Background pattern

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**Year 10 – Teacher Booklet B (Triple)**

Key Stage 4 Science:

**Infection & Response**

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**This booklet is for use in your Science lessons. Please look after it in the same way you would your exercise book and ensure that your presentation is always PROUD.**

**Ensure that your booklet is returned to your class book box at the end of the lesson.**

**Lesson Breakdown**

Lesson 1: 4.3.1.1 Communicable diseases

Lesson 2: 4.3.1.2 – 4.3.1.4 Viral diseases, bacterial diseases, fungal diseases

Lesson 3: 4.3.1.2 – 4.3.1.4 Viral diseases, bacterial diseases, fungal diseases

Lesson 4: 4.3.1.5 Protist diseases (including malaria)

**Lesson 5 (HT only): 4.3.3.1** **Detecting and identification of plant diseases**

**Lesson 6: 4.3.3.1 Plant defence responses**

Lesson 7: 4.3.1.6 Human defence systems (barriers and symptoms)

Lesson 8: 4.3.1.6 Human defence systems (white blood cells)

Lesson 9: 4.3.1.7 Vaccination

Lesson 10: 4.3.1.8 Antibiotics and painkillers

Lesson 11: 4.3.1.9 Discovery and development of drugs

Lesson 12: 4.3.1.9 Discovery and development of drugs (placebo effects,

double blind trials etc).

**Lesson 13 (HT only): 4.3.2.1 Producing monoclonal antibodies**

**Lesson 14 (HT only): 4.3.2.1 Uses of monoclonal antibodies**

**Keystone words**

Microorganism

Communicable

Pathogen

Vector

Response

Infection

Resistance

Immune

**Lesson 7: Human defence symptoms**

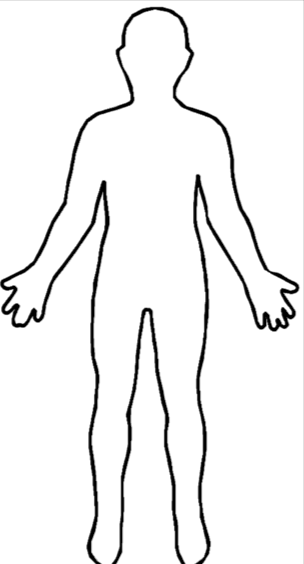
**Objective: By the end of this lesson, you will be able to explain how the human body uses three non-specific defences to combat pathogens.**

**Skills Drill / Retrieval**

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**Connect**

List the different ways that pathogens can enter the body



The trachea contains goblet cells that release mucus.

The mucus is a physical barrier that traps pathogens.

Ciliata on ciliated epithelial cells waft the mucus to the top of our throats and so remove pathogens from the airways.

The purpose of the mucus in our respiratory system is to trap dust and pathogens.

In a dusty area, the dust is trapped which makes the mucus appear black.

**I DO**

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**In an area where there is a lot of air pollution or somewhere very dusty and dirty, the mucus produced is black in colour when the nose is blown. Explain why.**

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The skin is a physical barrier that prevents pathogens from entering tissues. The skin can repair itself quickly.

The airways contain goblet cells that release mucus. This traps pathogens. The mucus is moved to the top of the throat by cilia on ciliated epithelial cells.

The stomach produces hydrochloric acid. This is mixed with food. The acid kills pathogens in the food.

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**WE DO / YOU DO -** The figure below shows some of the ways that the body defends itself against infectious diseases.

Diagram

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(d)  Describe how the skin, airways and stomach defend against diseases.

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**Lesson 8: Teacher notes**

**AQA Content**

**Students should be able to** explain the role of the immune system in the defence against disease.

If a pathogen enters the body the immune system tries to destroy the pathogen.

White blood cells help to defend against pathogens by: • phagocytosis • antibody production • antitoxin production..

**Key direct and explicit teacher explanations:**

1. The immune system protects us from **pathogens; pathogens** are micro-organisms that cause harm (e.g. bacteria, viruses, fungi and protists). Our bodies have **specific** and **non-specific** responses to pathogens. **Non-specific** responses attempt to address all **pathogens**. For example, the skin acts as a **barrier** to prevent all **pathogens** entering our organs and tissues.

If a **pathogen** does enter the body, the uses **specific responses** involving white blood cells; the processes involved are very complicated but there are three general strategies. The white blood cells respond to specific **pathogens** (e.g. a specific strain of SARS-Cov-2) and specific **toxins** that bacteria produce.

1. Some white blood cells, called **macrophages**, find and **engulf** pathogens and then **digest** them. They use enzymes to digest the pathogen. This process is called **phagocytosis**.
2. All cells and viruses have **antigens** on their surface. These help white blood cells to recognise which cells are foreign and which cells are part of the **organism**.

White blood cells use the **antigens** to identify foreign cells. Once they have done this, they then produce **antibodies** that **adhere** to the **antigen** on the surface of the pathogen and cause them to clump together (this is called **agglutination**). This is a signal to other white blood cells to **engulf** and **digest** the pathogen. The body retains the ability to produce the **antibodies** very quickly and in large amounts; this protects the body from re-infection. The body can do this because it has a type of white blood cell called a **memory cell**.

1. Some pathogens, including bacteria, release **toxins** (poisons) into the body. The **toxins** cause some of the symptoms of the infection. Some white blood cells identify the *toxins* in the body and make **antitoxins**. The **antitoxins** are released into the blood. When they find a **toxin** molecule they break it down.

