

September 2020



SELFCheck training

Pharmacist information

About SELFCheck

SELFCheck self test kits are assembled by JR Biomedical Ltd at ISO9001 and ISO13485 certified laboratories in North Wales.

As well as manufacturing the SELFCheck range, JR Biomedical supplies medical diagnostics for research and clinical use by UK universities and the NHS.

The company has current research collaborations with Cardiff University to develop a new rapid sepsis test and with the University of South Wales to develop a new analytical instrument for hospital laboratories.

Assembled according to a full medical device quality assurance system ISO13485:2016

Collaboration with UK universities

Supplies medical diagnostics to NHS and university laboratories

Research and development program to develop new diagnostic technology

Sepsis biomarkers research



02 Benefits of self testing

Self testing isn't new

Self test kits have been available from pharmacies for decades including pregnancy tests, ovulations tests and blood glucose monitoring.

Recent advances in immunoassay technology has meant that the very same principles can be transferred from the hospital laboratory to a rapid test, lateral flow (immunochromatographic) format.

- Easy to use
- Results in minutes
- Same technology used in hospital laboratories
- Reliable results
- Strictly regulated



CE certified self test kits

Self test medical devices are strictly regulated in the UK according to the requirements of the EU In-Vitro Diagnostic Directive 98/79EC (IVDD/IVDR).

All self test diagnostics sold in the UK must comply with these regulations and carry the CE mark together with Notified Body number to show compliance.

