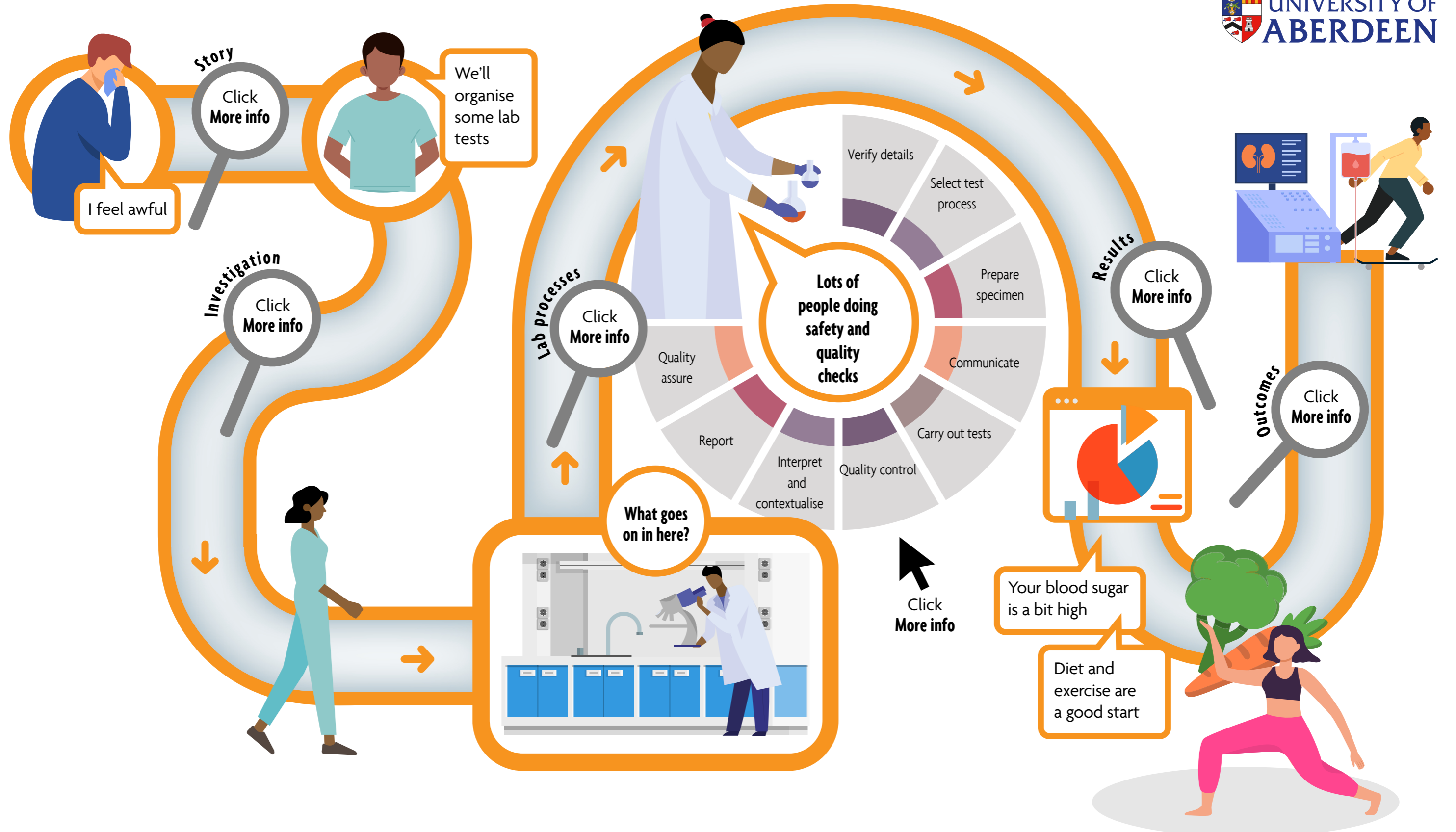


# Patient safety depends on pathologists and laboratories



The Royal College of Pathologists  
Pathology: the science behind the cure



# Story

For you as the patient, the 'laboratory test' that has been requested by your GP may require you to have a sample of blood taken from a vein in your arm, or to give a sample of urine, a swab from your throat or another sample of body fluid or even tissue (a biopsy). Once you have provided the sample, your part of the 'laboratory test' is finished – but the real test happens in the laboratory where trained doctors and scientists analyse the sample on specialised instruments and/or examine the specimens under the microscope. Let's look at a blood sample.



