

1. New medicines, including vaccines, have to be tested before being made widely available.

Preclinical and clinical tests are used to assess the safety and effectiveness of new medicines.

For each test, complete the table by putting a tick (✓), in **one** box next to the test to indicate if it assesses **safety**, **effectiveness** or **both**.

For each test, one example has been done for you.

Preclinical tests	Safety	Effectiveness	Both
Cultured human cells			✓
Whole animals			

Clinical tests	Safety	Effectiveness	Both
Healthy volunteers			
Humans with the disease			✓

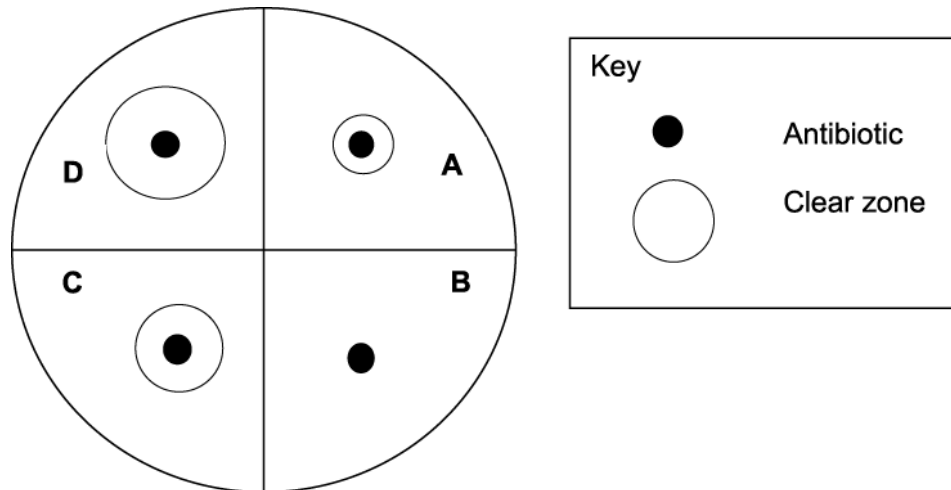
[2]

2. Jack has a bacterial infection caused by *Streptococcus pneumoniae*.

A doctor takes a sample from Jack to work out which antibiotic will kill the bacteria.

The diagram below shows the effectiveness of four different antibiotics when grown on agar jelly.

The clear zone for each antibiotic is shown on the diagram. The clear zone is the area of the bacteria that has been killed by the antibiotic. The table shows the areas of the clear zones.



Antibiotic	Clear zone (mm ²)
A	50.24
B	0.00
C	94.99
D	

(i) Using the formula πr^2 calculate the clear zone for antibiotic D.

Show your working.

$$\pi = 3.14$$

Clear zone = mm²[2]

(ii) Jack's doctor must decide which antibiotic to prescribe him.

Use the information provided at the start of this question to decide which of the following conclusions can be

made.

Put a tick (✓) in the box next to the correct conclusion.

Antibiotic A works best.

Jack should be given antibiotic A.

Antibiotic B has the least effect.

Jack should not be given antibiotic B.

Antibiotic C works best.

Jack should be given antibiotic C.

All antibiotics worked equally well.

Jack can be given any antibiotic.

[1]

(iii) The control for this test could have been a disc which did not contain any antibiotic.

State a reason for using a control in this experiment.

----- [1]

3. Swelling of the aorta is called an aneurysm. An aneurysm is repaired by inserting a plastic tube called a stent into the aorta.

In 1990, the risk of death from this operation was 5.7%.

Explain the difference between **perceived** and **calculated** risk when patients decide whether or not to have the operation.

----- [2]

4. Scientists have developed a drug that could be used to treat Ebola.

The drug was tested in a human trial.

(i) In a human trial, different treatments are given to different groups of people.

- Some groups are treated with the new drug.
- Some groups are treated with a different drug or a placebo.

Put a tick (✓) in the correct box next to each statement to show whether it is true or false.

