TEST

Trypsinogen test

A trypsinogen test measures a pancreatic digestive-enzyme precursor in blood.

WHAT IT MEASURES
Inactive digestive-enzyme precursor made by the pancreas

SAMPLE
Blood

FASTING NEEDED?
No, unless required for other tests

HOW LONG IT TAKES
Usually 5 to 10 minutes

RESULTS IN
Usually several days; timing varies by laboratory

USED FOR
Newborn screening and evaluating pancreatic enzyme production

MAIN LIMITATION
Normal results can miss mild pancreatic enzyme insufficiency

Overview

Trypsinogen is an inactive substance made by the pancreas. After it enters the small intestine, it is changed into trypsin, an enzyme that helps digest protein.

A trypsinogen test usually measures trypsinogen in blood. In newborn screening, it is commonly called an immunoreactive trypsinogen , or IRT , test. IRT is used as an early screening test for cystic fibrosis.

In older children and adults, a blood trypsinogen test may help assess the pancreas's ability to make digestive enzymes. It is not used as often as tests such as stool elastase for pancreatic enzyme insufficiency or blood lipase for acute pancreatitis.

Some centres use a separate urine test called urine trypsinogen-2 when assessing possible acute pancreatitis. That test has different methods and limits. This article focuses on blood testing.

Why the test is ordered

The reason for testing changes how the result is interpreted.

For newborns, IRT testing is part of cystic fibrosis screening in many countries. Cystic fibrosis is an inherited condition that can affect the lungs, digestive system and other organs. A raised IRT result does not mean that a baby has cystic fibrosis. It means that the screening program may recommend another blood test, genetic testing or a sweat chloride test.

For an older child or adult, a clinician may order serum trypsinogen when looking for reduced pancreatic enzyme production. This is called exocrine pancreatic insufficiency . It can make it difficult to digest food and absorb nutrients.

The test may also become abnormal when the pancreas is inflamed or injured. However, trypsinogen alone cannot identify the cause. Blood lipase is generally a more useful test when acute pancreatitis is suspected.

Who should have the test

Newborns may have IRT measured routinely as part of a blood spot screening program. A few drops of blood are collected from the heel and placed on a special card.

Outside newborn screening, you may be offered a trypsinogen test if there is concern about pancreatic enzyme production. Reasons might include ongoing greasy stools, unexplained weight loss, difficulty gaining weight or poor absorption of nutrients. These symptoms can have many causes, so the test is only one part of an assessment.

Trypsinogen is not usually a routine wellness test. A normal result also cannot rule out every pancreatic condition, especially mild pancreatic enzyme insufficiency.

How to prepare

Fasting is not usually needed for a blood trypsinogen or newborn IRT test. You can generally eat and drink as usual unless other blood tests ordered at the same time require fasting.

Tell the healthcare professional collecting or arranging the test about medicines and supplements. There are few well-established medicine effects that apply to every trypsinogen assay, but the laboratory may use a method with specific sources of interference.

No preparation is needed for a newborn heel-prick sample. Feeding can usually continue normally.

What happens during the test

For an older child or adult, blood is usually taken from a vein in the arm. A band may be placed around the upper arm, the skin is cleaned and a small needle is inserted. Collection usually takes a few minutes.

For newborn screening, a healthcare professional warms and cleans the baby's heel, then makes a small prick. Drops of blood are placed onto a screening card and allowed to dry before being sent to the laboratory.

The laboratory measures trypsinogen using antibodies, which are proteins designed to recognise the substance. Different assays may produce results that are not directly interchangeable.

Understanding your results

Your report should show the laboratory's reference range or the newborn screening program's cut-off. There is no single result that applies to every assay or purpose.

Ranges and interpretation vary by laboratory, age, sex, pregnancy status, medicines and clinical context. Newborn IRT results also depend strongly on the baby's age when the sample was collected and on the screening program's testing method.

In a newborn:

Follow-up may involve a repeat IRT test, testing for changes in the CFTR gene, or a sweat chloride test. A sweat test measures salt in sweat and is used to help confirm or exclude cystic fibrosis.

In an older child or adult, a very low serum trypsinogen result can support substantial loss of pancreatic enzyme production. A normal result does not reliably exclude mild or moderate insufficiency.

A raised blood result may occur with pancreatic inflammation or blockage. Reduced kidney function can also raise the result because trypsinogen is cleared less efficiently from the blood. The number must therefore be considered alongside symptoms, kidney tests and other pancreatic tests.

- A result below the program's cut-off usually means no further cystic fibrosis screening test is needed
- A raised result means more testing may be needed
- A raised result does not diagnose cystic fibrosis

What affects the results

Several factors can change a result without there being a laboratory error.

