

# **In Vitro Diagnosis of rapid test**

A Dissertation Report submitted  
for the partial fulfilment of the Degree of Master of Science

By

Avani Gondaliya

**210621015**

[M.Sc. Biotechnology]



Under the supervision of

**Mahima patel**

**Production manager**

**DEPARTMENT OF BIOTECHNOLOGY  
ATMIYA UNIVERSITY  
'YOGIDHAM GURUKUL' KALAWAD ROAD  
RAJKOT (GUJARAT) – 360005**

**2022-23**

(On letterhead of the Department)

## **C E R T I F I C A T E**

This is to certify that this training report entitled “**TITLE**” was successfully carried out by Mr./Miss <**Name of Student**> towards the partial fulfilment of requirements for the degree of Master of Science in Biotechnology of Atmiya University, Rajkot. It is an authentic record of his/her own work, carried out by him/her under the guidance of Name of Supervisor for a period of 3 months during the academic year of 2022-23. The content of this report, in full or in parts, has not been submitted for the award of any other degree or certificate in this or any other University.

Signature

Name of the Head of the Department

Signature

Name of the Supervisor

## *DECLARATION*

I hereby declare that the work incorporated in the present dissertation report entitled “**title of the topic**” is my own work and is original. This work (in part or in full) has not been submitted to any University for the award of any Degree or a Diploma.

Date (Name and signature of Student)

# Guideline to write the Training Report

- **Font:** Times New Roman
- **Size:** 12
- **Spacing:** 1.5
- All figures, tables and pages should be numbered. The figures and tables should be placed as close to their citations in the text as possible.
- The label of each figure or tables should be written directly below the corresponding figure or table.
- The reports should include the following:
- **Index:** Index of each section titles.
- **Abstract:** Introductory information about the training report. Maximum one page.
- **Company information:** Introduction of the company where the training is held, its organizational structure, activity areas, departments, employee information, production activities, marketing and product information.
- **Report:** Your work and experiences.
- **References:** Please ensure that every reference cited in the text is also present in the reference list (and vice versa).
- **Reference to a journal publication:**
- Van der Geer, J., Hanraads, J. A. J., & Lupton, R. A. (2010). The art of writing a scientific article. *Journal of Scientific Communications*, 163, 51–59. <https://doi.org/10.1016/j.sc.2010.00372>.
- **Reference to a journal publication with an article number:**
- Van der Geer, J., Hanraads, J. A. J., & Lupton, R. A. (2018). The art of writing a scientific article. *Heliyon*, 19, Article e00205. <https://doi.org/10.1016/j.heliyon.2018.e00205>
- **Reference to a book:**
- Strunk, W., Jr., & White, E. B. (2000). *The elements of style* (4th ed.). Longman (Chapter 4).

- **Reference to a chapter in an edited book:**
- Mettam, G. R., & Adams, L. B. (2009). How to prepare an electronic version of your article? In B. S. Jones, & R. Z. Smith (Eds.), *Introduction to the electronic age* (pp. 281–304).

**Content:**

1. Abstract .....
2. Company information.....
3. Lateral low immune assay principle.....
4. Sample pad.....
5. Conjugate pad.....
6. Nitrocellulose membrane.....
7. Absorbant pad.....
8. Results.....
9. References.....

**Abstract:**

Lateral flow assays (LFAs) are the technology behind low-cost, simple, rapid and portable detection devices. Lateral flow immunochromatographic assays (LFIAs) are analytical devices used to detect the presence of one or more target analytes in a liquid sample. This type of assay has recently attracted considerable interest because of its potential to provide instantaneous diagnosis directly to patients. The concept of rapid diagnostic tests based on body fluids dated back significantly further. Documented evidence of saliva- and urine-based diagnostics existed several thousand years ago.

The Lateral Flow Immunoassay (LFIA) is by far one of the most successful analytical platforms to perform the on-site detection of target substances. The rapidity, simplicity, relative cost-effectiveness, and the possibility to be used by nonskilled personnel contributed to the wide acceptance of LFIAs.

The features of LFIAs made them a very attractive tool in clinical diagnostic where they can improve patient care by enabling more prompt diagnosis and treatment decisions. The LFIA application has been rapidly extended to other fields, including food and feed safety, veterinary medicine, environmental control, and many others.

The LFIA is a paper-based (bio)analytical technique for the on-site detection of target substances, where the sample is added on a standalone device and the result is obtained in a few minutes.

LFA is performed over a strip, different parts of which are assembled on a plastic backing. These parts are sample application pad, conjugate pad, nitrocellulose membrane and adsorption pad.

