

Lab Results Tracker

A guide to help you understand and track your multiple myeloma blood tests.

What is POMALYST® (pomalidomide)?

POMALYST is a prescription medicine, taken along with the medicine dexamethasone, used to treat adults with multiple myeloma who have previously received at least 2 medicines to treat multiple myeloma, including a proteasome inhibitor and lenalidomide, and whose disease has become worse during treatment or within 60 days of finishing the last treatment. It is not known if POMALYST is safe and effective in children.

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

Boxed WARNINGS

Selected Important Safety Information

Some of the serious side effects of POMALYST include:

- Possible birth defects (deformed babies) or death of an unborn baby.
- Can cause harm to unborn babies and blood clots.

Please see detailed POMALYST Important Safety Information on pages 13-18, as well as full Prescribing Information, including Boxed WARNINGS regarding risk to unborn babies and blood clots, and Medication Guide.

Blood tests help your doctor monitor your multiple myeloma (MM)

With multiple myeloma (MM), 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, you'll find:

- Common blood tests your doctor may have you take
- Possible symptoms of MM and what abnormal lab values may mean
- Charts where you can track the results of your blood tests
- A glossary to help you understand some of the terms in your lab results



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 MM is affecting you and how 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 MM is affecting your bones, heart, kidneys, and liver.

Immunoglobulin levels

Helps to monitor MM by counting abnormal antibodies.

Serum protein electrophoresis (SPEP)

Helps to monitor MM by measuring the abnormal monoclonal protein (M protein) in the blood.

Immunofixation

Helps to monitor MM by identifying the types of M protein in the blood.

Freelite® serum free light chain assay

Helps to monitor MM by measuring immunoglobulin light chains.

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Understanding your lab results

Your test results can help your doctor understand why you might be experiencing certain MM 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 MM. Your doctor may also check your blood calcium levels, which are an indicator of bone health.

Below are some of the 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 and 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 M protein

The blood thickens and becomes sticky, which causes shortness of breath, chest pain, and confusion.



Blood tests may help explain your symptoms.

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Tracking your lab results

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

Lab Assessment	Normal Range*	Appt. Date	Lab Result				
Serum Protein Electrophoresis (SPEP)							
Protein	6-8 g/dL						
Albumin	3.3-5.7 g/dL						
α_1 -Globulin	0.1-0.4 g/dL						
a 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 Profil	е					
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						

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

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Tracking your lab results

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

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						
С	omplete Blood Count (CBC) with Di	ifferential					
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						

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

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.

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Tracking your lab results (continued)

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

Lab Assessment	Normal Range*	Appt. Date	Lab Result				
Urine Protein Electrophoresis							
Total Protein	<167 mg/24 hours						
Urine Albumin	<5 mg/dL						
$\alpha_{_1}$ -Globulin	0%						
α ₂ -Globulin	0%						
β-Globulin	0%						
γ-Globulin	0%						

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

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.

References:

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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 MM 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 by-product 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 MM.

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Glossary (continued)

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 MM. Calcium levels can be used to help diagnose MM.

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 chains 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.

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 MM.

Immunoglobulin (antibody)

See "Antibody".

Lactate dehydrogenase (LDH)

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

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Glossary (continued)

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, their 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 MM, your B cells become damaged and mature into malignant (or cancerous) MM cells instead. This is why your lymphocyte levels may be low if you have MM.

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 MM. 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 MM.

Platelet

A type of blood cell that helps blood clot and stops bleeding.

Proteins

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

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Glossary (continued)

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 MM 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 MM 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.

MM 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.



If you find any other terms that you don't understand, you can write them down here and ask your doctor about them at your next appointment.

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Important Safety Information

WARNINGS: Risk to unborn babies, and blood clots.

What is the most important information I should know about POMALYST® (pomalidomide)?

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

POMALYST can cause serious side effects, including:

- Possible birth defects (deformed babies) or death of an unborn baby.
 Females who are pregnant or plan to become pregnant must not take POMALYST.
 - POMALYST is similar to the medicine thalidomide (THALOMID®),
 which is known to cause severe life-threatening birth defects. POMALYST
 has not been tested in pregnant females. POMALYST has harmed unborn
 animals in animal testing.
 - Females must not get pregnant:
 - For at least 4 weeks before starting POMALYST
 - While taking POMALYST
 - During any breaks (interruptions) in your treatment with POMALYST
 - For at least 4 weeks after stopping POMALYST
 - Females who can become pregnant:
 - Will 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 acceptable forms of effective birth control at the same time, for at least 4 weeks before, while taking, during any breaks (interruptions) in treatment, and for at least 4 weeks after stopping POMALYST.
 - Talk with your healthcare provider to find out about options for acceptable forms of birth control that you may use to prevent pregnancy during and after treatment with POMALYST.