	True	False
A placebo contains a very small amount of the new drug.	<input type="checkbox"/>	<input type="checkbox"/>
The safety and effectiveness of the drug are tested using a group of people who have the disease.	<input type="checkbox"/>	<input type="checkbox"/>
One of the groups treated with the drug is a group of healthy people.	<input type="checkbox"/>	<input type="checkbox"/>
In an 'open-label' trial, the doctor knows which treatment the patient receives, but the patient does not know.	<input type="checkbox"/>	<input type="checkbox"/>
In a 'blind' trial, neither the doctor nor the patient knows which treatment the patient receives.	<input type="checkbox"/>	<input type="checkbox"/>


[3]

(ii) Explain why it is important to test drugs in **long-term** human trials.

[2]

(iii) One woman infected with Ebola virus was not treated with drugs.

She was treated with blood taken from a man who had recovered from Ebola.

 Suggest how this could help the woman to recover and suggest reasons why this treatment might not work.

The quality of written communication will be assessed in your answer.

[6]

5(a). Helen is investigating the effect of antibiotics on the growth of bacteria.

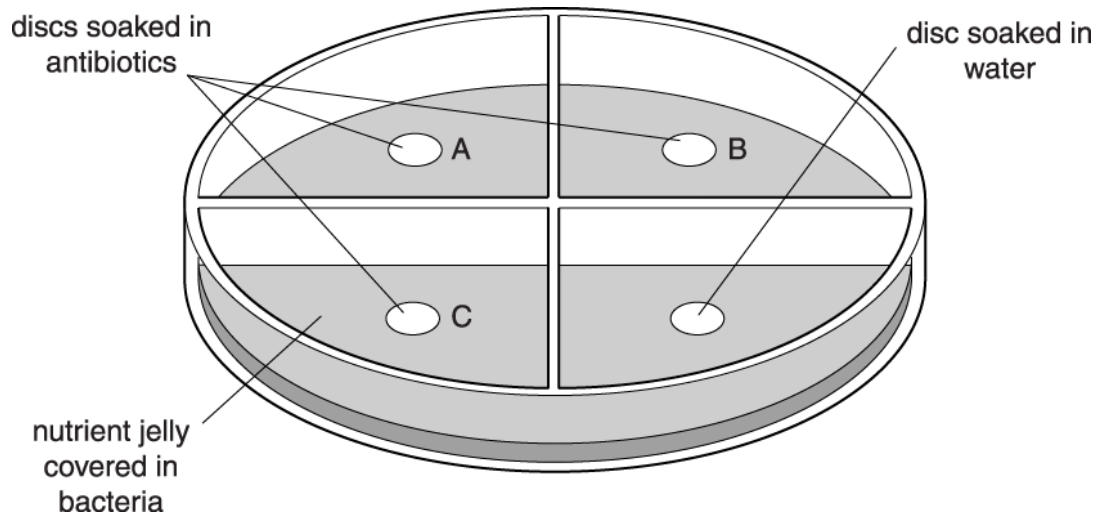
Bacteria are grown on nutrient jelly. This makes the jelly look cloudy.

Helen puts a small paper disc into each of three different antibiotic solutions, A, B and C.

She puts another paper disc into water.

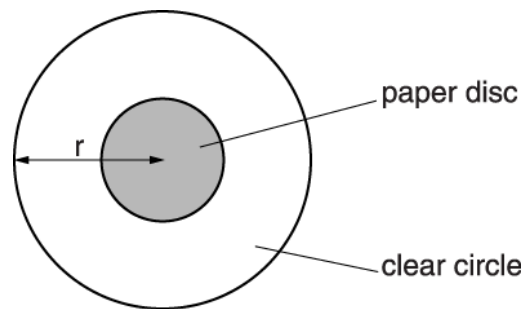
She then places all of the paper discs onto the nutrient jelly.

The diagram shows the apparatus she uses for her investigation.



After two days Helen sees clear circular areas around some of the paper discs.