**Chunking**

1. Specific and non-specific immune responses
2. Phagocytosis
3. Antibody production
4. Antitoxin production

**Teacher notes (e.g. key questions, examples, non-examples, explanations)**

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**Lesson 8: Specific human defence symptoms**

**Objective: By the end of this lesson, you will be able to explain how the human body uses three specific defences to combat pathogens.**

**Skills Drill / Retrieval**

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**Connect**

State the different components of blood & describe the function of each

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1. Macrophages find, engulf and digest pathogens.
2. Produce antibodies that adhere to antigens on the surface of specific pathogens. They cause the antigens to agglutinate / clump together.
3. Produce antitoxins that are released into the blood. They find and break down toxins that are released by bacterial cells.

Bacteria release toxins into the body. The antitoxins find and break down the toxin molecules.

Antibodies attach to the antigens of specific pathogens. They cause pathogens to clump together (agglutinate). Other white blood cells then destroy the pathogens.

Describe the roles of white blood cells when a pathogen enters the body.

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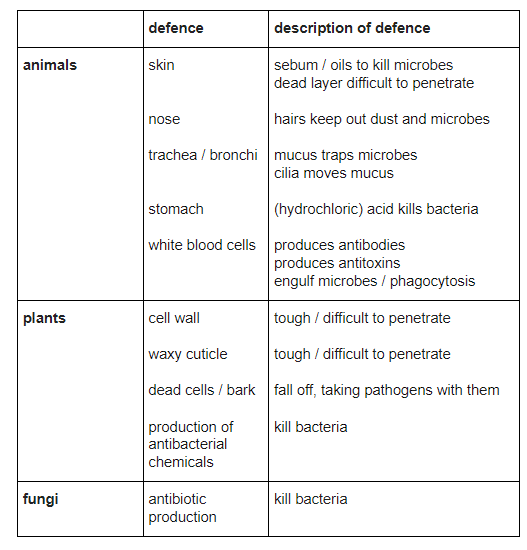
White blood cells make and release antitoxins and antibodies when you have a bacterial infection.

Explain why they release both antitoxins and antibodies.

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Description automatically generated



Explain how different **types of organism** defend themselves against microorganisms.

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Describe the role of memory cells in protecting our bodies from future infections.

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After an infection, a type of white blood cell called a memory cell remains in the body.

If the pathogen reinfects the body, the memory cells can cause massive amounts of antibodies, specific to the pathogen, to be released into the blood very quickly.

**Lesson 9: Teacher notes**

**AQA Content**

**Students should be able to** explain how vaccination will prevent illness in an individual, and how the spread of pathogens can be reduced by immunising a large proportion of the population.

Vaccination involves introducing small quantities of dead or inactive forms of a pathogen into the body to stimulate the white blood cells to produce antibodies. If the same pathogen re-enters the body the white blood cells respond quickly to produce the correct antibodies, preventing infection. **Students do not need to know details of vaccination schedules and side effects associated with specific vaccines.**

WS 1.4 Evaluate the global use of vaccination in the prevention of disease.

**Key direct and explicit teacher explanations:**

1. **Communicable** diseases spread from one **organism** to another. This can be prevented if **herd immunity** exists in a **population**. **Herd immunity** occurs when the majority of a **population** are **immune** to a **communicable** disease. For example, of the majority or the **population** have been **vaccinated** against a disease, it is very unlikely that **unvaccinated** people will catch the **communicable** disease. This is because they are very unlikely to meet somebody who has the **communicable** disease.

**Herd immunity** can also occur if the majority of the **population** has been infected with the **pathogen**. However, this only works if the **pathogen** has a **stable strain.**

1. A vaccine contains small quantities of a dead or **inactive** form of a **pathogen**; this contains antigens that white blood cells respond to. When the **vaccine** is introduced into the body, white blood cells respond as if the live **pathogen** is there:

White blood cells use the **antigens** to identify foreign cells or viruses. Once they have done this, they then produce **antibodies** that **adhere** to the **antigen** on the surface of the dead or inactive pathogen and cause them to clump together (this is called **agglutination**). This is a signal to other white blood cells to **engulf** and **digest** the dead or inactive pathogen. The body retains the ability to produce the **antibodies** very quickly and in large amounts; this protects the body from re-infection. The body can do this because it has a type of white blood cell called a **memory cell**

1. If a **vaccinated** person is exposed to the **live pathogen**, the body has a **very rapid and strong response**. White blood cells can make the correct **antibodies** very quickly and in large quantities. The **pathogen population** is killed very quickly so they do not produce a large enough **population** to cause the disease. This also means that the **population** is too small to produce enough **toxin** to cause symptoms.

**Chunking**

1. Herd immunity
2. What do vaccines contain? How does the body respond to vaccinations?
3. How does a vaccinated person’s body respond to an infection?

**Teacher notes (e.g. key questions, examples, non-examples, explanations)**

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**Lesson 9: Vaccinations**

**Objective: By the end of this lesson, you will be able to explain how vaccinations and herd immunity are used to fight disease.**

**Skills Drill / Retrieval**

|  |  |  |
| --- | --- | --- |
| Answer | | PA / SA |
| 1 |  |  |
| 2 |  |  |
| 3 |  |  |
| 4 |  |  |
| 5 |  |  |

**Connect**

State and describe five different ways of preventing spread of disease

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2. No open rubbish bins or stagnant water – removes breeding grounds for insects which act as vectors (e.g. for malaria)
3. Provide safe drinking water or means to boil / treat water – reduces microbial contamination
4. Isolate infected people to reduce exposure of others
5. Avoid overcrowding – reduces transmission of airborne disease
6. Healthy diet – to build the immune system

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A vaccine contains small quantities of a dead or inactive form of a pathogen; this contains antigens that white blood cells respond to. The white blood cells produce antibodies.

Memory cells are also produced. These respond to the live pathogen by producing massive amounts of the specific antibody quickly.