**Common symptoms of hyperglycemia, which is a high level of sugar (or glucose) in the blood stream:**

**Increased thirst**

**Passing increasing amounts of urine**

**Feeling tired**

**Blurred vision**

**Feeling sick**

**Losing weight without trying**

**Breath that smells 'fruity'**

**Stomach pain (especially in children)**

**Slow healing of infections**

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# Investigation

Your GP will investigate the cause of your symptoms. Many specialties within pathology may be involved in helping your GP make the correct diagnosis.



## Using diabetes as an example:

### **Clinical biochemistry:**

blood tests to assess blood glucose, renal function and blood fats such as cholesterol. Also urine test for protein to screen for kidney damage.

### **Haematology:**

tests to check blood cell count and haemoglobin.

**Immunology:** diabetes autoantibodies may help distinguish between type 1 and type 2 diabetes if the diagnosis is unclear.

**Genetics:** tests may be performed to detect specific gene alterations associated with rarer forms of diabetes.

# Laboratory processes

After the sample has been collected and labelled, it is transported to the laboratory to be booked in. Depending on the test needed and where you have the sample taken, your blood may go to the laboratory in the local hospital, or it may be sent to a laboratory that specialises in analysing samples for a particular test and interpreting the results.

Once the specimen arrives in the laboratory, a number of different staff in the laboratory will be involved in the care of your samples.



First, medical laboratory assistants will check your details on the sample sent and the matching request form to ensure all the relevant details are present to allow us to unequivocally identify who the sample belongs to. In addition, important information around the time and date of sample collection and the consultant or GP who is in charge of your care will be required.

The medical laboratory assistant staff will then program all this important information, along with the tests requested, into the laboratory computer system. This system connects to the different laboratory analysers and passes on all the relevant information to allow testing to progress.

In some laboratories it is necessary to spin the samples in a centrifuge at high speed to separate the cells from the fluid part of blood called serum or plasma.

After these initial checks and processing have finished, your sample is sent to the relevant scientists to conduct the tests.

Biomedical scientist (BMS) staff are in charge of operating the laboratory analysers used to test your sample.

In modern-day laboratories the vast majority of tests are carried out using high-tech automated analysers, which are capable of analysing a high number of tests in a short period (for example up to 2,000 tests per hour in some cases).

High-throughput laboratories operate on a 24/7 basis receiving samples from both hospital wards and general practice. Many of these analysers are never turned off!

Each day before patient samples are loaded, a number of quality checks are performed for each analyser. One of the checks will be to perform the required daily maintenance and checks as instructed by the manufacturer. An important safety check carried out by BMS staff will be to run quality controls – these are samples purchased with a known amount of each test compound present. The results of these quality controls are checked to make sure these fall within the set limits set by the laboratory. Only when all the conditions are met and quality checks are passed will that analyser be used for your sample.

**Did you know?** Some large biochemistry laboratories offer over 100 different tests and can generate up to 2,500 quality control results per day. And suitably trained laboratory scientists spend time going through each of these to ensure the required targets are met. When quality checks fail then that particular test or analyser will not be used for patient samples until it is repaired.



# Results

A number of further checks are performed before your test results are sent back to your GP or consultant.

First, test results will be checked against set credibility limits. This allows for any errors in terms of analyser miss-sampling or a problem sample to be detected. Problem samples can include samples where there has been contamination, for example from a patient intravenous line. Laboratory scientists are trained to pick up these errors and to stop any wrong results being reported and the wrong diagnosis or treatment being given.



Once the validity of the test results are confirmed these are then released to the laboratory IT system. Clinically important results may be automatically highlighted at this stage and held for further action. This may involve BMS staff communicating the result directly to the responsible consultant or GP or passing the result onto the clinical team.

Clinically trained staff such as clinical scientists and medical doctors also work in many hospital laboratories. They will usually be involved in the review of any such clinically remarkable results. They will compare these with other/previous test results and consider any medication a patient may be on that could be known to cause such a result pattern. These highly trained specialists in laboratory medicine may also suggest further tests that can be performed on the sample already tested, to help make a more definitive diagnosis. They may also contact the consultant or GP in charge of your care to communicate the result directly and ensure that it is acted on and followed up immediately. In the case of blood sugar, any levels that are significantly raised above a critical concentration are immediately communicated to your GP surgery or ward (if you are an in-patient).



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# Outcomes

Once your GP has seen the result from the laboratory they will be able to decide the most appropriate treatment and follow-up required and what the urgency of this might be.

In the case of a high blood sugar, this could be a sign of diabetes and you will be referred to the appropriate diabetic or endocrine specialist to take over your care and provide you with the required medications and lifestyle advice to help manage your condition.