Helen measures the radius (r) as shown in the diagram.



She then calculates the total area of the clear circle (including the paper disc) using the formula:
 $\text{area} = \pi r^2$ (where $\pi = 3.14$).

Here are her results.

	Radius in mm	Total area of the clear circle (including the paper disc) in mm ²
A	8	
B	14	615.44
C	3	28.26
water	3	28.26

Complete the table by calculating the total area of the clear circle (including the paper disc) for A.

Show your working below.

[2]

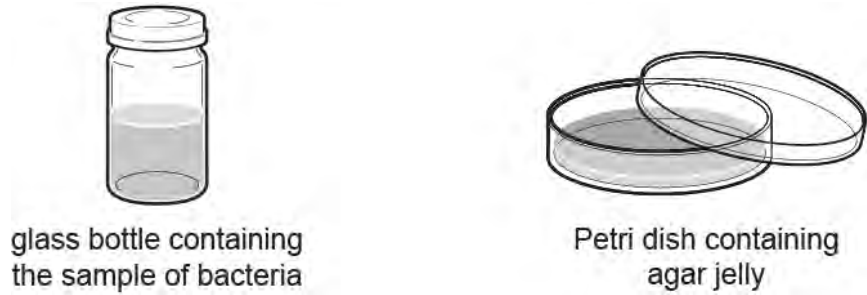
6. Amir works in a laboratory. His job is to identify pathogens that cause plant diseases.

Amir has a sample of one species of bacteria from an infected plant.

He wants to test the effectiveness of different antibiotics against this species of bacteria.

Amir must start by transferring bacteria from the sample bottle into four Petri dishes containing agar jelly.

He needs to set up four identical dishes of this species of bacteria.



He intends to pour some of the liquid from the glass bottle into each Petri dish.

(i) Write down **two** ways he could improve his method and explain why each is an improvement.

Improvement 1

.....

Explanation

.....

Improvement 2

.....

Explanation

.....

[4]

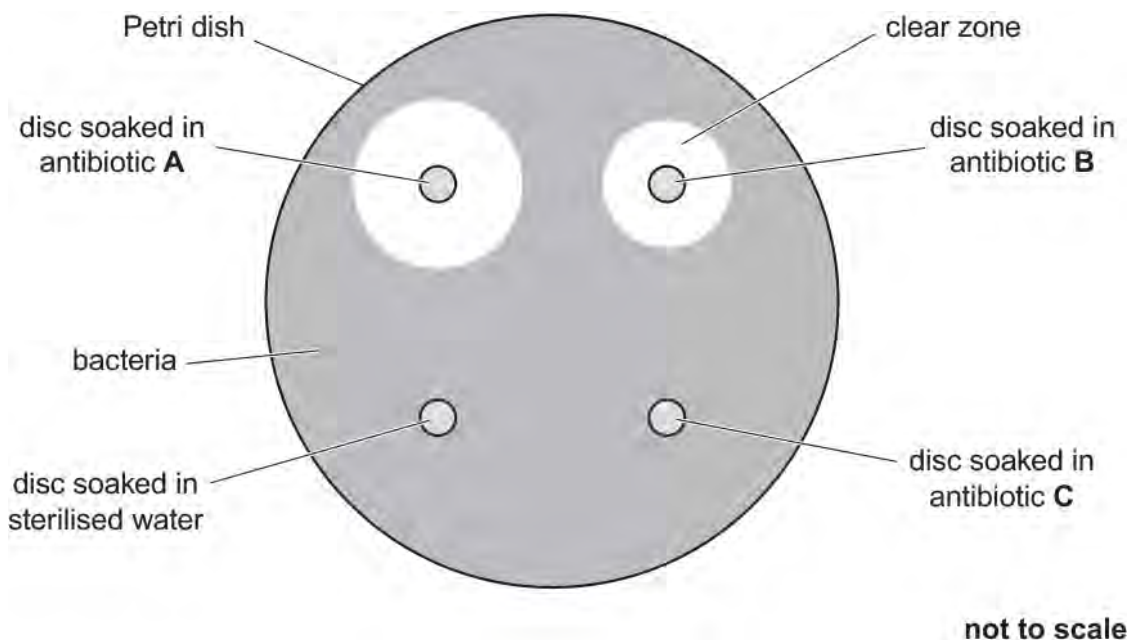
After transferring bacteria from the sample to the four Petri dishes, Amir adds four different paper discs to each dish.

