In vitro Diagnosis in SR BIOERA

A Internship Report submitted
for the partial fulfillment of the
Degree of Master of Science
By

Yashvi Jesadiya
210621021

[M.Sc.Biotechnology]

Under the supervision of
Mahima patel

DEPARTMENT OF BIOTECHNOLOGY
ATMIYA UNIVERSITY
'YOGIDHAM GURUKUL' KALAWAD ROAD
RAJKOT(GUJRAT)-360005

2022-23

C E R T I F I C A T E

This is to certify that this training report entitled “In Vitro Diagnosis in SR BIOERA” was successfully carried out by Miss Yashvi Jesadiya towards the partial fulfillment of requirements for the degree of Master of Science in Biotechnology of Atmiya University, Rajkot. It is an authentic record of her own work, carried out by her under the guidance of Miss Mahima patel 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.

Nutanprakash vishvakarma

Mahima Patel

DECLARATION

I hereby declare that the work incorporated in the present dissertation report entitled“In Vitro Diagnosis” 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: March 31,2023 Yashvi Jesadiya

INDEX

Abstract

In vitro diagnostics are tests done on samples such as blood or tissue that have been taken from the human body.In vitro diagnosis can detect diseases or other conditions, and can be used to monitor a person’s overall health to help cure, treat, or prevent diseases.Lateral flow assays (LFAs) are the technology behind low-cost, simple, rapid and portable detection devices popular in biomedicine, agriculture, food and environmental sciences. This review presents an overview of the principle of the method and the critical components of the assay, focusing on lateral flow immunoassays. This type of assay has recently attracted considerable interest because of its potential to provide instantaneous diagnosis directly to patients. The range and interpretation of results and parameters used for evaluation of the assay will also be discussed. Finally, the major recent advances and future diagnostic applications in the LFA field will be explored.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. Low development costs and ease of production of LFAs have resulted in the expansion of its applications to multiple fields in which rapid tests are required. LFA-based tests are widely used in hospitals, physician's offices and clinical laboratories for the qualitative and quantitative detection of specific antigens and antibodies. A variety of biological samples can be tested using LFAs, including urine, saliva, sweat, serum, plasma, whole blood and other fluids. Further industries in which LFA-based tests are employed include veterinary medicine, quality control, product safety in food production, and environmental health and safety. In these areas of utilization, rapid tests are used to screen for animal diseases, pathogens, chemicals, toxins and water pollutants, among others.

Founded in 2016, A privately held Life Science company, has grown to be a leader in the Indian life science community, specializing in providing innovative high-quality products and services for research, diagnostic and clinical use.

SR Bioera has been focusing on providing affordable innovation to worldwide rapid test manufacturers.

SR Bioera's entire business is in accordance with international ISO 9001, ISO 13485 & CE standards.

SR Bioera's products bear the CE mark, a certificate that confirms that the products are in accordance with the European union's standards.

They are declared as in vitro diagnostic medical devices (IVD) classified.

"We continue to build on the strong momentum from the last seven years to create high-quality products and provide excellent customer service."

1-IVD Raw Materials (gold nanoparticles, gold chloride salt, antigen and antibodies)

2-OEM Service

3-Technical Service-Technology Transfer Services from A to Z

4-Consumables (sample pad, conjugate pad, absorbent pad, PVC backing cad, Nitrocellulose Membrane)

5-Plastic Ware (extraction buffer tubes, test cassettes, VTM tubes etc.)

6-Specimen Collection Apparatus

7-Rapid Test Kit (infectious diseases, Drug of Abuse, Respiratory diseases, animal tests etc.)

SR Bioera offers only the best quality products at competitive prices and has one of the widest ranges of medical products in south-eastern Europe.

Our experience and flexibility towards the client make us a sought -after business partner, which has been recognized on the global market.

Report

Production materials

- IVD Raw Materials
- Consumables
- Plastic Ware
- Rapid test kit

Objective decided for work

- Cassette assembly
- Uncut sheet

Process of card coating

- PVC card
- NC membrane
- Absorbent pad
- Card Coating
- Primary treatment of conjugation pad
- Gold dipping
- Lamination of gold and conjugation pad

Dispenser

The equipment is a high-tech product researched and developed by Kinbio, which integrates membrane dispensing and gold spraying as a whole.There are 4 types of pump in dispenser.Three pumps are glide and one pump is spray.