Herd immunity occurs when the majority of a population are immune to a disease. For example, if they have been vaccinated or if most of the population have had the disease.

Unvaccinated people are protected because they are very unlikely to encounter a person who is carrying the disease.

Describe the concept of herd immunity.

Explain how herd immunity can prevent unvaccinated people from contracting a communicable disease.

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Explain how vaccination makes a person immune to a disease.

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•   dead / inactive / weakened form of pathogen / bacterium / microorganism is introduced / injected

*allow introduce / inject antigen(s) from the pathogen*

*allow dead / inactive / weakened form of Gonorrhoea (bacteria) introduced / injected*

*do****not****accept inject Gonorrhoea disease*

•   white blood cells stimulated to produce antibodies

*do****not****accept incorrect white blood cell, eg phagocyte*

•   reference to memory cells made or remain

•   on re-exposure specific / correct antibodies are made (very) quickly

*allow on re-exposure specific / correct antibodies are produced in large quantities*

•   bacteria / pathogens / microorganisms killed and do not produce a large enough population to cause the disease

*allow bacteria / pathogens / microorganisms killed and do not produce a large enough population to produce toxins*

Gonorrhoea is a bacterial disease.

A new vaccine is being developed against gonorrhoea.

Describe how a vaccine would work to prevent gonorrhoea.

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**Level 3:** Relevant points (comparisons / reasons) are identified, given in detail and logically linked to form a clear account.

**5−6**

**Level 2:** Relevant points (comparisons / reasons) are identified and there are attempts at logical linking. The resulting account is not fully clear.

**3−4**

**Level 1:** Points are identified and stated simply, but their relevance is not clear and there is no attempt at logical linking.

**1−2**

**No relevant content**

**0**

**Indicative content**

**differences (after exposure to measles virus):**

•   greater number / higher concentration of antibodies produced

•   quantitative statement, e.g. 9 times higher **or** 0.8 to 7.2

•   antibodies produced sooner − idea of immediate response

•   antibodies produced quicker

•   antibodies stay (in higher concentration) for longer

**explanation**

•   white blood cells / leucocytes / lymphocytes / B cells

    ignore phagocytes / macrophages

•   reference to previous exposure (of white blood cells) to pathogen / virus

•   (white blood cells) recognise pathogen / virus / antigen

•   memory cells

•   production of specific / correct antibodies

Icon

Description automatically generated

The graph below shows the concentration of measles antibodies in the blood of a boy.

Chart, line chart

Description automatically generated

Explain the differences between antibody production after the vaccine injection and after exposure to the measles virus.

You should include data from the graph above.

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Small pox and cow pox are very similar viruses.

When exposed to the cow pox virus, Phipps’s white blood cells would have reacted by producing antibodies to suppress / destroy the virus.

His body would also have produced memory cells.

When infected with the small pox virus, Phipps’s memory cells would have produced large amounts of antibodies very quickly. The antibodies would destroy the small pox virus because it was very similar to the cow pox virus (so it had similar antigens).

**Edward Jenner – the first vaccination**

1. Edward Jenner tested the hypothesis that infection with cowpox could protect a
2. person from smallpox infection.
3. Cowpox is an uncommon illness in cattle, usually mild, that can be spread from a cow to
4. humans via sores on the cow. During an infection, dairy workers may have pustules on
5. their hands. Sufferers can spread the infection to other parts of the body.
6. We know now that the cowpox virus belongs to the Orthopox family of viruses.
7. Orthopox viruses also include horsepox virus, monkeypox virus, and variola virus, which
8. causes smallpox.
9. On May 14, 1796, Jenner inoculated eight-year-old James Phipps with matter from a
10. cowpox sore on the hand of milkmaid Sarah Nelmes.Phipps suffered a local reaction and
11. felt poorly for several days but made a full recovery. In July 1796, Jenner inoculated Phipps
12. with matter taken from a fresh human smallpox sore, as if he were variolating the boy, in an
13. attempt to challenge the protection from cowpox. Phipps remained healthy. Jenner next
14. demonstrated that cowpox matter transferred in a human chain, from one person to the
15. next, provided protection from smallpox.
16. Jenner was not precisely sure about the nature of the cowpox material he used. He
17. suspected that cowpox actually came from horsepox; in other words, he speculated that
18. cows became infected with the same agent that caused a similar disease in horses. Recent
19. genetic analysis ofold samples of smallpox vaccine have revealed that the samples were
20. more closely related to horsepox virus than cowpox virus.

**Edward Jenner did not understand why his procedure protected people from smallpox.**

**Use your knowledge of vaccinations and white blood cells to explain why his procedure worked.**

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**Lesson 10: Teacher notes**

**AQA Content**

Painkillers and other medicines are used to treat the symptoms of disease but do not kill pathogens. It is difficult to develop drugs that kill viruses without also damaging the body’s tissues.

Traditionally drugs were extracted from plants and microorganisms. • The heart drug digitalis originates from foxgloves. • The painkiller aspirin originates from willow. • Penicillin was discovered by Alexander Fleming from the Penicillium mould.

**Students should be able to** explain the use of antibiotics and other medicines in treating disease.

Antibiotics, such as penicillin, are medicines that help to cure bacterial disease by killing infective bacteria inside the body. It is important that specific bacteria should be treated by specific antibiotics.

The use of antibiotics has reduced deaths from infectious bacterial diseases. However, the emergence of strains resistant to antibiotics is of great concern.

Antibiotics cannot kill viral pathogens.