The paper discs have been soaked in different solutions.

Amir places the dishes in an incubator overnight.

The bacteria grow to cover the surface of the agar jelly.

The diagram shows what Amir sees on one of the dishes after it has been incubated.



(ii) The diameter of the clear zone around the disc soaked in antibiotic A is 23 mm.

Calculate the area of this clear zone.

Use the equation: area of clear zone = $3.14 \times r^2$.

Give your answer to 3 significant figures.

Area of clear zone = mm²[3]

(iii) Table 4.1 shows Amir's results for all four dishes.

Disc soaked in	Area of clear zone (mm ²)			
	Petri dish 1	Petri dish 2	Petri dish 3	Petri dish 4
Antibiotic A		363	346	346
Antibiotic B	227	254	227	214
Antibiotic C	0	0	0	0
Sterilised water	0	0	0	0

Table 4.1

Suggest **two** possible explanations for the results for antibiotic C.

1 -----

2 -----

[2]

7. New drugs and treatments have to go through rigorous clinical trials.

A clinical trial was conducted to see if using a particular combination of chemotherapy drugs increased survival rates for a type of cancer of the ovaries.

The two drug combinations being tested were:

- drugs 1 and 2
- drugs 3 and 4.

(i) The table shows some details of the clinical trial design.

Use your knowledge of clinical trials to justify each part of the design.

Design	Justification
Only women took part in the trial.	
All women who took part in the trial had ovarian cancer.	
A placebo was not used.	
An open trial was conducted.	

[4]

The results of the trial are shown in the table.

	Group A (Drugs 1 and 2)	Group B (Drugs 3 and 4)
Number of women who took part in the trial.	305	314
Number of women who were still alive two years after treatment.	247	222
Most severe side effects.	<ul style="list-style-type: none">• A drop in total blood cell number• Nerve damage• Joint pain	<ul style="list-style-type: none">• Loss of appetite• Diarrhoea• Feeling or being sick• High temperature• Low white blood cell number

(ii) Use the information in the table to recommend which drug combination the doctors should use.

Justify your decision.

[2]

(iii) Explain why scientists should communicate findings such as these to a range of audiences.

[1]

END OF QUESTION PAPER

Question		Answer/Indicative content	Marks	Guidance																								
1		<table border="1"> <thead> <tr> <th>Preclinical tests</th> <th>Safety</th> <th>Effectiveness</th> <th>Both</th> </tr> </thead> <tbody> <tr> <td>Cultured human cells</td> <td></td> <td></td> <td>✓</td> </tr> <tr> <td>Whole animals</td> <td></td> <td></td> <td>✓</td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th>Clinical tests</th> <th>Safety</th> <th>Effectiveness</th> <th>Both</th> </tr> </thead> <tbody> <tr> <td>Healthy volunteers</td> <td>✓</td> <td></td> <td></td> </tr> <tr> <td>Humans with the disease</td> <td></td> <td></td> <td>✓</td> </tr> </tbody> </table>	Preclinical tests	Safety	Effectiveness	Both	Cultured human cells			✓	Whole animals			✓	Clinical tests	Safety	Effectiveness	Both	Healthy volunteers	✓			Humans with the disease			✓	2	Tick in correct box for mark If more than one box is ticked in each empty row, do not award the mark even if the correct box is also ticked
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		Total	2																									
2	i	FIRST CHECK THE ANSWER ON THE ANSWER LINE IF answer = 177.63 award 2 marks $\pi (7.5 \times 7.5)$ ✓ 177.63 mm^2 ✓	2																									
	ii	✓ Antibiotic B has the least effect. Jack should not be given antibiotic B	1																									
	iii	Any one from Used as a comparison ✓ To show that it is the antibiotic that has the effect ✓	1																									
		Total	4																									
3		Calculated risk is 5.7% / based on data / stats / results / numbers; Perceived risk is what the patient thinks (the risks are) / opinion;	2	Ignore risk is calculated / probability / valueb Ignore doctors opinion Examiner's Comments This question discriminated well between candidates. Many candidates struggled with this. Good answers included responses such as perceived risk is what the patients think the risk is and calculated risk includes data/statistics/numbers. Candidates should avoid tautology such as saying perceived risk is what the patient perceives and calculated risk is what the patient calculates.																								
		Total	2																									

