Examiners' Report – Paper A 2025

1. INTRODUCTION

1.1. General considerations

The purpose of the Examiners' report is to assist candidates in preparing for future examinations (Article 6(6) of the Regulation on the European qualifying examination for professional representatives). The Examiners' report sets out the expected solution, explains why this solution was expected, and shows how the marks were distributed. In addition, it highlights the most common mistakes and explains which deductions were made for these mistakes.

1.2. Introduction

The paper relates to lateral flow test devices which are commonly used for at-home diagnostic testing, for example for the SARS-CoV2 (COVID-19) virus or as pregnancy tests.

The client's letter explains that these tests previously used coloured latex particles in the detection agent (as a conjugate with an antibody) but they had seen significantly improved results using gold nanoparticles instead. The client also emphasises that they want to cover both COVID-19 testing and other potential uses of the device, as they hope to expand into additional markets.

Prior art document D1 describes lateral flow pregnancy tests. These devices use blue-coloured latex particles as part of the detection agent. D2 describes gold nanoparticles and their use in various contexts, for example as a conjugate with an antibody, but does not mention using these conjugates as a detection agent in a lateral flow test.

Although candidates may be familiar with these types of tests from their own personal experience, they should only rely on the information provided in the paper and must not use any of their own knowledge.

1.3. Marking scheme

Candidate's answers were awarded marks on a scale of 0 to 100 based on the following:

- Up to 40 marks for an independent device claim;
- Up to 10 marks for an independent method claim;
- Up to 10 marks for a kit claim;
- Up to 25 marks for dependent claims; and
- Up to 15 marks for the introductory part of a description.

As usual, only the lowest scoring claim in each category is awarded marks. The client explicitly states that they will not pay any additional claim fees, and therefore any claims over the 15 expected are not marked.

2. EXPECTED INDEPENDENT CLAIMS

2.1. Independent device claim

Candidates were expected to draft a single independent device claim to a lateral flow test, wherein the novel and inventive feature was a detection agent comprising a gold nanoparticle of specific size range conjugated to an antibody. The claim should also include all the features described as essential in the client's letter. A suitable independent device claim which would gain the full 40 marks is set out below:

> *A lateral flow test device for detecting a target molecule in a liquid sample, comprising;*
>
> - *a sample pad (1) for receiving the liquid sample (5);*
> - *a conjugate pad (2) downstream from the sample pad (1) comprising a conjugate (11) of a first antibody (10) specific for the target molecule (6) and a coloured particle (9); and*
> - *a reaction membrane (3) downstream of the conjugate pad (2) comprising a second antibody (12) specific for the target molecule (6) immobilized in a test line (7) across the surface of the membrane (3);*
>
> ***characterized in that*** *the coloured particle (9) is a spherical gold nanoparticle with a diameter of 20nm to 100nm.*

2.1.1. Novelty and inventive step over prior art

Claims lacking novelty did not attract any marks. For example, a claim to a conjugate of a spherical gold nanoparticle and an antibody lacks novelty over the disclosure of D2 (D2 paragraph [003]).

Some candidates used only the feature of a "spherical" particle to establish novelty over D1. There is no explicit disclosure of the term "spherical" in D1, and so such a claim can be considered as formally novel. However, Figure A of D1 depicts the coloured latex particles as circles, which strongly suggests they are spherical particles (. Therefore, it is at least obvious from D1 to use spherical particles and so such a claim received a deduction of 35 marks for lack of inventive step.

Device claims that were not inventive for other reasons lost 25 marks. For example, using the size feature of 20 to 100 nm diameter in relation to the colour particles provides novelty over D1, which refers only to "small, blue-coloured latex particles" (paragraph [006]). However, there is no inventive step associated with this feature alone. The inventive step is provided by using gold nanoparticles in this size range, as they provide a test with 10-fold improved sensitivity compared to the coloured latex particles (paragraph [015] client's letter).