**Chunking**

1. What is a drug? Here do they come from?
2. Painkillers – treating symptoms
3. Antibiotics and anti-viral drugs
4. Natural selection

**Key direct and explicit teacher explanations:**

1. **Drugs** are **substances** that modify or affect the **chemical reactions** in the body. They include illegal substances, like cocaine, and legal substances such as caffeine, paracetamol and antihistamines. Traditionally **drugs** were extracted from plants and **microorganisms**. For example:

* Digitalis is a heart **drug** that comes from foxgloves
* Aspirin comes from willow leaves
* Penicillin comes from the Penicillium mould (a type of fungi) and was discovered by Alexander Fleming.

**Drugs** are now designed and tested. However, they are often based on **substances** found in living things.

1. When you have a **communicable disease**, you might take **drugs** for several reason. These include **drugs**:

* To reduce the **symptoms** of the disease
* To kill the **pathogen** causing the **communicable disease**

Pain is a common **symptom**. Painkillers are a group of **drugs** that are used to reduce pain.

1. Some **drugs** can be used to kill **pathogens**. **Viruses** can be treated with **anti-viral** **drugs**. However, it is hard to develop **anti-viral drugs** that do not damage the patient’s **tissues**. This is why they are rarely prescribed.

**Antibiotics**, such as Penicillin, can cure **bacterial** diseases by killing the **bacteria** causing the infection; they can not be used to kill **viruses** because the drug cannot reach the **virus** when it is inside a cell**.** It is important to use **specific antibiotics for specific bacteria**; this is because an **antibiotic** will only be effective against some **bacteria.**

Doctors do not like to prescribe **antibiotics** because if they are used too much, **antibiotic resistant strains** of **bacteria** can emerge. These **bacteria** are hard to kill using **antibiotics.**

1. **Antibiotic resistant bacteria** arise due to **natural selection**. **Natural selection** enables **populations to adapt** to changes in the environment (e.g. the presence of antibiotics). **Natural selection** follows well known steps:
2. Mutations in the population cause **variation**
3. The best **adapted** individuals survive
4. Those that survive **reproduce**
5. Beneficial **genes** are passed on to offspring

**Teacher notes (e.g. key questions, examples, non-examples, explanations)**

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**Lesson 10: Antibiotics and painkillers**

**Objective: By the end of this lesson, you will be able to explain how drugs are used to treat people with communicable diseases.**

**Skills Drill / Retrieval**

|  |  |  |
| --- | --- | --- |
| Answer | | PA / SA |
| 1 |  |  |
| 2 |  |  |
| 3 |  |  |
| 4 |  |  |
| 5 |  |  |

**Connect**

Categorise the following medicines

Penicillin Advil Paracetamol Asprin Caffeine Streptomycin Digitalis Statins Ibuprofen Amoxicillin Doxycycli**ne**

|  |  |  |
| --- | --- | --- |
|  |  |  |
|  | PAINKILLERS - advil ,paracetamol, asprin, Ibuprofen  ANTIBIOTIC - Penicillin Streptomycin Amoxicillin Doxycycli**ne**  NEITHER Caffeine, Statin, Digitalis |  |

Viruses reproduce inside cells.

The antibiotics can not reach the virus once it is inside the cell.

The antibiotic may not be effective because they viruses are very different to bacteria (e.g. in terms of biochemistry, lifecycle etc).

Overuse of antibiotics in the past has caused antibiotic resistant bacteria to develop. These bacteria are hard to treat because treatments other than antibiotics need to be found.

Antiviral drugs, when they are available, can cause a lot of damage to the patient’s tissues.

They also want to avoid viruses developing widespread resistance to the drugs.

To reduce pain felt by the patient.

A patient has a viral infection.

Explain why the doctor:

1. Might prescribe painkillers

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1. Is unlikely to prescribe antiviral drugs

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1. Won’t prescribe antibiotics

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Explain why antibiotics cannot be used to treat viral infections.

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Variation exists in the population / a mutation occurred

So, some head lice are resistant to the chemical / not killed by it

These survive

And reproduce

And pass on the gene for resistance to offspring.

The shell colour and banding varies (variation)

Those with plain brown shells are camouflaged in the hedgerow

The plain brown shelled snails are less likely to get eaten

The plain brown shelled snails are more likely to survive

And reproduce

The gene for plain brown shells is passed on to offspring

Icon

Description automatically generated with medium confidence



**WE DO / YOU DO – Natural Selection**

Head lice live on people’s heads and feed on their blood.  
Head lice cause itching and people may develop open wounds from scratching.

A poisonous chemical has been used to kill head lice for many years.  
Recently, the chemical has not been as successful at killing head lice. Many head lice now survive treatment with the chemical.

Explain in terms of **natural selection** why most head lice are no longer killed by the chemical.

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**I DO – Natural Selection**

A particular species of snail has a shell which may be pink, yellow or brown. It may also be plain or have bands running round it.

The snails are eaten by song thrushes.

Explain why snails with plain brown shells are the most common in hedgerows.

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Icon

Description automatically generated with medium confidence

**WE DO / YOU DO – Natural Selection**

Penicillin is an antibiotic which stops bacteria from reproducing. It was used a lot in

the past to treat bacterial infections in humans and other animals. In many hospitals

there are now strains of penicillin resistant bacteria.

Explain how natural selection could have produced these strains of penicillin resistant bacteria.

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Variation exists in the population / a mutation occurred

So, some bacteria are resistant to the Penicillin / are not killed by it

These survive

And reproduce

And pass on the gene for resistance to offspring.

Much of the rain forests are unexplored; we do not know which species live there and how they might benefit us.

Using your knowledge of drugs and where they originate from, to explain why destroying the rain forests could harm the human population.