Question			Answer/Indicative content	Marks	Guidance																		
4		i	<table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 60%;"></th> <th style="width: 20%; text-align: center;">T</th> <th style="width: 20%; text-align: center;">F</th> </tr> </thead> <tbody> <tr> <td>A placebo...</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input checked="" type="checkbox"/></td> </tr> <tr> <td>The safety...</td> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>One of the...</td> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>In an 'open-label'...</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input checked="" type="checkbox"/></td> </tr> <tr> <td>In a 'blind'...</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input checked="" type="checkbox"/></td> </tr> </tbody> </table>		T	F	A placebo...	<input type="checkbox"/>	<input checked="" type="checkbox"/>	The safety...	<input checked="" type="checkbox"/>	<input type="checkbox"/>	One of the...	<input checked="" type="checkbox"/>	<input type="checkbox"/>	In an 'open-label'...	<input type="checkbox"/>	<input checked="" type="checkbox"/>	In a 'blind'...	<input type="checkbox"/>	<input checked="" type="checkbox"/>	3	<p>ignore any row in which there is more than one tick all correct = 3 marks four correct = 2 marks three correct = 1 mark</p> <p>Examiner's Comments</p> <p>The majority of candidates were able to identify at least 3 statements concerning drug trials to score 1 mark.</p>
	T	F																					
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		ii	<p>some side-effects may only appear years after taking the drug (1)</p> <p>the drug may become less effective over time (1)</p>	2	<p>accept specific examples if clearly linked to long-term / years later</p> <p>ignore ref. to resistance</p> <p>Examiner's Comments</p> <p>Only some candidates could discuss the long term effectiveness of the drug as well as long term side effects to score full marks.</p>																		
		iii	<p>[Level 3] Answer suggests how it could help the woman AND describes why it might not work, including at least one Level 3 idea from either area. Quality of written communication does not impede communication of the science at this level.</p> <p style="text-align: right;">(5 – 6 marks)</p> <p>[Level 2] Answer suggests how it could help the woman AND describes why it might not work. Quality of written communication partly impedes communication of the science at this level.</p> <p style="text-align: right;">(3 – 4 marks)</p> <p>[Level 1] Answer suggests how it could help the woman OR describes why it might not</p>	6	<p>This question is targeted at grades up to A*</p> <p>Indicative scientific points may include:</p> <p><i>How it could help the woman:</i></p> <ul style="list-style-type: none"> • the man's blood / it may contain antibodies against Ebola virus • the man's blood may contain white blood cells against Ebola virus • the man's blood may contain memory cells • (antibodies / white blood cells from) the man's blood will help to destroy the Ebola virus <p>Level 3 idea:</p> <ul style="list-style-type: none"> • the memory cells (from the man's blood) can respond / produce antibodies more quickly (than the 																		