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What is the most important information I should know about POMALYST? (continued)

- If you become pregnant while taking POMALYST, 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
 - Celgene Corporation at 1-888-423-5436

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

POMALYST 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 POMALYST, during any breaks (interruptions) in your treatment with POMALYST, and for 4 weeks after stopping POMALYST.
- 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 POMALYST, during any breaks (interruptions) in your treatment, and for 4 weeks after stopping POMALYST. If a female becomes pregnant with your sperm, the baby may be exposed to POMALYST and may be born with birth defects.

Men, if your female partner becomes pregnant, you should call your healthcare provider right away.

Do not donate blood while you take POMALYST, during any breaks
 (interruptions) in your treatment, and for 4 weeks after stopping POMALYST.
 If someone who is pregnant gets your donated blood, her baby may be exposed to POMALYST and may be born with birth defects.

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What is the most important information I should know about POMALYST? (continued)

- Blood clots in your arteries, veins, and lungs, heart attack, and stroke can happen if you take POMALYST.
 - Most people who take POMALYST will also take a blood thinner medicine to help prevent blood clots.
 - Before taking POMALYST, tell your healthcare provider:
 - o 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).
 - 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 POMALYST:

- 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.
- 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 POMALYST:

- $\circ \;\;$ swelling of your lips, mouth, tongue, or throat
- trouble breathing or swallowing
- o raised red areas on your skin (hives)

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What is the most important information I should know about POMALYST? (continued)

- a very fast heartbeat
- you feel dizzy or faint

Who should not take POMALYST?

Do not take POMALYST if you:

- Are pregnant, plan to become pregnant, or become pregnant during treatment with POMALYST. See "What is the most important information I should know about POMALYST?"
- Are allergic to pomalidomide or any of the ingredients in POMALYST.

What should I tell my healthcare provider (HCP) before taking POMALYST?

- If you smoke cigarettes (POMALYST may not work as well in people who smoke), have any other medical conditions, or are breastfeeding. Do not breastfeed during treatment with POMALYST—it is not known if POMALYST passes into breast milk and can harm the baby.
- If you have liver problems
- If you have kidney problems and are receiving hemodialysis treatment
- Tell your HCP about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. POMALYST and other medicines may affect each other, causing serious side effects. Talk with your HCP before taking any new medicines.

How should I take POMALYST?

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

- Swallow POMALYST capsules whole with water 1 time a day. Do not break, chew, or open capsules.
- Take POMALYST at the same time each day with or without food.
- If you are on hemodialysis, take POMALYST after hemodialysis on hemodialysis days.

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How should I take POMALYST? (continued)

- Do not open POMALYST capsules or handle them any more than needed. If you touch a broken POMALYST capsule or the medicine in the capsule, wash the area of your body right away with soap and water.
- If you miss a dose of POMALYST and it has been less than 12 hours since
 your regular time, take POMALYST 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 POMALYST, call your healthcare provider (HCP) right away.
- Do not share POMALYST with other people. It may cause birth defects and other serious problems.

What are the possible side effects of POMALYST?

- See "What is the most important information I should know about POMALYST?"
- POMALYST can cause serious side effects, including:
 - Low white blood cells (neutropenia), low platelets (thrombocytopenia), and low red blood cells (anemia) are common with POMALYST, but can also be serious. You may need a blood transfusion or certain medicines if your blood counts drop too low. Your blood counts should be checked by your healthcare provider (HCP) weekly for the first 8 weeks of treatment and monthly after that.
 - Severe liver problems, including liver failure and death. Your HCP should do blood tests to check your liver function during your treatment with POMALYST. Tell your HCP right away if you develop any of the following symptoms: yellowing of your skin or the white parts 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, or feeling very tired.
 - Severe allergic and severe skin reactions can happen with POMALYST and may cause death.
 - Dizziness and confusion. Avoid taking other medicines that may cause dizziness and confusion during treatment with POMALYST. Avoid situations that require you to be alert until you know how POMALYST affects you.

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What are the possible side effects of POMALYST? (continued)

- Nerve damage. Stop taking POMALYST and call your HCP if you develop numbness, tingling, pain, or a burning sensation in your hands, legs, or feet.
- New cancers (malignancies). New cancers, including certain blood cancers (acute myelogenous leukemia or AML) have been seen in people who received POMALYST. Talk with your HCP about your risk.
- 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 HCP may do blood tests to check you for TLS.
- The most common side effects of POMALYST include tiredness and weakness, constipation, nausea, diarrhea, shortness of breath, upper respiratory tract infection, back pain, and fever.
- These are not all the possible side effects of POMALYST. Your HCP may tell you to stop taking POMALYST if you develop certain serious side effects during treatment. Call your HCP for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see full Prescribing Information, including Boxed WARNINGS and Medication Guide at links below.

Notes:			

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Please see detailed POMALYST Important Safety Information on pages 13-18, as well as full <u>Prescribing Information</u>, including Boxed WARNINGS and <u>Medication Guide</u>.

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