CE certified self test kits

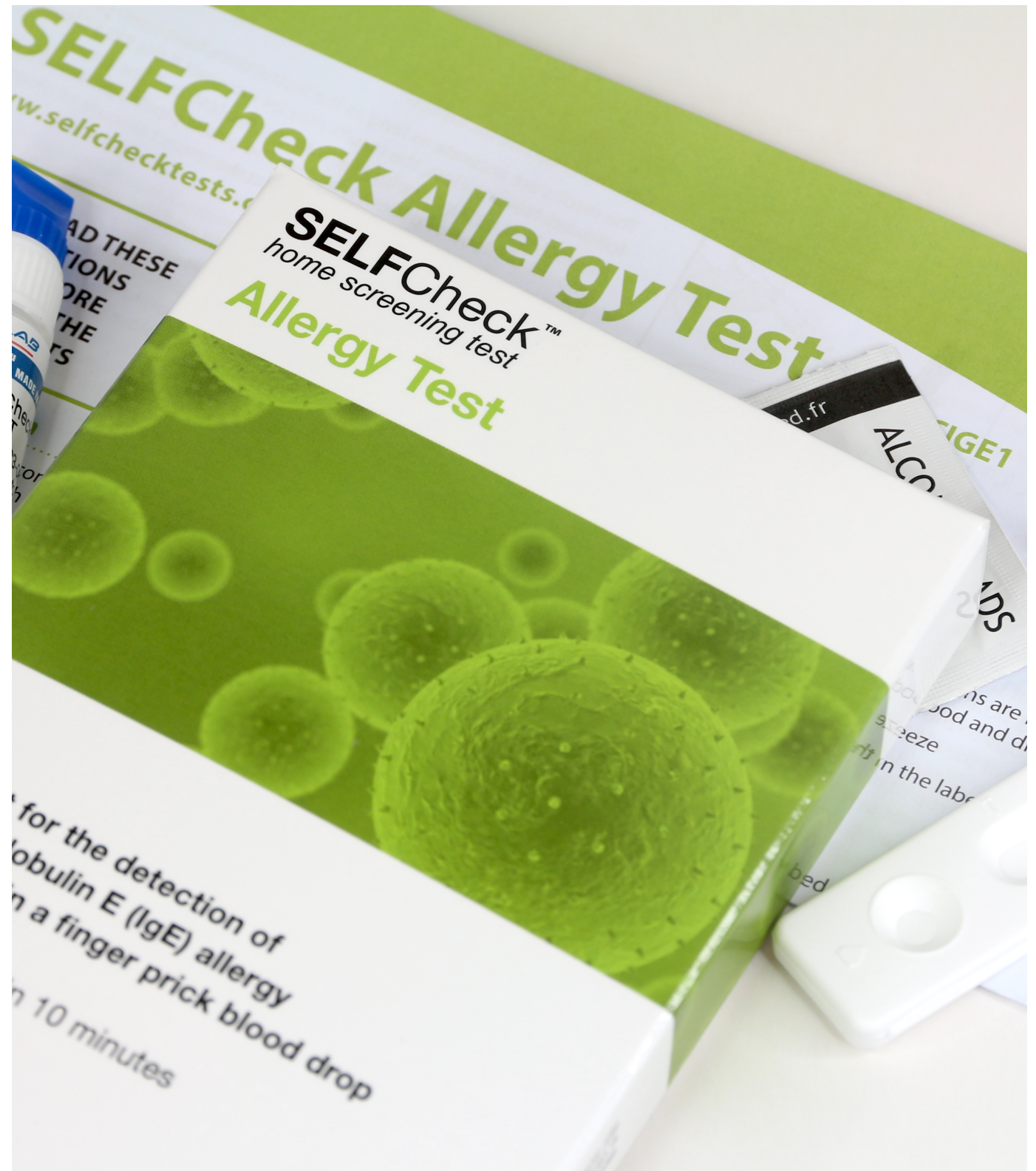
ISO13485:2016

ISO9001:2015

External audits twice a year by UKAS accredited auditors

Full traceability of test kits and components

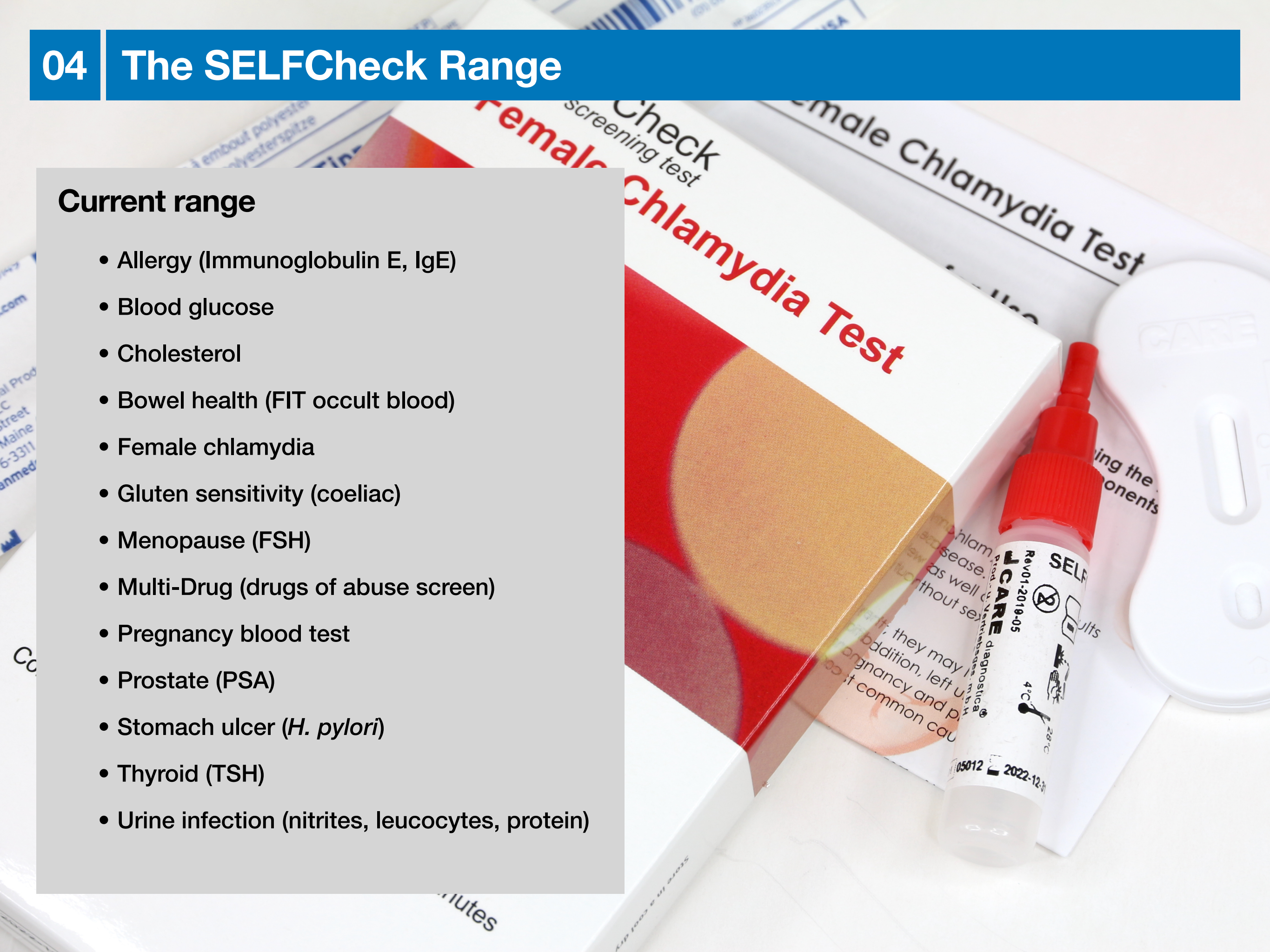
Based on same immunoassay principles used in hospital labs



04 The SELFCheck Range

Current range

- Allergy (Immunoglobulin E, IgE)
- Blood glucose
- Cholesterol
- Bowel health (FIT occult blood)
- Female chlamydia
- Gluten sensitivity (coeliac)
- Menopause (FSH)
- Multi-Drug (drugs of abuse screen)
- Pregnancy blood test
- Prostate (PSA)
- Stomach ulcer (*H. pylori*)
- Thyroid (TSH)
- Urine infection (nitrites, leucocytes, protein)



Clinical grade components

All the components supplied in SELFCheck tests are of the highest quality and are used in hospitals and clinics around the world.