Question	Answer/Indicative content	Marks	Guidance
	<p>work. Quality of written communication impedes communication of the science at this level.</p> <p style="text-align: right;">(1 – 2 marks)</p> <p>[Level 0] Insufficient or irrelevant science. Answer not worthy of credit.</p> <p style="text-align: right;">(0 marks)</p>		<p>woman / patient)</p> <p>do not credit the idea that the man's blood (or virus it contains) acts as a vaccination, or contains drugs</p> <p><i>Why it might not work:</i></p> <ul style="list-style-type: none"> • the blood might not contain enough antibody / memory cells • the woman / patient might already be too ill to recover • the man's blood may be rejected / different blood type • the virus has changed / mutated / new strain <p>Level 3 ideas:</p> <ul style="list-style-type: none"> • changed / mutated / different strain / antigens virus won't be recognised by the man's antibodies / memory cells <p>ignore idea that the man's blood may cause an infection</p> <p>Use the L1, L2, L3 annotations in Scoris; do not use ticks.</p> <p>Examiner's Comments</p> <p>This question tested the full range of abilities. Many candidates produced detailed descriptions of how white blood cells work against a pathogen. Some candidates struggled with this idea in the context of the question, often discussing the concept of vaccinations, which did not gain credit.</p>
	Total	11	

Question		Answer/Indicative content	Marks	Guidance
5	a	200.96 / 201.06 / 201.14 / 201.1 / 201 (2)	2	<p>correct answer = 2 marks $3.14 \times 8 \times 8 / ? \times 8 \times 8 / ? \times 8^2 = 1$ mark</p> <p>Examiner's Comments</p> <p>Most candidates were able to calculate correctly the total area of A.</p>

Question		Answer/Indicative content	Marks	Guidance
	b	<p>[Level 3] Answer contains: description AND conclusion AND explanation Quality of written communication does not impede communication of the science at this level. (5 – 6 marks)</p> <p>[Level 2] Answer contains: description AND conclusion OR description AND explanation OR conclusion AND explanation Quality of written communication partly impedes communication of the science at this level. (3 – 4 marks)</p> <p>[Level 1] Answer contains a description OR an explanation OR a conclusion. Quality of written communication impedes communication of the science at this level. (1 – 2 marks)</p> <p>[Level 0] Insufficient or irrelevant science. Answer not worthy of credit. (0 marks)</p>	6	<p>This question is targeted at grades up to A*</p> <p>Indicative scientific points may include:</p> <p>descriptions:</p> <ul style="list-style-type: none"> • B has the greatest clear area around it • A has a clear area around it (although not as big as B) • C has no / smallest clear area around it • water has the same area as C <p>conclusions:</p> <ul style="list-style-type: none"> • B is the most effective antibiotic • A is effective against the bacteria but not as effective as B • suggests C is not effective against the bacteria • water as good as C against bacteria <p>explanations:</p> <ul style="list-style-type: none"> • antibiotics are killing / destroying or inhibiting bacteria • where antibiotics are effective the plate appears clear • bacteria may be resistant to C • mechanism of resistance • water acts as a control • to show that water / paper disc has no effect on the bacteria • allows other results to be compared against it <p>Examiner's Comments</p> <p>A good discriminator. Only some candidates were able to link correct descriptions to explanations and conclusions. Recognition that clear areas were due to antimicrobial action was required to gain level 3 marks.</p>

Question		Answer/Indicative content	Marks	Guidance
	c	controls all variables except that which is being investigated (1) Increase confidence in results (1)	2	allow keep everything the same apart from the thing being tested. have trust in results / to allow results to be compared Examiner's Comments Good responses were able to explain what a fair test is and why it is important.
	d	Any 2 from: (firstly) tested on human cells / animals (1) (subsequently) trialled on humans (1) blind trials / use of placebo (1)	2	Examiner's Comments This was a well answered question, demonstrating that candidates have secure knowledge on how drug trials are carried out.
		Total	12	