Age and timing are especially important in newborns. IRT is usually highest soon after birth and falls over time. A sample collected later than the screening program recommends may be harder to interpret.

Premature birth, a difficult delivery or illness around the time of birth may raise newborn IRT. Babies born with meconium ileus, a bowel blockage associated with cystic fibrosis, can sometimes have an IRT result that is not clearly raised. This is one way screening can miss the condition.

Kidney function matters for serum testing. Reduced kidney clearance may increase trypsinogen even when pancreatic enzyme production is not increased.

The assay method also matters. Laboratories may use different antibodies, instruments and cut-offs. Poor sample quality, including a newborn blood spot that is too small or unevenly applied, may lead to repeat collection.

Eating, coffee, ordinary daily activity and the time of day are not known to have major consistent effects on this test. There is also no common medicine effect that applies to every assay. Follow any instructions provided for tests being collected at the same appointment.

Accuracy and limitations

A trypsinogen result cannot diagnose a condition by itself.

Newborn IRT screening is designed to identify babies who need further testing, not to give a final diagnosis. Some babies without cystic fibrosis have a raised result, particularly after premature or stressful births. This is a false-positive screen. Some babies with cystic fibrosis have an IRT result below the cut-off, so screening can occasionally miss the condition.

The chance of a false result differs among screening programs because they use different collection times, cut-offs and combinations of IRT and genetic testing. A diagnostic sweat test is usually more appropriate after an abnormal screen.

For pancreatic enzyme insufficiency, low serum trypsinogen is more useful when insufficiency is advanced. It often remains normal in mild or moderate disease. Stool elastase is generally the preferred first test because it more directly reflects pancreatic enzyme output into the intestine, although that test also has limitations.

For suspected acute pancreatitis, blood lipase and clinical assessment are more useful than

serum trypsinogen. Imaging may be needed in selected situations. A raised trypsinogen result cannot show the cause or severity of pancreatic inflammation.

Risks and complications

A blood draw may cause brief discomfort, a small bruise or light-headedness. A newborn heel prick may cause short-lived pain and minor bleeding.

What happens next

A newborn screening result that needs follow-up is usually handled promptly through the screening program. This is routine follow-up rather than proof that the baby has cystic fibrosis. Attend the recommended repeat blood test, genetic assessment or sweat test even if the baby appears well.

For an abnormal serum result, the next step may include repeat testing, kidney function tests, stool elastase, nutritional blood tests or pancreatic imaging. The choice is based on why the test was ordered and any other findings.

Arrange routine medical follow-up for ongoing greasy stools, unexplained weight change, poor growth or repeated digestive problems.

Seek urgent medical care for severe or worsening upper abdominal pain, especially with repeated vomiting, fainting, breathing difficulty, confusion or signs of dehydration. Do not wait for a trypsinogen result before seeking help for severe symptoms.

Common questions

Can I drink coffee before a trypsinogen test?

Usually, yes. Fasting is not normally required. Avoid coffee only if another test collected at the same time has fasting instructions.

Does the time of day matter?

Not usually for an older child or adult. For newborn screening, the baby's age in hours or days matters more than the time on the clock.

Can I exercise beforehand?

Ordinary exercise is not known to meaningfully change trypsinogen. Follow separate instructions if you are having other blood tests.

Does a high newborn IRT result mean cystic fibrosis?

No. It is a screening result, not a diagnosis. Repeat IRT, genetic testing or a sweat test may be needed.

Can a normal result rule out pancreatic problems?

No. Serum trypsinogen can remain normal when pancreatic enzyme insufficiency is mild or moderate. Another test, often stool elastase, may be more useful.

How soon will results be ready?

Serum results are often available within several days. Newborn screening results may take several days or longer, depending on transport, the laboratory and whether additional testing is performed.

Sources

- MedlinePlus Medical Encyclopedia: Trypsinogen blood test . US National Library of Medicine.
- Cystic Fibrosis Foundation: Newborn Screening for CF . Overview of IRT screening and follow-up testing.
- American College of Medical Genetics and Genomics: Elevated Immunoreactive Trypsinogen ACT Sheet . Guidance on follow-up after an abnormal newborn screen.
- Farrell PM, White TB, Ren CL, et al. Diagnosis of Cystic Fibrosis: Consensus Guidelines from the Cystic Fibrosis Foundation . The Journal of Pediatrics . 2017;181S:S4-S15.e1.
- Whitcomb DC, Buchner AM, Forsmark CE. AGA Clinical Practice Update on the Epidemiology, Evaluation, and Management of Exocrine Pancreatic Insufficiency: Expert Review . Gastroenterology . 2023;165(5):1292-1301.
- National Institute of Diabetes and Digestive and Kidney Diseases: Diagnosis of Pancreatitis . US National Institutes of Health.