- Dispensing efficiency: 200-300 sheets (30cm) /hour
- Spraying efficiency: 700~900 strips (30cm)/hour
- Dispensing pump standard capacity: 500ul
- Spraying pump standard capacity: 1000ul
- Dispenser reagent concentration: 0.2ul/cm
- Minimum fill and drain volume: 1ul

PVC backing card

Backing cards for lateral flow rapid diagnostic test kit is usually made of PS or PVC materials with self-adhesive, with main features of good flatness, strong adhesive and aging resistance.adhesive is a stronger type, though only small amount of adhesive coated, 20g/square meters, whereas other backing card producers have to apply 38g/square meters on it.As a result, it will significantly lessen the cleaning time and frequency of the strip cutter and reduce the defects, then further benefit a smooth continuous large scale production, especially those engaged a lot of automatic instruments.adhesive is non-reactive, non-volatile with a stable shelf-life of 2.5 years. A typical lateral flow test strip consists of overlapping membranes that are mounted on a backing card for better stability and handling.

Sample pad

A sample pad can be used for urine, whole blood, saliva and serum specimen.This is a specially treated pad that enhances releasing capacity of assay analytes and low retention volume of the analytes to provide the ultra-sensitive test result.which is impregnated with buffer salts and surfactants that make the sample suitable for interaction with the detection system. The sample pad can be used to perform multiple tasks, foremost of which is to promote the even and controlled distribution of the sample onto the conjugate pad. It may also control the rate at which liquid enters the conjugate pad, preventing flooding of the device. When impregnated with components such as proteins, detergents, viscosity enhancers, and buffer salts, the sample pad can also be used to:

1. Increase sample viscosity.
2. Enhance the ability of the sample to solubilize the detector reagent.
3. Prevent the conjugate and analyte from binding non-specifically to any of the downstream materials.
4. Modify the chemical nature of the sample so that it is compatible with immunocomplex formation at the test line.
5. Promote even flow of the sample along the membrane.

The presence of added protein (such as albumin) and detergents and surfactants (such as SDS or TWEEN® 20 at a very low concentration) may promote resolubilization of the conjugate, reduce nonspecific binding of the conjugate, and possibly minimize adsorption of the analyte to the membrane.By adding blocking agents to the sample pad, it may be possible to eliminate blocking of the membrane. This approach may be much easier and considerably more cost-effective than attempting to block the membrane directly. Unless the antibody (or antigen) is covalently attached to the detector particle, it is not advisable to dry the detector reagent into the conjugate pad in the presence of blocking proteins or detergents. Thus, the sample pad may be the only place in the test device other than the membrane where blocking and resolubilization agents can be added safely.Some tests require samples that exhibit wide variation in chemical composition. Human urine, for instance, can have a pH between 5 and 10. Differences in pH and ionic strength may shift the specificity and sensitivity of capture and detector reagents and promote varying degrees of non-specific binding of detector reagents due to changes in charge densities. Adding a relatively high concentration of buffer salts to the sample pad (for example, by pre-treating with 1.0 M borate buffer, pH 9.5) can minimize variation by controlling the pH and ionic strength of the solution that emerges from the sample pad.There are two types of materials that are commonly used as sample pads: cellulose fiber filters and woven meshes.Woven meshes, sometimes called screens, normally work very well to distribute the sample volume evenly over the conjugate pad. Meshes have very low bed

volumes, meaning that they retain very little sample volume, normally 1 – 2 µL/ cm2.Meshes can also be expensive relative to other porous media and difficult to process through strip cutting machinery.Cellulose filters have properties that are nearly the opposite of woven meshes. They are thick (> 250 µm), weak, and relatively inexpensive. Cellulose filters also have large bed volumes (> 25 µL/ cm2). Paper can be very difficult to handle, especially when wet. Cellulosic filters are the most commonly used materials to make the sample pad because they can be loaded with a wide array of blocking agents..For many urine-based assays, especially pregnancy and ovulation tests, porous plastic wicks protrude from the end of the cassette. Their primary function is to collect liquid from the urine stream so that it can be transferred to the test strip within the cassette. The dimensions of the wick are tailored to the design of the test strip cassette and the requirement to absorb enough liquid to run the test. The wick may or may not be chemically treated, depending on the chemistries of the other materials within the cassette. It is conceivable that the plastic wick can serve the function of a sample pad.