Question		Answer/Indicative content	Marks	Guidance
6	i	<p>Any two pairs of improvement + explanation from:</p> <p><i>improvement:</i> put on gloves before starting / disinfect the bench (with alcohol) before starting ✓ <i>explanation:</i> prevent/reduce risk of contaminating sample/dish ✓</p> <p><i>improvement:</i> use a wire loop to transfer bacteria from sample jar to dish ✓ <i>explanation:</i> can be flamed to prevent/reduce risk of contaminating sample/dish / regulates the amount of bacteria transferred to each sample/dish ✓</p> <p><i>improvement:</i> pass the neck of the jar through a flame before dipping wire loop in / pass wire loop through a flame (and allow to cool) before dipping into sample jar ✓ <i>explanation:</i> prevent/reduce risk of contaminating sample/dish ✓</p> <p><i>improvement:</i> idea of not taking lid fully off Petri dish ✓ <i>explanation:</i> prevent/reduce risk of contaminating sample/dish ✓</p> <p><i>improvement:</i> idea of working close to a (roaring) Bunsen flame ✓ <i>explanation:</i> prevent/reduce risk of aerial contamination of sample/dish ✓</p>	4 (AO 3.3b × 4)	<p>If only improvements given with no explanation, only a max. of 2 marks can be awarded' Explanation can only be credited if it relates to the improvement</p> <p>ALLOW suitable improvement if regulates the amount of bacteria transferred e.g. pipette/syringe</p> <p>ALLOW 'sets up a convection current' for explanation</p> <p>Examiner's Comments</p> <p>Aseptic techniques are a key element to one of the practical activities in section B2.4 of the specification and it was evident that many candidates were aware of methods involved. However, the explanations were not always linked to the improvements.</p>
	ii	<p>FIRST CHECK THE ANSWER ON ANSWER LINE If answer = 415 award 3 marks</p> <p>$3.14 \times (23 \div 2)^2$ ✓ = 415.265 ✓ = 415 (to 3 s.f.) ✓</p>	3 (AO 2.2 × 3)	<p>Examiner's Comments</p> <p>Most candidates were able to calculate the area of the clear zone. There were a number of common mistakes including the use of the diameter instead of the radius and giving the answer to 3 decimal places and not to 3 significant figures.</p>

Question		Answer/Indicative content	Marks	Guidance
	iii	<p>Any two from:</p> <p>the bacteria are resistant to antibiotic C ✓</p> <p>is not effective/does not kill the bacteria ✓</p> <p>the solution of antibiotic C was too dilute ✓</p> <p>the discs were soaked in only water by mistake ✓</p>	<p>2 (AO 3.2a × 2)</p>	<p>DO NOT ALLOW bacteria are tolerant or immune to antibiotic C</p> <p>ALLOW no antibiotic on disc / not enough antibiotic on disc</p> <p>Examiner's Comments</p> <p>Common mistakes involved the use of the word 'immune' when 'resistance' was required as well as the use of 'antibodies/antigens' instead of 'antibiotic'. Also some candidates wrongly referred to disc A as a placebo.</p>
		Total	9	