Lateral flow immunochromatographic assays (LFIAs) are analytical devices used to detect the presence of one or more target analytes in a liquid sample.

**Company information:**

SR Bioera has been a worldwide leader partnering with rapid test manufactures since 2016. SR Bioera has been focusing on providing affordable innovation to worldwide rapid test manufacturer.

providing an exciting opportunity for distribution of quality products at a very competitive price. Founded on 2016, A privately held Life Science company, has grown to be a leader in the Indian life science community, specializes in providing innovative high-quality products and services for research, diagnostic and clinical use.

**Product information**

Sr bioera provides repid test training, technology transfer and original equipment manufacture services.

**Repid tes ttraining:**

The training service is for researchers and start-up producers who want to develop and produce. You can choose different training sessions according to your needs, or let us know your demand and target

**Technology transfer:**

Our technology transfer contains training, knowledge, and document for practical small to large-scale production systematic management.

**OEM services:**

An OEM (Original Equipment Manufacturer) builds a customer's product that is fully designed by that customer and then contracted out to produce.

Sr bioera products is machine/equipments, raw materials, reagent, consumables, rapid test kit, uncut sheet, plastic ware.



## Report

### Lateral flow immune assay

#### **Principle:**

The principle of LFA is a liquid sample containing the analyte of interest moves without the assistance of external forces through various zones of polymeric strips, on which molecules that can interact with the analyte are attached.

A lateral flow test strip consists of overlapping membranes on a backing card for better stability and handling. The sample pad ensures that the analyte present in the sample will be capable of binding to the capture reagents of conjugates and on the membrane. The treated sample migrates through the conjugate pad, which contains antibodies that are specific to the target analyte and are conjugated to coloured or fluorescent particles. The sample together with the conjugated antibody bound to the target analyte, migrates along the strip into the detection zone.

The specimen containing the antigen to be detected is placed on the sample pad, The fluid then migrates to the conjugate pad, which contains conjugated antibodies directed against the antigen. Here, the antigen-antibody-conjugate complex is formed. Ag-Ab complex continues to migrate across the membrane until it reaches the capture zone where the complex will bind to immobilized antibodies. As more and more Ag-Ab complexes are captured at the “test” line, the line becomes visible on the membrane.

The lateral flow assay (LFA) is a paper-based platform for the detection and quantification of analytes in complex mixtures, where the sample is placed on a test device and the results are displayed within 5–30 min.

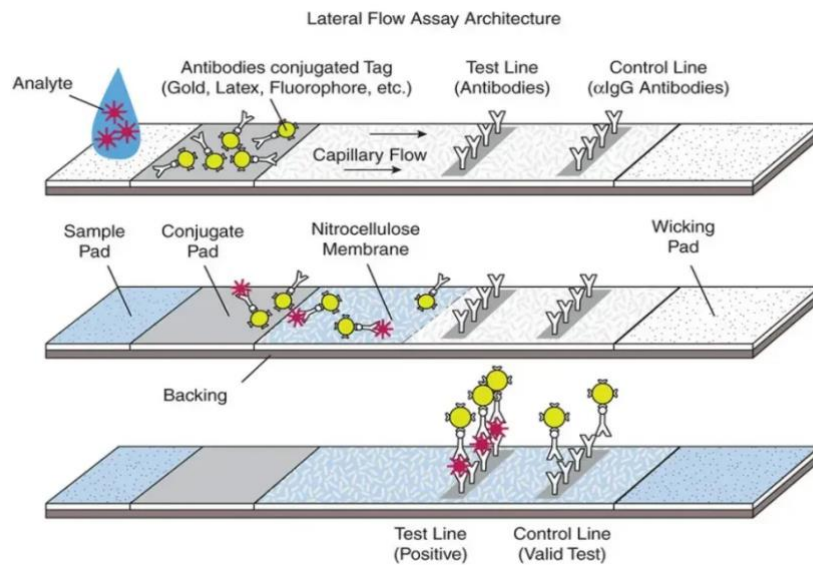


Figure 1. lateral low assay

**Sample pad:**

This is an sample pad on to which the sample is applied, and composed of a cellulose fiber. The sample pad should also demonstrate low protein binding to avoid loss of analyte. The function of the sample pad is to promote even and controlled distribution of the sample and to direct it to the conjugate pad. however the sample pad can be modified to enable conditioning of the sample. By pretreating the sample pad with components such as proteins, detergents or salts it is possible to reduce non-specific binding, increase the sample viscosity, or alter the pH.