Buffer dipping(Primary treatment)

Strips are given a primary treatment because of the hydrophobic nature. Strips are dipped into the buffer until stripes are wet. Now strips are dried into a hot air oven until it dries completely. Stripes are collected and sealed into an aluminum pouch.

Gold dipping(Secondary treatment)

Primary treated strips are dipped into a pure gold solution. Strips are separated one by one on a try. The tray is placed in the hot air oven for 4 hours.

Conjugate pad

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.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 release pad, which contains antibodies that are specific to the target analyte and are conjugated to coloured or fluorescent particles–most commonly colloidal gold and latex microspheres. The sample, together with the conjugated antibody bound to the target analyte, migrates along the strip into the detection zone. This is a porous membrane (usually composed of nitrocellulose) with specific biological components (mostly antibodies or antigens) immobilized in lines. Their role is to react with the analyte bound to the conjugated antibody. Recognition of the sample analyte results in an appropriate response on the test line, while a response on the control line indicates the proper liquid flow through the strip. The read-out, represented by the lines appearing with different intensities, can be assessed by eye or using a dedicated reader. On the other hand, multiple test lines loaded with the same antibody can be used for semi-quantitative assays. The conjugate pad can perform multiple tasks, the most important of which is uniform transfer of the detector reagent and test sample into the membrane. When the sample flows into the conjugate pad, the detector reagent solubilizes, lifts off the pad material, and moves with the sample front into the membrane.An important function of the conjugate pad is to deliver the detector particles into the membrane in a consistent volume of sample on every test strip. Ultimately, the sample volume required to release the detector particle into the sample stream determines how much analyte can be measured. Only the analyte contained in the volume of the sample that migrates ahead of and with the detector particles can contribute to the signal. The volume of sample that enters the conjugate pad and membrane after the detector particles have been completely released does not contribute to signal, although it does serve to reduce assay background. Analytes that pass over the capture reagent line after all of the detector particles have migrated farther downstream may bind at the capture reagent line but will lack additional detector particles to complete the immunocomplex.The porous materials commonly used for conjugate pads are non-woven filters, which are manufactured by compressing fibers of cellulose, glass, or plastic (such as polyester, polypropylene, or polyethylene) into thin mats. They are specified by fiber size, thickness, basis weight, extractables, and air flow rate. In most cases, they cost considerably less than membranes. Materials commonly used to make conjugate pads

include glass fiber filters, cellulose filters, and surface-treated (hydrophilic) polyester or polypropylene filters.

Nitrocellulose membrane

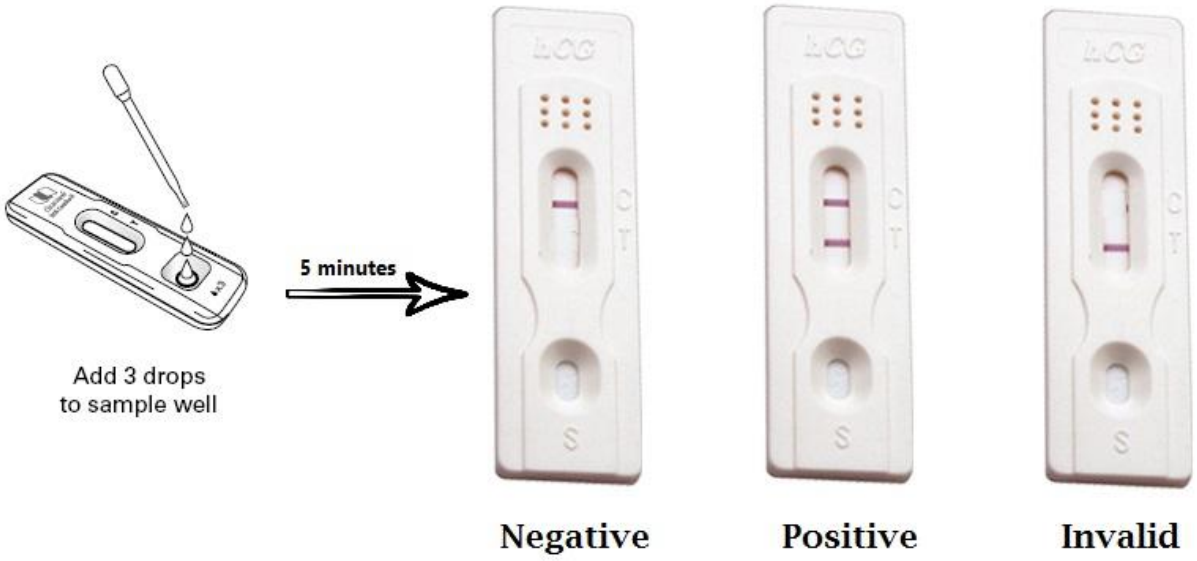
The membrane is considered the most critical element in LFA strips and nitrocellulose is by far the most commonly used material. Moreover, there are also ‘pillar-based’ capillary LFA devices used for deoxyribonucleic acid (DNA) hybridization detection (where micropillar arrays replace the membrane), which have the advantage of more precise control of the capillary flow. Important parameters characterizing a good membrane material are the capillary forces, as well as the ease of binding and immobilizing proteins necessary for subsequent selection, reaction and detection. A range of nitrocellulose pore sizes are available, from 0.05 to 12 μm. However, as the pores are not equally distributed (because of the manufacturing process), capillary flow time is a more accurate parameter and it should be used when selecting the most effective strip material. The capillary flow time is the time required for the liquid to travel to and completely fill the strip of the membrane.Microporous nitrocellulose membranes are used in lateral-flow assays as the substrate upon which immune complexes are formed and visualized to indicate the presence or absence of an analyte in a liquid sample. The pore sizes of membranes used in this application are comparatively large, ranging from 3 to 20 μm. Several attributes have resulted in nitrocellulose being the preferred substrate for lateral-flow assays.nitrocellulose adsorbs protein at a high level.To facilitate the utilization of nitrocellulose in lateral-flow assays, the membrane can be cast directly into a polyester backing. The backing does not interfere with the function of the nitrocellulose.