Question	Answer/Indicative content	Marks	Guidance					
7	<p data-bbox="225 237 240 259">i</p> <table border="1" data-bbox="304 271 810 891"> <thead> <tr> <th data-bbox="304 271 810 315">Justification</th> </tr> </thead> <tbody> <tr> <td data-bbox="304 315 810 427">Men do not get ovarian cancer /do not have ovaries /testing for effectiveness ✓</td> </tr> <tr> <td data-bbox="304 427 810 607">Testing for effectiveness (so patients needed to have ovarian cancer)/ drugs were to be used in ovarian cancer patients only ✓</td> </tr> <tr> <td data-bbox="304 607 810 752">Unethical as patient needs treatment/ patient could die if not treated/ placebos won't treat the cancer ✓</td> </tr> <tr> <td data-bbox="304 752 810 891">Patient needs to agree to having the treatment / neither patient or doctor can influence the survival rate ✓</td> </tr> </tbody> </table>	Justification	Men do not get ovarian cancer /do not have ovaries /testing for effectiveness ✓	Testing for effectiveness (so patients needed to have ovarian cancer)/ drugs were to be used in ovarian cancer patients only ✓	Unethical as patient needs treatment/ patient could die if not treated/ placebos won't treat the cancer ✓	Patient needs to agree to having the treatment / neither patient or doctor can influence the survival rate ✓	<p data-bbox="890 237 906 259">4</p> <p data-bbox="839 271 954 338">(AO 3.1b x 4)</p>	<p data-bbox="991 271 1262 304"><u>Examiner's Comments</u></p> <p data-bbox="991 338 1501 1167">5 (c) (i) was designed to test not only candidates' knowledge of the key terms and stages of drug trials, but whether they understood why trials would use particular methods. Most candidates did score between 1-2 marks on this question, it was rare to see a candidate scoring 4 marks. Most candidates could correctly identify why only women would be used in this trial and why it would be necessary for them to have ovarian cancer to take part in this trial. Candidates clearly understood what a placebo was but did not fully understand why placebos are not used routinely in all drug trials. Very few candidates understood why an open trial would be used in such a trial, most answers for this part focussed on what an open trial was, and candidates did not seem to be aware of the reasons to use open trials when testing drugs such as this. Centres should be encouraged to develop candidates understanding of drug trials using case studies. Examples of drug trials can be readily found on the NHS website.</p>
Justification								
Men do not get ovarian cancer /do not have ovaries /testing for effectiveness ✓								
Testing for effectiveness (so patients needed to have ovarian cancer)/ drugs were to be used in ovarian cancer patients only ✓								
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Question	Answer/Indicative content	Marks	Guidance
	<p>ii</p> <p><i>Group A because:</i></p> <p>a higher proportion/percentage of the women survived ✓</p> <p>cancer death rate is high, so increased survival outweighs the risk of the severe side effects ✓</p> <p>OR</p> <p><i>Group B because:</i></p> <p>the side effects are less severe ✓</p> <p>increased survival rate using drugs 1 and 2 does not outweigh the more severe side-effects ✓</p>	<p>2 (AO 3.2a x 2)</p>	<p>ALLOW 81% of women survived in Group A compared to 71% in Group B</p> <p><u>Examiner's Comments</u></p> <p>This question asked candidates to weigh up the evidence presented to decide what drug combination they would recommend for the treatment of ovarian cancer. Candidates were able to gain credit for selecting either drug combination, provided, they could justify their decision. For those that selected Group A (Drugs 1 and 2) many candidates did not score a mark as their analysis of the data was too superficial. Many simply considered the differences in the number of deaths and simply stated that more or less patients died, without taking into consideration the sample sizes. To access this mark candidates needed to process the data as the different number of patients used in the two trials differed. Only those candidates that processed the data were able to score the first mark point for the idea of proportion or percentage survival rate being greater. Higher ability candidates calculated and stated the percentage survival rates within their answer. This question provides a good learning opportunity to demonstrate to for future cohorts how data may need further processing beyond the basic presentation.</p> <p>An additional point worthy of note relates to candidates understanding of side effects. Many felt that because less side effects were observed in Group A, this would be a reason to use this drug combination. They did not consider the difference in the severity of the side effects.</p>

Question			Answer/Indicative content	Marks	Guidance
		iii	<p>Any one from:</p> <p>raises awareness ✓</p> <p>it allows decisions to be made based on new information ✓</p> <p>so people (doctors, nurses, NHS trusts, patients) are better informed/ education ✓</p> <p>so they can be verified/checked/peer reviewed/further tests or research AW ✓</p>	1 (AO 1.1)	<p>ALLOW examples of decisions that could be made in this context e.g what drugs to prescribe, what risks are associated with the drugs being used</p> <p><u>Examiner's Comments</u></p> <p>It was very pleasing to see a great variety of responses to this question. Candidates provided some excellent examples of reasons why scientific findings should be communicated to a wide range of audiences and it was refreshing to see candidates thinking out of the box, rather than answers that had been rote learned. Centres should be congratulated for preparing candidates to 'think' and apply their answers to the situations presented.</p>
			Total	7	