeloma treatments. Anemia can cause weakness, a reduced ability to exercise, shortness of breath, and dizziness.

Red blood cell distribution width (RBW)

A calculation of the differences in the size of red blood cells (blood cells that carry oxygen through your body) in your blood. Your doctor may monitor your RBW to look for signs of anemia.

White blood cell (WBC) count

The total number of white blood cells in a sample of your blood. White blood cells help to protect your body by fighting against foreign materials such as bacteria and viruses.

Multiple myeloma and its treatment can cause a drop in white blood cells, which can leave you at greater risk for infection. Your doctor may monitor your WBC count and adjust treatment as needed.

Important Safety Information

What is the most important information I should know about REVLIMID?

Before you begin taking REVLIMID, you must read and agree to all of the instructions in the REVLIMID REMS® program. Before prescribing REVLIMID, your healthcare provider will explain the REVLIMID REMS program to you and have you sign the Patient-Physician Agreement Form.

REVLIMID may cause serious side effects, including:

- **Possible birth defects (deformed babies) or death of an unborn baby.** Females who are pregnant or who plan to become pregnant must not take REVLIMID.

  REVLIMID is similar to the medicine thalidomide which is known to cause severe life-threatening birth defects. REVLIMID has not been tested in pregnant females. REVLIMID has harmed unborn animals in animal testing.

  Females must not get pregnant:
  - For at least 4 weeks before starting REVLIMID
  - While taking REVLIMID
  - During any breaks (interruptions) in your treatment with REVLIMID
  - For at least 4 weeks after stopping REVLIMID

  Females who can become pregnant:
  - Must have pregnancy tests weekly for 4 weeks, then every 4 weeks if your menstrual cycle is regular, or every 2 weeks if your menstrual cycle is irregular.
  - If you miss your period or have unusual bleeding, you will need to have a pregnancy test and receive counseling.
  - Must agree to use 2 different forms of effective birth control at the same time, for at least 4 weeks before, while taking, during any breaks (interruptions) in your treatment, and for at least 4 weeks after stopping REVLIMID.
  - Talk with your healthcare provider to find out about options for effective forms of birth control that you may use to prevent pregnancy before, during, and after treatment with REVLIMID.
  - If you had unprotected sex or if you think your birth control has failed, stop taking REVLIMID immediately and call your healthcare provider right away.

If you become pregnant while taking REVLIMID, stop taking it right away and call your healthcare provider. If your healthcare provider is not available, you can call Celgene Customer Care Center at 1-888-423-5436. Healthcare providers and patients should report all cases of pregnancy to:
- FDA MedWatch at 1-800-FDA-1088, and
- Celgene Corporation at 1-888-423-5436.

There is a pregnancy exposure registry that monitors the outcomes of females who take REVLIMID during pregnancy, or if their male partner takes REVLIMID and they are exposed during pregnancy. You can enroll in this registry by calling Celgene Corporation at the phone number listed above.

REVLIMID can pass into human semen:
- Males, including those who have had a vasectomy, must always use a latex or synthetic condom during any sexual contact with a pregnant female or a female that can become pregnant while taking REVLIMID, during any breaks (interruptions) in your treatment with REVLIMID, and for up to 4 weeks after stopping REVLIMID.

- Do not have unprotected sexual contact with a female who is or could become pregnant. Tell your healthcare provider if you do have unprotected sexual contact with a female who is or could become pregnant.
- Do not donate sperm while taking REVLIMID, during any breaks (interruptions) in your treatment, and for 4 weeks after stopping REVLIMID. If a female becomes pregnant with your sperm, the baby may be exposed to REVLIMID and may be born with birth defects.

Men: If a female becomes pregnant with your sperm, you should call your HCP right away.

- **Low white blood cells (neutropenia) and low platelets (thrombocytopenia).** REVLIMID causes low white blood cells and low platelets in most people. You may need a blood transfusion or certain medicines if your blood counts drop too low. Your healthcare provider should check your blood counts often, especially during the first several months of treatment with REVLIMID, and then at least monthly. Tell your healthcare provider if you develop any bleeding or bruising during treatment with REVLIMID.
- **Blood clots.** Blood clots in the arteries, veins, and lungs happen more often in people who take REVLIMID. This risk is even higher for people with multiple myeloma who take the medicine dexamethasone with REVLIMID. Heart attacks and strokes also happen more often in people who take REVLIMID with dexamethasone. To reduce this increased risk, most people who take REVLIMID will also take a blood thinner medicine.

Before taking REVLIMID, tell your healthcare provider:

- if you have had a blood clot in the past;
- if you have high blood pressure, smoke, or if you have been told you have a high level of fat in your blood (hyperlipidemia); and
- about all the medicines you take. Certain other medicines can also increase your risk for blood clots

Call your healthcare provider or get medical help right away if you get any of the following during treatment with REVLIMID:

- **Signs or symptoms of a blood clot in the lung, arm, or leg may include:** shortness of breath, chest pain, or arm or leg swelling
- **Signs or symptoms of a heart attack may include:** chest pain that may spread to the arms, neck, jaw, back, or stomach area (abdomen), feeling sweaty, shortness of breath, feeling sick or vomiting
- **Signs or symptoms of stroke may include:** sudden numbness or weakness, especially on one side of the body, severe headache or confusion, or problems with vision, speech, or balance

Who should not take REVLIMID?

Do not take REVLIMID if you:

- **are pregnant, plan to become pregnant, or become pregnant during treatment with REVLIMID. See "What is the most important information I should know about REVLIMID?"**
- are allergic to lenalidomide or any of the ingredients in REVLIMID. See the Medication Guide for a complete list of ingredients in REVLIMID.

What should I tell my healthcare provider before taking REVLIMID?