Absorbent 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.Absorbent pads, when used, are placed at the distal end of the test strip. The primary function of the absorbent pad is to increase the total volume of sample that enters the test strip. This increased volume can be used to wash unbound detector particles away from the test and control lines, thereby lowering the background and enhancing assay sensitivity. Since the volume of sample that ultimately contributes to signal is controlled by the volume required to solubilize the detector particles, and not by the total volume of sample that enters the device. If the strip design does not include an absorbent pad, the volume of sample analyzed in the strip is determined solely by the bed volume of the membrane.There are two major considerations associated with the use of absorbent pads. First, a suitable material must be identified, specified, purchased, and integrated into the manufacturing process. Ultimately, this leads to a higher cost for the finished product. Second, an absorbent pad makes it difficult to incorporate an end-of-assay indicator in the test device.Most absorbent pads are made from cellulose filters. The material should be selected on the basis of thickness, compressibility, manufacturability, and, most of all, uniformity of bed volume. Once an absorbent material has been chosen, optimizing the overall volume absorbed by the test strip is best managed by changing the dimensions (usually the length) of the absorbent pad.The role of the absorbent pad is to wick the fluid through the membrane and to collect the processed liquid. The absorbent pad allows the use of larger sample volumes, which results in increased test sensitivity. The most popular absorbent pads are made of cellulose filters.