2.1.2. Unnecessary limitations

While it was necessary to limit claim 1 to spherical gold nanoparticles with a diameter of 20 to 100 nm as discussed above, some candidates further limited their claims to nanoparticles with a diameter of exactly 40 nm. This was considered a very restrictive limitation, resulting in a deduction of 30 marks.

The client's letter clearly states that they wish to cover other possible uses of the lateral flow device in addition to COVID-19 testing. As a result, any claims with limitations to the target molecule to be detected were penalised. Limiting the device claim to SARS-CoV-2 virus spike protein and/or the hCG hormone resulted in a deduction of 20 marks, while claims limited to viral or bacterial molecules, or to hormones in general, received a deduction of 10 marks.

The client also describes preferred materials for various components of the test. Including any of these in the independent device claim was considered an unnecessary limitation. Specifying the material used for the sample or conjugate pad resulted in a deduction of 18 marks, whereas claims limited to test strips made of nitrocellulose membrane received a deduction of 15 marks.

The client explains that the type of antibody used in the detection agent and test line can be either the same or different (paragraph [009] of client's letter). Limiting the claim to a device where these antibodies are the same as each other was therefore an unnecessary limitation and resulted in a deduction of 15 marks.

It is also mentioned in the client's letter that the presence of a control line is "advantageous" to show that the test has been carried out correctly, but it is not an essential feature of the test. This point is underscored by the teaching of D1, which discloses that some commercially available tests do not have a control line (D1 paragraph [008]). Device claims specifying the presence of a control line therefore received a deduction of 10 marks.

Other major unnecessary limitations also attracted a deduction of 10 marks each. Examples include:

- Presence of a wicking pad
- Presence of a plastic cassette
- Antibody with high binding affinity

Any minor unnecessary limitations resulted in a deduction of 5 marks each, for example, limiting the sample pad to an absorbent pad, requiring a sphericity of > 99% or particles having a uniform size.

The inclusion of a functional feature (e.g. a sample pad “for receiving a liquid sample”) was generally not considered to be an unnecessary limitation. However, such functional language was not strictly necessary and so its absence was also not penalised.

2.1.3. Missing essential features

As usual, the client mentions various essential features which should be included in the independent device claim. The client specifies that the particles must be spherical to ensure consistent speed of movement along the test strip (paragraph [008]). Claims missing this feature received a deduction of 15 marks.

The client also explains that only gold nanoparticles with a diameter of 100nm or less are suitable for use in the test, since larger particles do not have the necessary red colour. D2 also teaches that spherical particles with a diameter of 100 nm or less are red (paragraph [002]). Further, gold nanoparticles with a diameter of less than 20 nm cannot carry sufficient antibodies to give an accurate result. As a result, claims that were not limited to this size range lacked the essential features to achieve the claimed technical effect. Claims that were lacking a lower diameter of 20 nm received a deduction of 15 marks as the test would not be accurate. Claims missing the upper diameter limit of 100 nm received a deduction of 10 marks, since the gold nanoparticles might be colourless and so not functional in the test. Finally, claims that were missing upper diameter limit but which specified that the nanoparticles were coloured received a deduction of 7 marks, since it is unclear whether gold nanoparticles which are blue or black would achieve the same effect.

In a lateral flow test, the liquid sample is drawn along the test strip by capillary flow (paragraph [004] of the client’s letter). It is therefore important to specify in which order along the test strip the components are placed so that the liquid sample can interact with them in the correct sequence. Claims which did not specify the arrangement of one or more of the various test features (e.g. failing to locate the conjugate pad downstream of the sample pad), received a deduction of 6 marks.

Any other missing essential features resulted in a deduction of 6 marks each.

2.1.4. Clarity and formal issues

Any major clarity issues resulted in a deduction of 8 marks each, and minor clarity issues were deducted 4 marks each. For example, specifying that the particles were of “fairly uniform size” was considered a minor clarity issue.

Incorrect use of the two-part claim format (e.g. a characterising part containing prior art features) received a 2 mark deduction. There was no deduction for claims that were not in the two-part claim format, so long as the prior art was discussed in the description. Lack of reference signs resulted in a 2 mark deduction, and incorrect or incomplete reference signs received a 1 mark deduction.