# Verify details

**There are a number of steps we will take in the laboratory to ensure that the details on the specimen match with your records.** Trained skilled laboratory staff – scientists, medically qualified staff and other staff – are involved at every step of the pathway of a sample through the laboratory. People are at the heart of the laboratory, just as they are for every bit of the health service.

1

Many laboratories receive millions of samples from hundreds of thousands of patients every year. When a specimen arrives in an accredited laboratory, the information about it needs to be correct.

2

Is the sample what it says it is? For example, is it blood or urine, or a biopsy?

3

Are the patient details correct? Do they fit with existing records in the hospital or community? We check all these records to make sure we log the sample to the right patient.

4

Is it clear who requested the test and can we identify to whom to send the result of any test, analysis or interpretation? We need to ensure the information is being sent to the person who can act on results to the patient's benefit in a timely and appropriate way.

5

Can we carry out the test requested on the sample sent? The range of processes we can follow varies with the specimen type.

**These are vital steps in ensuring patient safety – we need to know the sample is yours and no-one else's.**

We then need to book the specimen into the Laboratory Information Management System to enable us to follow its progress through the laboratory and ensure the right processes are undertaken to allow us to provide the right result.

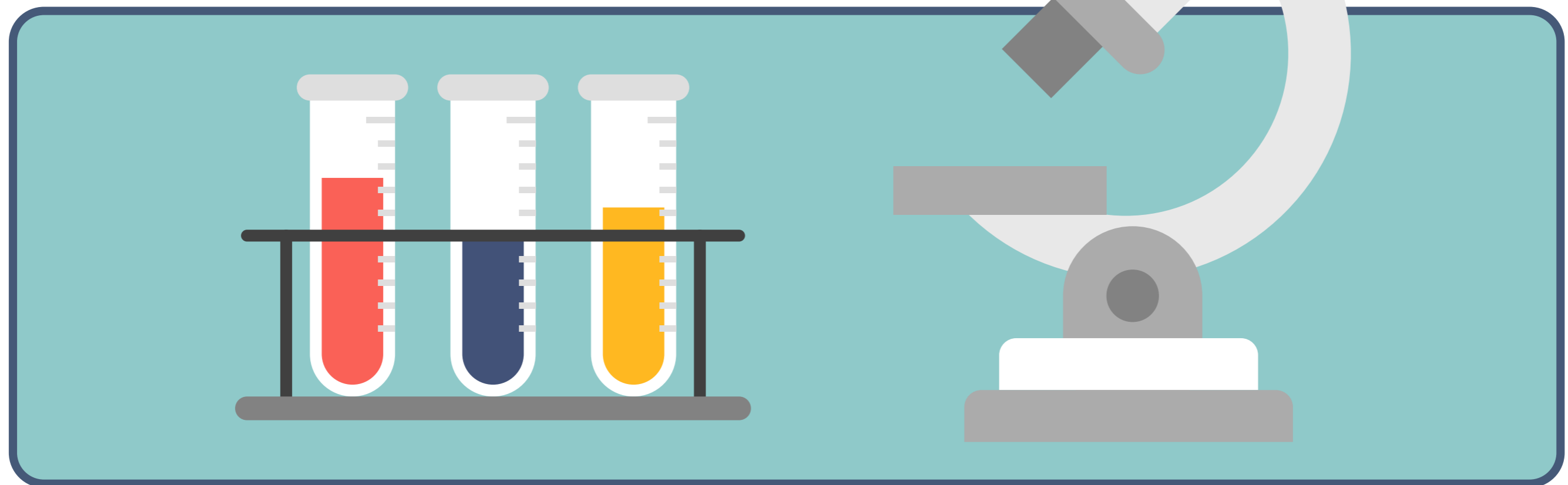


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# Select test process

We, the staff in the laboratories, need to make sure we send the specimen in the laboratory for the right test. If it is a biopsy, for example, it may need to be fixed in chemicals (usually formalin) to prevent decay and help with processing; it will need to be described and, often, dissected before processing.

In the case of blood or other fluid samples, we need to choose the right analytical process and analyser to carry out the test.



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# Prepare sample

1

Many samples arrive in containers that can be loaded into analysers.

2

Blood, for example, can be analysed as it is to count the number and nature of blood cells.

3

It may be necessary to remove the cells to leave the plasma and serum for biochemical analysis, for instance.

4

Other samples, like swabs, need to be transferred to other equipment.

5

Biopsies will need to be counted, measured, described and often dissected so samples can be taken for processing and later analysis.

