



MRI Measurement of Liver Iron Concentration

FAQ on FerriScan® for Patients

What is FerriScan?

FerriScan is an MRI-based, non-invasive test for measuring Liver iron Concentration (LIC) in patients who may be suffering from liver iron overload. It is a service provided by the company Resonance Health.

What is a MRI?

Magnetic Resonance Imaging (MRI) is a technology that uses a magnetic field and pulses of radio wave energy to make pictures of organs and structures inside the body. In many cases, MRI gives different information about structures in the body than can be seen with an X-ray, ultrasound, or computed tomography (CT) scan.

What is “Iron Overload”?

When the body absorbs more iron than is required, it has no natural mechanism to remove it. This may happen as a result of the body absorbing too much iron through the diet or where additional iron is introduced through regular blood transfusions in the treatment of disease. Surplus iron accumulates in the organs and tissues of the body, particularly the liver, potentially leading to liver fibrosis, liver cancer and death. Most cases of iron overload are the result of genetic conditions such as Thalassaemia, Sickle Cell Disease or Hereditary Haemochromatosis.

What is liver fibrosis?

Liver fibrosis is scarring of the liver. Like any other scars, this indicates that some damage has occurred. If the cause of the fibrosis is identified and early treatment provided, it is often possible for the damage to be reversed, otherwise further liver complications may ultimately occur.

How does FerriScan work?

FerriScan is an image analysis service that can be established on most makes and models of 1.5 Tesla magnetic resonance imaging scanners at MRI centres around the world. These centres are given a set of instructions (the FerriScan protocol) to adjust their scanner’s settings so that it can collect FerriScan images correctly. Abdominal (mid-section) images are captured by the scanner and uploaded to a secure server at Resonance Health’s central Service Centre. This data is processed by trained analysts using the patented FerriScan software under a quality-controlled system. A Liver Iron Concentration (LIC) Report is delivered back to the MRI Centre within two business days. It includes:

- the patient’s Liver Iron Concentration
- a table to indicate the clinical relevance of their LIC measurement
- a map of the iron distribution across their liver
- a histogram showing indicative iron distribution
- where available, historical data showing the patient’s progress over time

The report is then sent to the referring clinician to help them confirm the patient's diagnosis and develop their treatment plan. Due to the quality-controlled, standardized nature of the test, a patient may have a FerriScan at any FerriScan-verified MRI centre, anywhere in the world, and receive accurate, reliable results.

Why do I need an MRI scan to measure my liver iron concentration?

An MRI scan allows detailed information to be gathered about the body's organs without the need for invasive surgical procedures such as liver biopsy. The FerriScan images show an entire cross-section of the liver and allow a more accurate evaluation of the liver as compared to liver biopsy.

Why is FerriScan better than alternative tests?

FerriScan is non-invasive, cost effective and painless. An initial blood test ordered by your doctor will indicate whether a person has high levels of iron in their body. However, blood tests are only an indirect measurement of LIC and can be affected by other conditions such as inflammation or infection. Therefore, they cannot be used alone for the diagnosis and clinical management of iron overload. Prior to FerriScan, the gold standard (or accepted 'best practice') method for estimating the extent of iron loading in the liver was through liver needle biopsy, which is an invasive and unpleasant surgical procedure. The need for anesthesia, patient monitoring and recovery time also makes it expensive.

Other MRI-based tests exist to measure LIC, largely using methodologies known as T2* or Signal Intensity Ratio (SIR). These tests fail to offer the standardization and quality control systems offered by FerriScan. This causes variability in results between different scanners and MRI centres. This lack of reliability is why the majority of these methods do not have approval from international regulatory authorities such as FDA and CE Mark.

Globally, FerriScan has become the gold standard (best practice) test for liver iron concentration. It is used by both leading clinicians and pharmaceutical companies in trials of new medications. It is also recommended by international clinical guidelines (see <http://www.resonancehealth.com/products/ferriscan-mri-measurement-of-liver-iron-concentration/ferriscan-information-for-clinicians.html>). The accuracy and reliability of FerriScan enables clinicians to optimise patient treatment based on their actual level of liver iron overload.

How do I request a FerriScan from my doctor?

Ask your doctor if you need a FerriScan to measure your liver iron concentration and if there is a local radiology centre that offers the service. Further information and a map of FerriScan sites around the world can be found at <http://www.resonancehealth.com/find-a-centre/all.html>

Does FerriScan cause side effects?

No. MRI works using electro-magnetic energy, not radiation so it is safe for people of all ages to have a FerriScan as often as required. There are some restrictions associated with MRI use, such as in pregnancy or in people who have metal implants, but these will be discussed with patients by the MRI technicians beforehand.

Is FerriScan painful?

Being non-invasive, FerriScan is a painless test. Some people may experience anxiety in an MRI scanner as it can be noisy and can feel a little claustrophobic. However, MRI technicians are experienced at putting patients at their ease.

Is FerriScan approved by regulatory bodies? Can it be used anywhere in the world?

FerriScan has the following regulatory clearances:

- In the US by the FDA (Food and Drug Administration);
- In Australia by the TGA (Therapeutic Goods Administration);
- In Europe (CE Mark), which covers 27 countries.

In the rest of the world, FerriScan complies with local regulations. Resonance Health has an internal approval process to ensure all MRI centres wishing to offer FerriScan can legally and technically do so. The FDA has mandated the use of FerriScan in patients with Non-Transfusion Dependent Thalassaemia who are being treated with the iron chelator Exjade, a medication which helps reduce body iron levels.

Who is the test suitable for?

FerriScan is suitable for patients of all ages. Because it is non-invasive, it is painless and can be used repeatedly. It does not require a contrast agent or a breath-hold. This means that very young patients who may require some sedation to keep still enough for an MRI scan can also successfully have a FerriScan.

Who should have this test?

People who have had blood tests that indicate they may have high levels of body iron, especially if they have:

- a disease that is likely to lead to iron overload
- repeated blood transfusions

a genetic predisposition to absorb excessive amounts of iron.

How long does FerriScan take?

FerriScan has a 9-10 minute scan time. Results are then analysed and returned to the MRI Centre within a target time of two business days.

Do I need medicine before I take this test?

No medication is required before this test.

Is there anything special I have to do before I can have a FerriScan?

You may continue to take any medications prescribed by your physician. Only the normal restrictions relating to MRI procedures, such as limitations for patients who are pregnant or who have pacemakers or metal implants apply to FerriScan.

How much does FerriScan cost?

The way in which FerriScan is charged varies between countries and even between centres, depending on the health funding available. As FerriScan consists of an MRI scan and subsequent analysis with FerriScan software, some MRI centres will charge you for the test if funding is not available through local health arrangements.

Your clinician should be able to assist you to obtain information relevant to your local area.

Who is Resonance Health?

Resonance Health Limited is a publicly listed Australian healthcare company developing and delivering services to assist the non-invasive diagnosis and management of human disease.

Where can I find more information about FerriScan?

Log on to our website www.resonancehealth.com