2.2. Independent method claim

Although the independent device claim was considered the most valuable to the client, and hence attracted the largest share of the marks, an independent method claim was also expected. Such a claim might be relevant to a third party using the lateral flow tests to provide a commercial testing service, for example. A suitable independent method claim which would gain the full 10 marks is set out below:

> *A method of detecting a target molecule (6) in a liquid sample (5), the method comprising applying the liquid sample (5) to the sample pad (1) of a lateral flow test device according to any preceding claim, wherein the presence of the target molecule in the liquid sample is indicated by the development of a coloured line at the test line.*

A correctly drafted use claim with corresponding features could also be awarded marks. However, wherever both method and use claims were present the worst of these type of claims was marked. Second medical use claims were not considered appropriate and did not attract any marks.

Claims to “diagnostic” methods were also acceptable. These would only be excluded from patentability if the diagnostic method steps are "practised on the human or animal body" (Art 53(c) EPC). If the claim relates to testing a sample, then the exclusion does not apply.

Claims that did not refer to the device claim, or which were missing all or most of the device features, were not awarded any marks. Claims lacking an essential feature were deducted 8 marks, such as “use” claims that did not include a reference to development of a coloured line, or linking this result back to the intended use. Major unnecessary limitations received a 6 mark deduction (e.g. specifying a specific infection or target molecule), and minor unnecessary limitations received a 4 mark deduction each. Any clarity issues resulted in a 2 mark deduction per issue.

2.3. Kit claim

The client mentions that their lateral flow test is usually sold together with an extraction solution that can be used to suspend the test sample (paragraph [012] client’s letter). Therefore, a kit claim was considered to be of particular importance to the client. There were 10 marks available for a kit claim that covers their commercial product, for example:

> *A kit of parts comprising:*
> *a) a lateral flow test device according to any one of claims X to Y; and*
> *b) an extraction solution for suspending a test sample.*

It was also possible to use different wording to cover the same features, for example a system comprising the device and extraction solution. Claims to a “diagnostic” kit (or

device) were also acceptable. This term was not considered to be limiting since the purpose of the kit is to detect a molecule that is used to diagnose infection or pregnancy.

Claims missing all or most device features (e.g. not referring to the device claim) were not awarded any marks. Claims lacking an essential feature were deducted 6 marks. Major unnecessary limitations received a 6 mark deduction, and minor unnecessary limitations had a 3 mark deduction. Any clarity issues resulted in a 2 mark deduction per issue.

3. EXPECTED DEPENDENT CLAIMS

Dependent claims referring to the device were expected to cover features described by the client as preferred, with marks allocated depending on their usefulness as a fallback position. Only the following features received marks as set out below:

- Spherical gold nanoparticle has a diameter of 40nm: 2 marks
- Reaction membrane comprises nitrocellulose: 2 marks
- Nitrocellulose membrane has a pore size of at least 5 microns: 2 marks
- Nitrocellulose membrane has a pore size of from 8 to 12 microns: 1 mark
- Same type of antibody used in both detection agent and test line: 2 marks
- Detection agent comprises an antibody which has a high binding affinity for the target molecule with an equilibrium dissociation constant (KD) of 10-7M or less: 2 marks
- Control line downstream from the test line comprising an antibody specific for the detection agent: 3 marks
- Wicking pad downstream of the reaction membrane: 3 marks
- Wicking pad comprises a cellulose filter: 2 marks
- Sample pad comprises cellulose fibre: 2 marks
- Conjugate pad comprises a non-woven glass fibre: 2 marks
- Plastic cassette with a label indicating the location of the test line and optionally the control line if present: 2 marks
- Target molecule is a hormone or viral/bacterial molecule: 2 marks
- Target molecule is the SARS-CoV-2 virus spike protein or hCG hormone: 2 marks

There was also the opportunity to provide dependent claims relating to the subject matter of the independent method claim and kit claim, such as:

- Liquid sample comprises urine, blood, saliva, or a nasal or throat swab sample: 2 marks
- Extraction solution comprises phosphate buffered saline: 2 marks

Deductions were made for incorrect dependencies (e.g. method features depending on device claims or vice versa), missing essential features and lack of clarity.