**Trained skilled laboratory staff – scientists, medically qualified staff and other staff – are involved at every step of the pathway of a sample through the laboratory.**



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# Communication

Getting the right information to the right person who will act on it appropriately is necessary to ensure high-quality, safe and effective clinical care. We rely on IT systems, paper and verbal communication to ensure this occurs.



# Carry out tests

1

Many specimens are sent for specific tests, such as measuring the level of chemicals (e.g. glucose or sodium) in the blood. These tests provide data that allow appropriate treatment to be undertaken.

2

In other specimens, such as in medical microbiology or virology, we identify the presence of abnormal and harmful organisms like MRSA or COVID-19. The test results may indicate that treatment with specific drugs is required, or may have implications for ongoing care, for example, isolation or barrier nursing.

3

Immunology and biochemistry tests will also identify proteins or other substances that are not normally present but are in certain conditions and diseases, allowing us to provide diagnostic information.

4

Cellular pathology and haematology morphology use various methods to allow staff to look at tissue architecture and the cells that constitute the tissues. We use techniques that help us identify specific types of cell and others that help us to classify cell types according to what is in the cell, on its surface or in the DNA within its nucleus.

5

In genetics, we are looking at tiny fragments of DNA or RNA using techniques that allow us to identify these and their structure. This, in turn, shows abnormalities in these molecules that we can relate to what is wrong with the patient in question. Again, drugs can be selected on the basis of these findings and the outcome can be predicted.

**Trained skilled laboratory staff** – scientists, medically qualified staff and other staff – are involved at every step of the pathway of a sample through the laboratory and provide safe and reliable information with which patients' illnesses can be treated.



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# Quality control

**We need to be sure a result is what it looks like.** We must constantly check that our systems and processes are accurate, reliable and consistent.

1

**Internal quality control** – we run samples of known nature through our systems and on every occasion we check to be sure the result is the same. This is part of a continuous quality improvement process in each laboratory.

2

**External quality assurance** – we participate in nationally organised schemes that oversee the quality of laboratory systems and processes. We are sent material to process that assess our accuracy and we receive feedback on the results.

3

**We carry out audits** – we randomly select cases coming through the system and retest them to check the results are the same. We check levels of agreement in interpretative specialties to ensure we have similar opinions as to the nature of what we are seeing and observing and its clinical significance.

**Each of these steps requires leadership and input from trained skilled laboratory staff** – scientists, medically qualified staff and other staff.



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# Interpret and contextualise

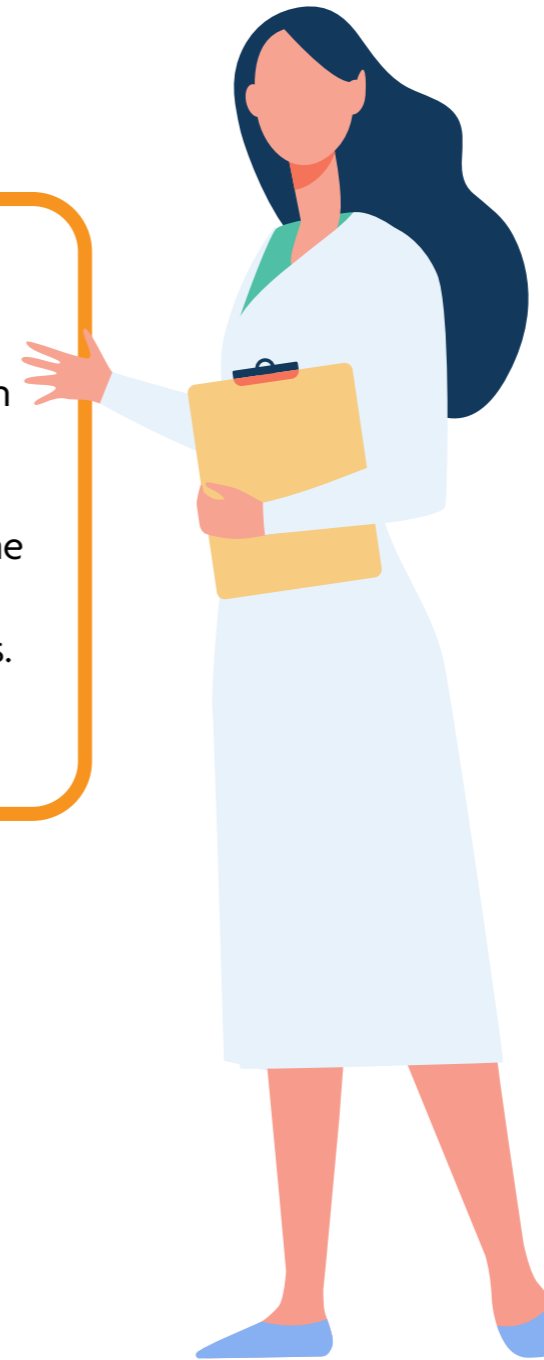
Some pathology disciplines report data, like biochemical concentrations and blood cell numbers. Others require interpretation by trained skilled laboratory staff – scientists, medically qualified staff and other staff.