**Conjugate pad:**

The conjugate pad is composed of non-woven glass fiber. Conjugate pads can perform multiple tasks, the most important of which is the uniform transfer of detection reagents and test samples to the membrane.

When the sample flows into the conjugate pad, the detection reagent dissolves, lifts the pad material, and moves into the membrane together with the sample. The important function of the conjugate pad is to deliver the test agent particles as a constant volume of sample on each test strip to the membrane.

**Membrane:**

The membrane is made of commonly materials such as nitrocellulose, polyvinylidene fluoride, cellulose acetate, or polyether sulfone. A nitrocellulose membrane pore sizes is 0.05 to 12  $\mu\text{m}$ . However, as the pores are not equally distributed. Capture antibodies are immobilized across the membrane, typically in two lines. The test line is used to bind the sample protein and control line consists of species-specific antibodies for the detection antibodies.

**Absorbant pad:**

These are specially treated absorbent pads made with compressed cellulose to absorb the reaction mixture of the rapid test assay and hold the reaction mixture for a longer duration of time

**Packaging:**

Packaging materials kit which contains: plastic cassettes, desiccant , aluminium foil bags, dropper.



Figure 2. HCG test kit

## Results

### Pregnancy test:

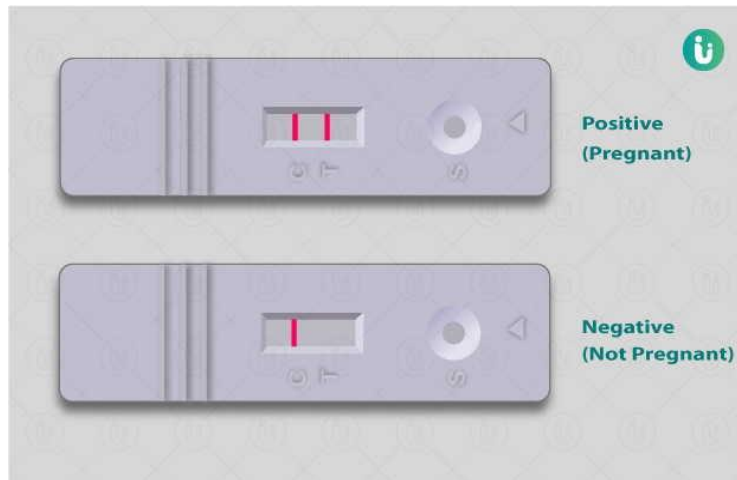


figure 3. pregnancy test

### Interpretation:

- Hcg is present- positive test
- Hcg is absent- negative test

Pregnancy tests work by detecting human chorionic gonadotropin (HCG), a hormone your body makes when you're pregnant.

## Dengue test:

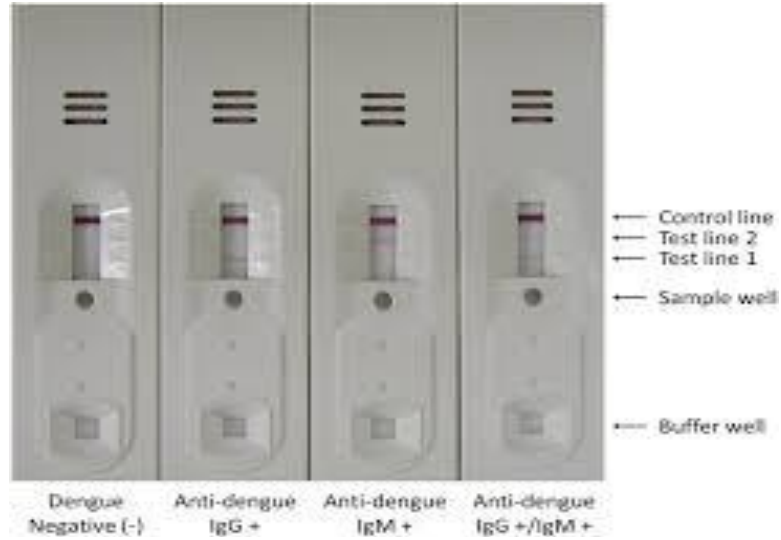


Figure 4. Dengue test

## Interpretation:

- In dengue test IgG and IgM antibody is present.
- If IgG and IgM antibody are detected in test that means person became infected with dengue virus.
- If IgG is positive but IgM is negative that means person had an infection sometimes in the past.