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 **Lesson 11: Teacher notes** 

Many drugs originate in plants, fungi etc

The rain forest contains many species, some of these haven’t been discovered yet

These species may contain useful substances

If their habitat is destroyed they might become extinct before the useful substances are discovered

Icon

Description automatically generated

**AQA Content**

**Students should be able to** describe the process of discovery and development of potential new medicines, including preclinical and clinical testing.

Most new drugs are synthesised by chemists in the pharmaceutical industry. However, the starting point may still be a chemical extracted from a plant.

New medical drugs must be tested and trialled before being used to check that they are safe and effective. New drugs are extensively tested for toxicity, efficacy, and dose. Preclinical testing is done in a laboratory using cells, tissues, and live animals.

**Key direct and explicit teacher explanations:**

1. Medicinal or pharmaceutical chemists design and make new drugs. They screen thousands of chemicals for the properties that they need a drug to have. They then modify any substances that look promising to improve their properties.
2. New medicines must be tested thoroughly before being used with people. They do this to check that the drug is safe and effective. The new drug is usually tested on cells and tissues first. They are then tested on live animals. The preclinical trials can be stopped at any point if the drug is found to be unsafe or if it doesn’t react the way it was designed to.
3. The scientists use three criteria to assess the effectiveness of a drug:
4. Toxicity
5. Efficacy
6. Dose required

If a drug has adverse effects at therapeutic doses it is said to be toxic. Some toxicity might be allowed if the benefits of the drug outweigh the problems caused by toxicity.

The efficacy of a drug is its ability to do what it was designed to do.

**Chunking**

1. Medicinal / pharmaceutical chemists
2. Preclinical trials
3. Toxicity, efficacy and dose

**Teacher notes (e.g. key questions, examples, non-examples, explanations)**

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**Lesson 11: Discovery and development of new drugs** 

**Objective: By the end of this lesson, you will be able to describe how new drugs are developed and assessed using pre-clinical trials.**

**Skills Drill / Retrieval**

|  |  |  |
| --- | --- | --- |
| Answer | | PA / SA |
| 1 |  |  |
| 2 |  |  |
| 3 |  |  |
| 4 |  |  |
| 5 |  |  |

**Connect**

Scientists need to understand the life cycle of pathogens and their vectors (if they have one) so that they can development control measures and treatments.

Mosquitoes are the vector for the protist that causes malaria.

1. Outline the life cycle of a mosquito.
2. Suggest control measures to prevent the spread of malaria.

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1. Mosquitos lay eggs. When the eggs hatch, larvae emerge. Larvae need to live in water.

The larvae develop into pupae; pupae also live in water.

Eventually the pupae, develop into adult mosquitos that can fly

1. Mosquito nets; insecticides; insect repellents; vaccination; draining paddy fields and other still bodies of water; releasing sterile male mosquito.
2. **Medicinal chemists play a vital role in the process of drug discovery, helping**
3. **to create new and more effective medicines**
4. As a medicinal chemist, you'll use a range of chemistry techniques, primarily synthetic organic chemistry and
5. data analysis tools, to design and create new pharmaceutically active molecules to combat a particular disease
6. or condition. You'll also work on improving existing pharmaceuticals.
7. Working closely with other scientists within a project team, you'll carry out biological testing of the compounds
8. that you've created to see if they're effective. You'll then analyse the results of these tests to identify how the
9. molecule could be improved until there's sufficient evidence that it works and is safe for testing in people.
10. Alternative job titles include synthetic organic chemist, (graduate) scientist and research chemist. It's important
11. to look beyond titles to the job description, to ensure you're finding roles in medicinal chemistry.

Responsibilities

1. As a medicinal chemist, you'll need to:
2. plan and conduct scientific experiments in the lab to create and refine target molecules
3. follow health and safety guidelines and safe working practices
4. undertake data analysis to assess the results of experiments and the characteristics of the molecules produced
5. ensure the structure and purity of compounds are correct
6. write up experiments accurately
7. work closely with other scientific colleagues across different disciplines
8. use computational techniques to model the properties of new molecules
9. explore how it may be possible to 'scale up' production of useful compounds that are created
10. generate reports and deliver presentations about your work for colleagues, partners and clients
11. attend and contribute to internal and external project meetings
12. liaise with partners and clients and respond to queries about the progress of your research
13. keep up to date with scientific literature
14. undertake ongoing professional development by attending training and conferences.

Salary

1. Starting salaries for medicinal chemists are between £22,750 and £33,000.
2. With experience, the salary range for medicinal chemists is between £38,300 and £83,000, with the median being £56,200.
3. General managers can earn a median salary of £82,000.
4. Salaries vary depending on a range of factors including location, the size of the company, the sector you work in
5. and the nature of the job.
6. Some employers will also offer additional benefits such as pension schemes, healthcare plans, share ownership
7. schemes and other employee lifestyle benefits.

**Questions (answer on the next page)**

1. **What do medicinal chemists do?**
2. **Which of the skills shown below would be useful if you were a medicinal chemist?**
3. **Explain your answer to question 2.**
4. **Which of the skills would be most important?**
5. **Explain your answer to question 4.**

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1. They design and create pharmaceutically active molecules

2 – 5. Answers will be variable. Students do need to justify their answers. For example:

Teamwork would be an important skill as medicinal chemists work closely with other colleagues across a variety of disciplines.

The low efficacy makes the drug ineffective. The low toxicity has no bearing on the decision in this case.

The trial should be aborted.

The drug has high efficacy and so has high potential. The low toxicity is not a barrier. So clinical trials should proceed.

Abort because the drug is too toxic to use with patients.

A possible exception would be a drug that treats a lethal condition. The benefits would outweigh the risk in tis case.



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Would you abort or continue trials of a new drug if preclinical trials showed that:

1. **I DO -** Efficacy was high and toxicity was high?