1

In cellular pathology, for example, we observe, analyse these observations and interpret them in the context of the specimen, the patient and their current clinical situation. These reports provide evidence, for example, of the presence of cancers, the type of cancer and severity, the prognosis and outlook, and the susceptibility of the cancer to drugs or other intervention.

2

Similar interpretation occurs in haematology and genetics in which we provide a clinically relevant opinion about the nature of the results obtained and their significance to the patient's condition. Again, the outcome can be predicted and drugs can be selected on the basis of these findings.



# Report

The report contains the result of any test, analysis or investigation.

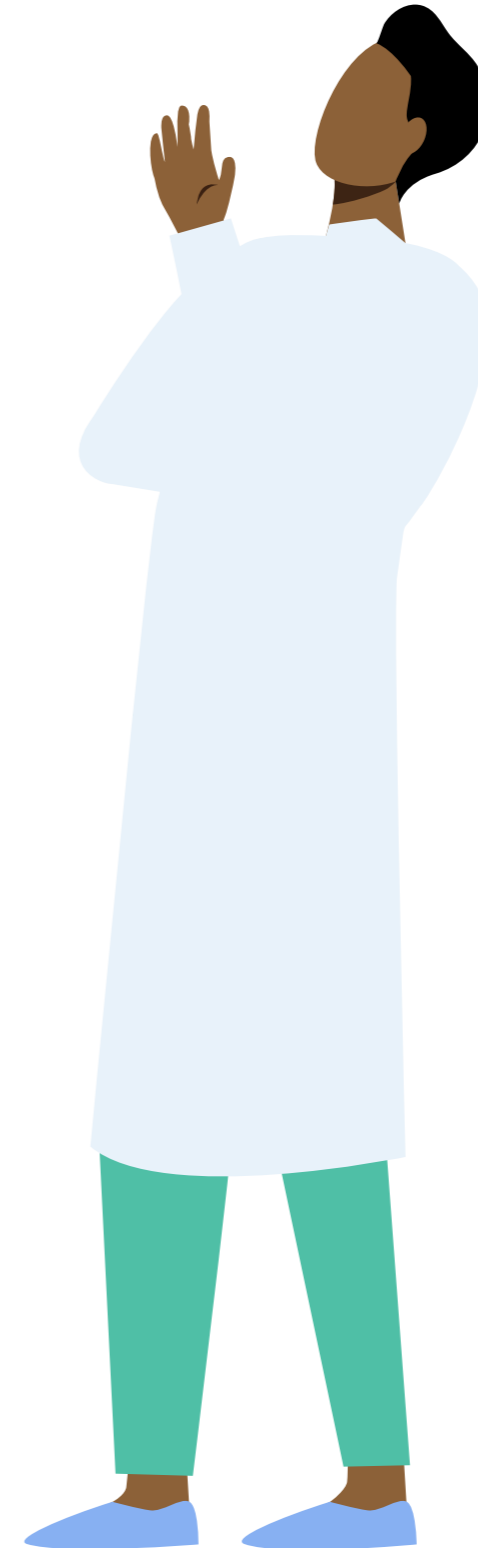
1

In blood sciences, the report – a series of numbers in association with expected normal ranges – is generated by the analyser and verified by a trained and skilled staff member, either a scientist or a medical doctor.

2

In the interpretative disciplines, like cellular pathology, the report is created by the pathologist. It contains a summary of the clinical condition, a description of what was received by the laboratory, followed by observations made and how these are interpreted together with guidance on their potential significance for the patient's management and care.

These reports provide timely, accurate and reliable information on which to base the safe and effective care of patients. They are the result of careful processes, analyses, assessments and interpretations, each one of which requires collaborative collective working by individuals from several staff groups to one end.



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# Quality assurance

The quality of reporting is set by nationally agreed standards led by the Royal College of Pathologists and other medical royal colleges and faculties. NICE, SIGN and many specialist societies play an important role in creating these standards based on the most up-to-date evidence. Quality assurance is about measuring our work against these standards, learning where we can do better and working to ensure we do so.

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