## Malaria test:

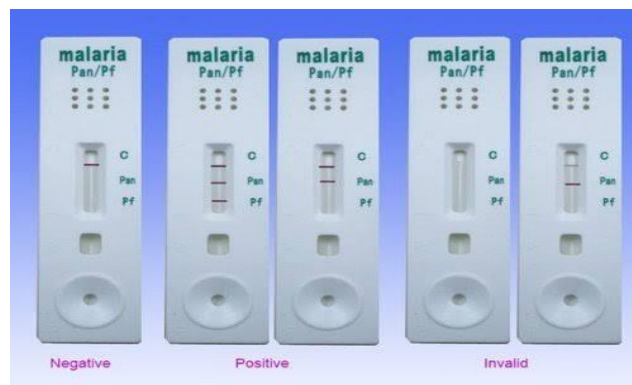


Figure 5. malaria test

Interpretation:

- A test is negative, meaning that you don't have any Plasmodium parasites in your blood.
- A positive result means that you have the parasites in your blood and that you may have malaria.

**Helicobacter pylori test:**

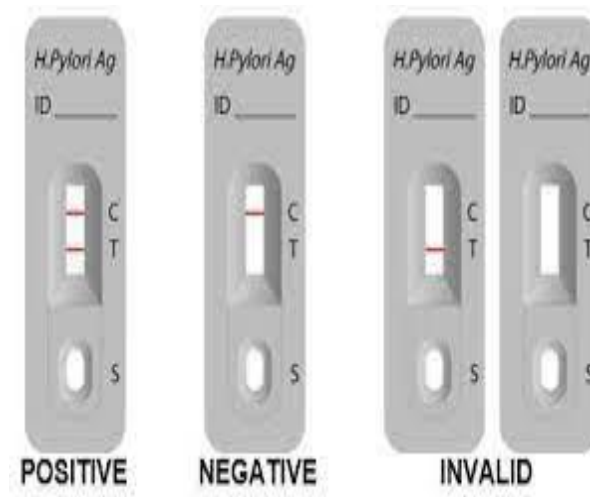


Figure 6 . helicobacter pylori test

Interpretation:

- If results were negative, it means you don't have an H. pylori infection.
- If results were positive, it means you have an H. pylori infection. H. pylori infections are treatable.

References:

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4986465/>

<https://www.abingdonhealth.com/services/what-is-lateral-flow-immunoassay/>

<https://pubs.rsc.org/en/content/articlelanding/2021/an/d0an02073g>

[https://en.m.wikipedia.org/wiki/Lateral\\_flow\\_test](https://en.m.wikipedia.org/wiki/Lateral_flow_test)

<https://microbeonline.com/immunochromatography-principle-application/>

<https://www.sepmag.eu/blog/lateral-flow-immunoassay-qualitative-quantitative-detection-protein>

[https://fnkprddata.blob.core.windows.net/domestic/download/pdf/IBS\\_A\\_guide\\_to\\_lateral\\_flow\\_immunoassays.pdf](https://fnkprddata.blob.core.windows.net/domestic/download/pdf/IBS_A_guide_to_lateral_flow_immunoassays.pdf)

<https://www.bio-rad.com/en-in/product/nitrocellulose-membrane-0-2-um?ID=14aba816-0b73-44bb96a7f5fe6853129d#:~:text=Pure%20nitrocellulose%20is%20the%20most,signal%2Dto%2Dnoise%20results>

[https://scholar.google.co.in/scholar\\_url?url=https://www.researchgate.net/profile/Maulik-Rachh/post/I\\_am\\_searching\\_for\\_a\\_good\\_source\\_to\\_read\\_about\\_lateral\\_flow\\_immunoassay\\_manufacturing\\_which\\_source\\_do\\_you\\_recommend/attachment/59d61dd679197b807797a99c/AS%253A273658696667149%25401442256726397/download/Lateral%2BFlow%2BImmunoassay.pdf&hl=en&sa=X&ei=orgvZlqoJPiH6rQP4JmliAc&scisig=AJ9-iYsMUn2-95ZDPS\\_qt7c7SV-v&oi=scholar](https://scholar.google.co.in/scholar_url?url=https://www.researchgate.net/profile/Maulik-Rachh/post/I_am_searching_for_a_good_source_to_read_about_lateral_flow_immunoassay_manufacturing_which_source_do_you_recommend/attachment/59d61dd679197b807797a99c/AS%253A273658696667149%25401442256726397/download/Lateral%2BFlow%2BImmunoassay.pdf&hl=en&sa=X&ei=orgvZlqoJPiH6rQP4JmliAc&scisig=AJ9-iYsMUn2-95ZDPS_qt7c7SV-v&oi=scholar)