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1. **WE DO / YOU DO** Efficacy was high and toxicity was low?

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1. **WE DO / YOU DO** Efficacy was low and toxicity was low?

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Microorganisms cause infections.

The human body has many ways of defending itself against microorganisms.

(a)     Describe **two** ways the body prevents the entry of microorganisms.

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(b)     In 2014 the Ebola virus killed almost 8000 people in Africa.

Drug companies have developed a new drug to treat Ebola.

Explain what testing must be done before the drug can be tested on humans.

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**Level 3 (5–6 marks):**

A clear, logical and coherent answer, with no significant redundancy. The student understands the process and links this to reasons for clinical trials.

**Level 2 (3–4 marks):**

A partial answer with errors and ineffective reasoning or linkage.

**Level 1 (1–2 marks):**

One or two relevant points but little linkage of points or logical reasoning.

**0 marks:**

No relevant content.

**Indicative content**

* Preclinical trials
* Test on cells and tissues
* Test on live animals
* Test for toxicity
* Test for dosage required
* Test for efficacy

Skin – physical barrier

Stomach acid – chemical barrier

Mucus and cilia – physical barrier

**Lesson 12: Teacher notes**

**AQA Content**

**Students should be able to** describe the process of discovery and development of potential new medicines, including preclinical and clinical testing.

Clinical trials use healthy volunteers and patients. • Very low doses of the drug are given at the start of the clinical trial. • If the drug is found to be safe, further clinical trials are carried out to find the optimum dose for the drug. • In double blind trials, some patients are given a placebo.

WS 1.6 Understand that the results of testing and trials are published only after scrutiny by peer review.

**Key direct and explicit teacher explanations:**

1. When a new drug is being developed it needs to be tested. Scientists test for efficacy, toxicity and the required dose. The first tests are called pre-clinical tests and are performed on cells, tissues and live animals. If the test results are promising, the scientists can start clinical tests. Clinical tests are performed on humans.

In clinical trials, the drugs are tested on healthy volunteers first. This enables scientists to assess toxicity in humans. The first tests use low doses.

If this stage is successful, the drug is tested on patients with the disease. This allows scientists to assess the efficacy (whether the drug does what it is designed to do). It also enables them to determine the dosage required.

1. Trials of new drugs must be carried out carefully to avoid bias. For example, a scientist might be biased if they would receive a large bonus if the trials were successful. They might also be biased if they worked hard to develop a drug and they naturally want the trials to be successful.

Clinical trials use placebos to reduce bias. Volunteers are either given the real drug or an alternative (a placebo). The volunteers do not know if they are receiving the real drug or a placebo. The scientists then compare the results. The placebo acts as a control; by comparing the results the scientists can see the effect of the drug on patients. It also takes into account psychological effects.

1. Bias can also be reduced using a double-blind trial. In a double blind trial neither the volunteers or the scientists know which volunteers received the drug and which ones received the placebo. The data is then analysed independently.

If the trials are successful, the results are published in journals that are peer-reviewed. This means that other scientists scrutinise and check the results.

**Chunking**

1. What is a clinical trial?
2. Placebos.
3. Double blind trials.

**Teacher notes (e.g. key questions, examples, non-examples, explanations)**

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**Lesson 12: Discovery and development of new drugs**

**Objective: By the end of this lesson, you will be able to describe how new drugs are developed and assessed.**

**Skills Drill / Retrieval**

|  |  |  |
| --- | --- | --- |
| Answer | | PA / SA |
| 1 |  |  |
| 2 |  |  |
| 3 |  |  |
| 4 |  |  |
| 5 |  |  |

**Connect**

Describe the steps that might be used in preclinical trials of a new drug.

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* Test on cells and tissues
* Test on live animals
* Test for toxicity
* Test for dosage required
* Test for efficacy

**Level 3 (5–6 marks):**

A clear, logical and coherent answer, with no significant redundancy. The student understands the process and links this to reasons for clinical trials.

**Level 2 (3–4 marks):**

A partial answer with errors and ineffective reasoning or linkage.

**Level 1 (1–2 marks):**

One or two relevant points but little linkage of points or logical reasoning.

**0 marks:**

No relevant content.

**Indicative content**

•        pre-clinical trials of the new drug on cells / tissues / live animals

•        to test toxicity, dosage and efficacy

•        clinical trials / test on healthy volunteers and Ebola patients at very low doses

•        so that you can monitor for safety / side effects

•        and only then do trials to find the optimum dosage and test for efficacy

•        double blind trial / use of placebo

•        which does not contain the new drug

•        random allocation of Ebola patients to groups

•        so no one knows who has placebo / the new drug

•        peer review of data

•        to help prevent false claims



Explain why placebos are used in clinical trials.

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Explain why double-blind trials are used during clinical trials.

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**I DO -**  In 2014 the Ebola virus killed almost 8000 people in Africa.

Drug companies have developed a new drug to treat Ebola.

Explain what testing must be done before this new drug can be used to treat people.

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**Level 2:** Scientifically relevant facts, events or processes are identified and given in detail to form an accurate account.

**4−6**

**Level 1:** Facts, events or processes are identified and simply stated but their relevance is not clear.

**1−3**

No relevant content

**0**

**Indicative content**

•   given first to healthy volunteers

○   at (very) low dose

○   to test it is safe **or** to test for toxicity **or** to check for any side effects

•   then to some patients (with the disease) **or** people with the disease

○   to test for the correct / optimum dose

○   to check for any side effects

○   to test for efficacy **or** to test if it works

○   in a double blind trial

○   where neither patients nor doctors know who has the mAbs and who has a placebo (or alternative treatment)

•   reference to large trial **or** long duration **or** control variables



**Key terms:** Dose toxicity efficacy placebo double blind control

**PARTIAL RESPONSE WE DO / YOU DO**

Monoclonal antibodies (mAbs) have many uses in medicine. For example, they are

being developed for treatment of *Candida albicans*.