A single dependent claim covering two or more alternative features only attracted marks for the worse (i.e. lower scoring) of the two or more features. Any additional features described as “preferable” or “optional” were not awarded any marks. Candidates are reminded that they will not gain additional marks by combining multiple features in a single dependent claim in an attempt to circumvent the limitation to only 15 claims.

As per usual practice, missing essential features from the independent claims did not gain any marks when presented in a dependent claim.

Although more than 25 marks are theoretically available for all the features listed above, a maximum of 25 marks was awarded for the dependent claims.

4. DESCRIPTION

The candidates were expected to draft the introductory part of the application, including the citation of prior art according to the requirements of Rule 42(1)(b) EPC, an indication of the problem to be solved, and an explanation of how the claimed invention solves the technical problem. Marks were awarded as follows:

- Summary of the relevant content of the two prior art documents: 6 marks
- Discussion of the technical problem: 6 marks
- Solution of the technical problem: 3 marks

To receive all available marks, the problem and solution must be consistent with the independent claim(s) of the answer. Arguments relating to problems that are not solved by the claims were not awarded marks.

Candidates were expected to demonstrate understanding of the invention and technical problem/solution and not simply copy passages from the client’s letter. Merely repeating the claims in the description was also unnecessary and was not awarded any marks.

ANNEX

Example set of claims

1. A lateral flow test device for detecting a target molecule in a liquid sample, comprising;

- a sample pad (1) for receiving the liquid sample (5);
- a conjugate pad (2) downstream from the sample pad (1) comprising a conjugate (11) of a first antibody (10) specific for the target molecule (6) and a coloured particle (9); and
- a reaction membrane (3) downstream of the conjugate pad (2) comprising a second antibody (12) specific for the target molecule (6) immobilized in a test line (7) across the surface of the membrane (3);

characterized in that the coloured particle (9) is a spherical gold nanoparticle with a diameter of 20nm to 100nm.

2. A lateral flow test device according to claim 1, wherein the spherical gold nanoparticle has a diameter of 40nm.

3. A lateral flow test device according to claim 1 or 2, wherein the reaction membrane comprises nitrocellulose.

4. A lateral flow test device according to claim 3, wherein the nitrocellulose membrane has a pore size of from 8 to 12 microns.

5. A lateral flow test device according to any preceding claim, wherein the same type of antibody is used in both the detection agent and the test line.

6. A lateral flow test device according to any preceding claim, wherein the conjugate comprises an antibody which has a high binding affinity for the target molecule with an equilibrium dissociation constant (KD) of 10^{-7}M or less.

7. A lateral flow test device according to any preceding claim, which further comprises a control line (8) downstream from the test line (7), the control line comprising an antibody (13) specific for the conjugate immobilized in a line across the surface of the membrane (3).

8. A lateral flow test device according to any preceding claim, which further comprises a wicking pad (4) downstream of the reaction membrane (3).

9. A lateral flow test device according to claim 8, wherein the wicking pad (4) comprises a cellulose filter.

10. A lateral flow test device according to any preceding claim, which further comprises a plastic cassette with a label indicating the location of the test line, and optionally the control line if present.

11. A lateral flow test device according to any preceding claim, wherein the target molecule is a hormone or a viral or bacterial molecule.

12. A method of detecting a target molecule (6) in a liquid sample (5), the method comprising applying the liquid sample (5) to the sample pad (1) of a lateral flow test device according to any preceding claim, wherein the presence of the target molecule in the liquid sample is indicated by the development of a coloured line at the test line (7).

13. A method according to claim 12, wherein the liquid sample comprises urine, blood, saliva, or a nasal or throat swab sample.

14. A kit of parts comprising:

a) a lateral flow test device according to any one of claims 1 to 11; and

b) an extraction solution for suspending a test sample.

15. A kit of parts according to claim 14, wherein the extraction solution comprises phosphate buffered saline.