Before you take REVLIMID, tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems
- have kidney problems or receive kidney dialysis treatment
- have thyroid problems
- have had a serious skin rash with thalidomide treatment. You should not take REVLIMID.
- are lactose intolerant. REVLIMID contains lactose.
- are breastfeeding. Do not breastfeed during treatment with REVLIMID. It is not known if REVLIMID passes into your breast milk and can harm your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. REVLIMID and other medicines may affect each other, causing serious side effects. Talk with your healthcare provider before taking any new medicines.
Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist.

How should I take REVLIMID?

Take REVLIMID exactly as prescribed and follow all the instructions of the REVLIMID REMS program

- Swallow REVLIMID capsules whole, with water, 1 time a day. **Do not open, break, or chew your capsules.**
- **REVLIMID may be taken with or without food.**
- Take REVLIMID at about the same time each day.
- Do not open the REVLIMID capsules or handle them any more than needed. If powder from the REVLIMID capsule comes in contact with:
  - your skin, wash the skin right away with soap and water.
  - inside of your eyes, nose, or mouth, flush well with water.
- If you miss a dose of REVLIMID and it has been less than 12 hours since your regular time, take it as soon as you remember. If it has been more than 12 hours, just skip your missed dose. Do **not** take 2 doses at the same time.
- If you take too much REVLIMID, call your healthcare provider right away.

What should I avoid while taking REVLIMID?

- See “What is the most important information I should know about REVLIMID?”
- **Females: Do not get pregnant and do not breastfeed while taking REVLIMID.**
- **Males: Do not donate sperm.**
- **Do not share REVLIMID with other people. It may cause birth defects and other serious problems.**
- **Do not donate blood** while you take REVLIMID, during any breaks (interruptions) in your treatment, and for 4 weeks after stopping REVLIMID. If someone who is pregnant gets your donated blood, her baby may be exposed to REVLIMID and may be born with birth defects.

What are the possible side effects of REVLIMID?

REVLIMID can cause serious side effects, including:

- **See “What is the most important information I should know about REVLIMID?”**
- **Increased risk of death in people who have chronic**

Important Safety Information (continued)

lymphocytic leukemia (CLL). People with CLL who take REVLIMID have an increased risk of death compared with people who take the medicine chlorambucil. REVLIMID may cause you to have serious heart problems that can lead to death, including atrial fibrillation, heart attack, or heart failure. You should not take REVLIMID if you have CLL unless you are participating in a controlled clinical trial.

- **Risk of new cancers (malignancies).** An increase in new (second) cancers has happened in patients who received REVLIMID and melphalan, or a blood stem cell transplant, including certain blood cancers, such as acute myelogenous leukemia (AML), myelodysplastic syndromes (MDS), and certain other types of cancers of the skin and other organs. Talk with your healthcare provider about your risk of developing new cancers if you take REVLIMID. Your healthcare provider will check you for new cancers during your treatment with REVLIMID.
- **Severe liver problems, including liver failure and death.** Your healthcare provider should do blood tests to check your liver function during your treatment with REVLIMID. Tell your healthcare provider right away if you develop any of the following symptoms of liver problems:
  - yellowing of your skin or the white part of your eyes (jaundice)
  - dark or brown (tea-colored) urine
  - pain on the upper right side of your stomach area (abdomen)
  - bleeding or bruising more easily than normal
  - feeling very tired
- **Severe skin reactions and severe allergic reactions** can happen with REVLIMID and may cause death.

Call your healthcare provider right away if you develop any of the following signs or symptoms during treatment with REVLIMID:

- a red, itchy, skin rash
- peeling of your skin or blisters
- severe itching
- fever

Get emergency medical help right away if you develop any of the following signs or symptoms during treatment with REVLIMID:

- swelling of your lips, mouth, tongue, or throat
- trouble breathing or swallowing
- raised red areas on your skin (hives)
- a very fast heartbeat
- You feel dizzy or faint
- **Tumor lysis syndrome (TLS).** TLS is caused by the fast breakdown of cancer cells. TLS can cause kidney failure and the need for dialysis treatment, abnormal heart rhythm, seizure, and sometimes death. Your healthcare provider may do blood tests to check you for TLS.
- **Worsening of your tumor (tumor flare reaction).** Tell your healthcare provider if you get any of these symptoms of tumor flare reaction while taking REVLIMID: tender, swollen lymph nodes; low- grade fever, pain, or rash.
- **Thyroid problems.** Your healthcare provider may check your thyroid function before you start taking REVLIMID and during treatment with REVLIMID.
- **Risk of early death in MCL.** In people who have mantle cell lymphoma (MCL), there may be a risk of dying sooner (early death) when taking REVLIMID. Talk with your healthcare provider about any concerns and possible risk factors.

The most common side effects of REVLIMID include:

- diarrhea
- rash
- nausea
- constipation
- tiredness or weakness
- fever
- itching
- swelling of your arms, hands, legs, feet, and skin
- sleep problems (insomnia)
- headache
- muscle cramps or spasms
- shortness of breath
- cough, sore throat, and other symptoms of a cold
- upper respiratory tract infection or bronchitis
- inflammation of the stomach and intestine ("stomach flu")
- nose bleed
- shaking or trembling (tremor)
- joint aches
- pain in your back or stomach area (abdomen)

These are not all of the possible side effects of REVLIMID. Your healthcare provider may tell you to decrease your dose, temporarily stop or permanently stop taking REVLIMID if you develop certain serious side effects during treatment with REVLIMID. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Please see full Prescribing Information, including Boxed WARNINGS and Medication Guide for REVLIMID.

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Please see full Prescribing Information, including Boxed WARNINGS and Medication Guide, and Important Safety Information pages 14-22.

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REVLIMID is only available through a restricted distribution program, REVLIMID REMS®.

Celgene