It has been shown that this mAbs treatment is effective in the laboratory using both:

•   infected tissue culture cells

•   infected live animals.

The mAbs treatment for *Candida albicans* is now ready for clinical trials on people.

Describe how the clinical trials should be carried out.

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**WE DO / YOU DO -**

Dravet syndrome is caused by a genetic mutation.

Dravet syndrome causes epileptic seizures. An epileptic seizure is caused by unusual brain activity.

Scientists have transferred the mutated gene for Dravet syndrome into zebrafish using genetic engineering.

This means the scientists could test a new drug to treat Dravet syndrome on the zebrafish.

Describe the processes that then need to happen to test the new drug before it can be used to treat all children with Dravet syndrome.

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**Level 2:** Scientifically relevant facts, events or processes are identified and given in detail to form an accurate account.

**4−6**

**Level 1:** Facts, events or processes are identified and simply stated but their relevance is not clear.

**1−3**

**No relevant content**

**0**

**Indicative content**

•   pre-clinical trials of the new drug on cells / tissues / live animals

•   to test for toxicity / dosage / efficacy

•   clinical trials / tests on healthy volunteers

•   clinical trials / tests on children with Dravet syndrome at very low doses

•   so you can monitor for safety / side effects

•   and only after these stages trial to find optimum dosage / test for efficacy

•   trial could be double blind / use a placebo

•   which does not contain the new drug

•   children with Dravet syndrome would be randomly allocated to the test groups

•   so no one knows who has the drug / placebo

•   comparison to existing drugs

•   peer review of data

•   to help prevent false claims

•   approval by NICE

to access **level 2** the key ideas of testing on healthy volunteers followed by testing on patients must be given

**Lesson 12: Teacher notes**

**AQA Content**

**Students should be able to** describe the process of discovery and development of potential new medicines, including preclinical and clinical testing.

Clinical trials use healthy volunteers and patients. • Very low doses of the drug are given at the start of the clinical trial. • If the drug is found to be safe, further clinical trials are carried out to find the optimum dose for the drug. • In double blind trials, some patients are given a placebo.

WS 1.6 Understand that the results of testing and trials are published only after scrutiny by peer review.

**Chunking**

1. What is a clinical trial?
2. Placebos.
3. Double blind trials.

**Lesson 13: Teacher notes**

**AQA Content**

**Students should be able to** describe how monoclonal antibodies are produced.

Monoclonal antibodies are produced from a single clone of cells. The antibodies are specific to one binding site on one protein antigen and so are able to target a specific chemical or specific cells in the body.

They are produced by stimulating mouse lymphocytes to make a particular antibody. The lymphocytes are combined with a particular kind of tumour cell to make a cell called a hybridoma cell. The hybridoma cell can both divide and make the antibody. Single hybridoma cells are cloned to produce many identical cells that all produce the same

antibody. A large amount of the antibody can be collected and purified.

**Key direct and explicit teacher explanations:**

1. Monoclonal antibodies are antibodies that are specific to one antigen. This means that they can be used to target specific chemicals or cells. The fact that they are specific makes them useful for a range of things. These include, identifying pathogens, pregnancy test kits and treatment of some diseases. Whilst they have a lot of potential, they also cause more side effects than doctors expected when they were first developed.
2. Monoclonal antibodies are made in laboratories. For them to be useful, they need to be produced in large amounts quickly. They must also be specific to one chemical or a specific type of cell in the body.

In the first step, mouse lymphocytes (white blood cells) are stimulated to produce a particular antibody. Unfortunately, the cells divide slowly so only small amounts of antibody’s are produced. Antibodies are produced more quickly by fusing the lymphocytes with a cancer cell; cancer cells divide very quickly. This cell is called a hybridoma cell; it can divide quickly and make the antibody.

Single hybridoma cells are cloned to produce many cells that produce the same antibody. The antibody is then collected and purified.

**Chunking**

1. What are monoclonal antibodies.
2. How monoclonal antibodies are made.

**Teacher notes (e.g. key questions, examples, non-examples, explanations)**

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**Lesson 13: Producing monoclonal antibodies**

**Objective: By the end of this lesson, you will be able to describe how to make monoclonal antibodies.**

**Skills Drill / Retrieval**

|  |  |  |
| --- | --- | --- |
| Answer | | PA / SA |
| 1 |  |  |
| 2 |  |  |
| 3 |  |  |
| 4 |  |  |
| 5 |  |  |

**Connect**

Monoclonal antibodies can be used to identify plant diseases.

1. List two other ways of identifying a plant disease.

Use a gardening manual or the internet.

Send the plant to a laboratory to be tested.

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1. Give one advantage and one disadvantage for one of the methods that you listed.

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Gardening manual / website: Advantage – relatively cheap Disadvantage – May not be up to date or complete.

Laboratory: Advantage – more likely to be accurate Disadvantage – Expensive.

Allow other sensible answers.

 inject the protein / it into a mouse

**1**

combine lymphocytes with tumour / cancer cells to make hybridoma (cells)

*ignore white blood cells*

*allow T or B lymphocytes*

*ignore tumour unqualified*

**1**

find a hybridoma which makes a monoclonal antibody specific to PVY

**1**

(the scientist) clones (the hybridoma) to produce many cells (to make the antibody)

*do****not****allow cloning of original stem cells*

*allow many rounds of cloning / mitosis*

**1**

**We Do / You Do**

A farmer thinks a potato crop is infected with potato virus Y (PVY).