All batches are thoroughly QC tested before released for sale.

Nevertheless, we are unable to control how the test will be used.

You can help by emphasising the need for your patients to read the instruction leaflet carefully **BEFORE** touching the components or starting the test.

A video is available on our website www.selfchecktests.com/customer-service



Frequently asked questions

Are the tests approved in the UK?

Yes. Self test medical devices are strictly regulated in the UK, having to comply with the requirements of the EU In-Vitro Diagnostic Directive 98/79EC (IVDD). All diagnostic tests sold in the UK and throughout the EU must comply with these regulations and carry the CE mark to show compliance.

Are the tests reliable?

Yes. The tests will provide accurate results providing the instructions are followed.

How accurate is the test?

The SELFCheck tests have been assessed according to UK and EU regulatory standards by independent Notified Bodies to ensure that our self tests give reliable results.

Will my doctor consider a self test result to be of any value?

Yes. The immunoassay technology used in SELFCheck tests is exactly the same as that used by NHS hospital laboratories.

Is the test easy to use?

Yes, All SELFCheck test have undergone extensive user trials under the scrutiny of external scientists and doctors responsible for the regulation of medical tests in the UK to show that the tests are easy to use by the general public.

How much blood is needed?

The SELFCheck blood tests require a finger prick blood drop about the size of a ladybird. This is easily produced with the sterile automatic lancet provided with the test.

What happens if I make a mistake?

The tests have been demonstrated in user trials to be very easy to use but it is essential to read the instructions carefully *even* if you have used similar devices in the past.

Can I see a video of how to use the test before I start?

Yes. It is strongly advised to watch the video on www.selfchecktests.com/customer-service - a card is included in each test with a QR code to the videos.

But always read the instructions!

How to ensure your customer gets a result every time

Due to the batch process for production, the high quality of manufacture and **clinical grade** components, it is *highly unlikely* that you will ever encounter a failure of the device.

Also, all SELFCheck tests have to undergo stringent independent user trials with the general public to show that they are easy to use before they are certified for sale.

Nevertheless, over the past 15 years we have found that a minority of the general public don't follow the instructions and fail to get a result

Although rare, the most common reasons are;

Not using the lancet correctly

For hygiene reasons self test manufactures **MUST** supply *single use* lancets where the needle retracts instantly after use.

- Some customers activate the lancet before reading the instructions which means it cannot be used
- Despite the instructions stressing to press the lancet firmly against the finger tip as it is activated, occasionally some users press lightly, which results in a small puncture site making it less easy to collect enough blood

SELFCheck blood test kits contain a spare lancet just in case it is used incorrectly.

Not using the pipette correctly

To ensure the correct amount of blood is collected, a self filling pipette is included with the test which fills automatically to the correct volume. For safety, the pipette is made from soft plastic rather than glass.

The pipette fills purely by capillary action and providing the pipette is held horizontally, as shown in the instructions (blood will not flow up-hill) and the lancet has been used correctly, it is easy to collect the required amount of blood.

Not adding the correct amount of diluent

Most SELFCheck tests require 4 drops of diluent to be added to the test cassette after the blood sample. This pushes the blood sample through the device. Occasionally, some customers do not add sufficient drops, or add the drops to the wrong place on the cassette.

Not adding enough diluent will give an 'invalid result'. The customer simply has to add *two more* drops to complete the test.

Follow up advice

It is a requirement of medical device regulations that users of self test kits are informed to speak with their doctor before acting on the result of their test.

This information is provided in the instruction leaflet with each test.

Although we are happy to provide customers with information to help them use the test or interpret their results, we are not allowed to provide any personal medical advice.

A card is included with SELFCheck tests with information on how to contact us for advice.

- **Scientific, clinical and regulatory staff available for customer support**
- **Over 25 years experience in developing new self test devices**



Any questions?

If you have any questions, whether technical, regulatory or anything else self test related we'd love to hear from you!

email: help@jrbiomedical.com

phone: 01745 535 207

web: www.selfchecktests.com

twitter.com/selfchecktests

facebook.com/selfchecktests