The farmer obtains a monoclonal antibody test kit for PVY.

To make the monoclonal antibodies a scientist first isolates the PVY protein from the virus.

Describe how the scientist would use the protein to produce the PVY monoclonal antibody.

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**I Do**

  One treatment for RSV uses monoclonal antibodies which can be injected into the patient.

Scientists can produce monoclonal antibodies using mice.

The first step is to inject the virus into a mouse.

Describe the remaining steps in the procedure to produce monoclonal antibodies.

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**Lesson 14: Teacher notes**

**AQA Content**

**Students should be able to** describe some of the ways in which monoclonal antibodies can be used.

Some examples include: • for diagnosis such as in pregnancy tests • in laboratories to measure the levels of hormones and other chemicals in blood, or to detect pathogens • in research to locate or identify specific molecules in a cell or tissue by binding to them with a fluorescent dye • to treat some diseases: for cancer the monoclonal antibody can be bound to a radioactive substance, a toxic drug or a chemical which stops cells growing and dividing. It delivers the substance to the cancer cells without harming other cells in the body.

**Students are not expected to** recall any specific tests or treatments but given appropriate information they should be able to explain how they work.

Monoclonal antibodies create more side effects than expected. They are not yet as widely used as everyone hoped when they were first developed.

**Key direct and explicit teacher explanations:**

1. Monoclonal antibodies have many uses. One of the uses with the most potential is to deliver drugs or other chemicals to specific cells in living things. For example, to deliver, anti-cancer drugs directly to tumour cells. This means that only the tumour cells are affected by the drug.

This only works because monoclonal antibodies will bind to specific cells or chemicals. Monoclonal antibodies for the cell are produced in the same way that we talked about yesterday. The drug is then attached to the monoclonal antibody.

The antibodies are then injected into the patient. They travel around the body in the blood stream. When the antibodies find a target cell they bind to the antigens on its surface and the drug is released into the cell.

1. Fluorescent or coloured molecules can be attached to monoclonal antibodies instead of a drug. These can be used to identify specific types of cells in a sample. For example, cancerous cells.

Monoclonal antibodies are made as described in the previous lesson. They are made so that they are specific to the target cell or molecule. They are then added to a slide containing a sample. The monoclonal antibodies will bind to the target cell or molecule and show where they are.

This method is also used in pregnancy test kits and lateral flow tests for Covid.

**Chunking**

1. Treating diseases with monoclonal antibodies.
2. Identifying specific molecules or cells.

**Teacher notes (e.g. key questions, examples, non-examples, explanations)**

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**Lesson 14: Uses of monoclonal antibodies**

**Objective: By the end of this lesson, you will be able to explain how antibodies are used in different applications.**

**Skills Drill / Retrieval**

|  |  |  |
| --- | --- | --- |
| Answer | | PA / SA |
| 1 |  |  |
| 2 |  |  |
| 3 |  |  |
| 4 |  |  |
| 5 |  |  |

**Connect**

Monoclonal antibodies are produced using lymphocytes and tumour cells.

1. Explain why a lymphocyte is used. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Lymphocytes are white blood cells. They produce antibodies.

1. Explain why a cancer cell is fused with the lymphocyte. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Cancer cells divide very quickly. They are fused with lymphocytes to produce a hybridoma cell. Hybridoma cells can produce antibodies and divide quickly. This means that antibodies can be produced quickly.

**We Do / You Do**

  A monoclonal antibody has been produced to treat pancreatic cancer.

Explain how the monoclonal antibody works to treat pancreatic cancer.

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Describe how injecting a monoclonal antibody containing an antiviral drug for RSV helps to treat a patient suffering with the disease.

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The monoclonal antibody will bind to the virus / antigens on the virus

Bind specifically to virus

Virus is exposed to the drug

**I Do**

  Monoclonal antibodies (mAbs) are usually made using mouse lymphocytes.

*Candida albicans* infection produces serious symptoms in patients with a poor immune system.

Recently scientists have produced mAbs to *Candida albicans* using human lymphocytes produced naturally after an infection.

*Candida albicans* lives in the throat of infected patients.

A sample is taken from the throat of a patient with a suspected *Candida albicans* infection.

The sample is transferred onto a microscope slide.

Describe how the mAbs and a fluorescent dye could be used to see any *Candida albicans* pathogens on the slide.

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**We Do / You Do**

Monoclonal antibodies are used to measure the levels of hormones in the blood.

Pregnant women produce the hormone HCG.

HCG is excreted in urine.

**Figure 1** shows four pregnancy test strips.

**Figure 1**

Diagram

Description automatically generated with low confidence

(a)     Which test strip shows a negative test result?

Tick **one** box.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **A** |  |  | **B** |  |  | **C** |  |  | **D** |  |

**(1)**

(b)     Monoclonal antibodies are used for pregnancy testing.

Give **one other** use of monoclonal antibodies.

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(a)     **A**

**1**

(b)     any **one** from:

•        identify / locate specific molecules / other hormones

•        locate blood clots

•        diagnose / treat some cancers

**1**

(c)     (as) urine passes through reaction zone

**1**

HCG hormone binds to the mobile HCG antibody (in the reaction zone)

**1**

(passes up the stick) HCG hormone binds to the immobilised HCG antibodies in the results zone

**1**

(the other) antibodies which do not attach to HCG

**1**

bind to antibodies in control zone

**1**

blue dye appears in both control and results zones (to show positive result)

**1**

(c)     **Figure 2** shows the parts of a pregnancy test strip.

**Figure 2**

Diagram

Description automatically generated

The pregnancy test strip will show a positive test result when a woman is pregnant.

Explain how the pregnancy test strip works to show a positive result.

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