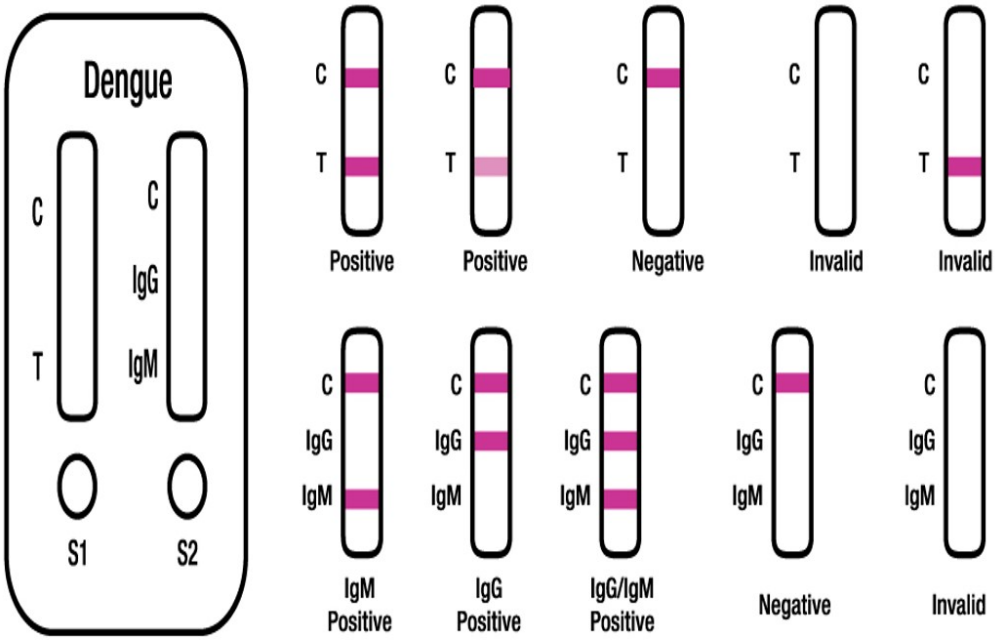
Result

HCG RESULT



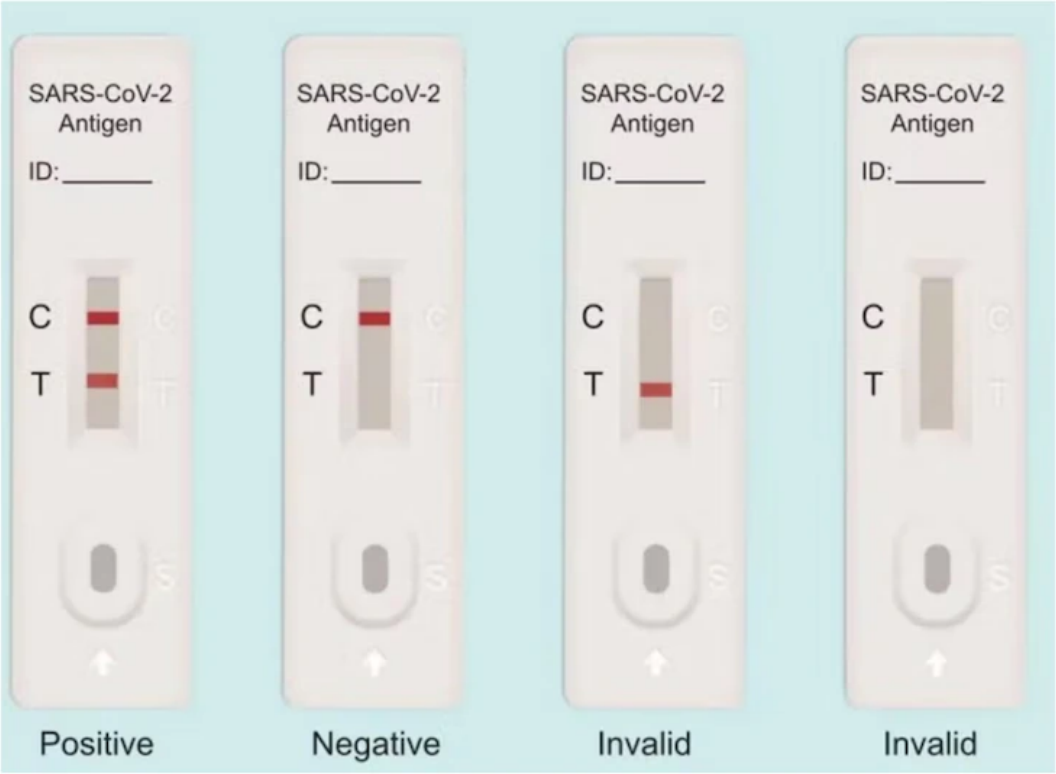
People must read the urine test instructions and follow them carefully. Most tests use lines to show when a test is positive. The test line does not have to be as dark as the control line to be positive. Any line at all indicates the test is positive.
An individual must check the test within the time frame the instruction indicates. This is typically around 2 minutes.
Test stripes can change color as they dry. Some people notice an evaporation line after several minutes. This is a very faint line that may look like a shadow.

Dengue result



A positive NS1 test indicates dengue virus infection but does not reveal the serotype. A negative NS1 test result does not rule out the absence of illness. People who have a negative NS1 test should be tested for dengue IgM antibodies to see if they have recently been exposed to the virus.

Covid test result



If SARS-CoV-2 RNA is detected then the test is positive.
If SARS-CoV-2 RNA is not Detected then the test is negative.

References

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

2. https://www.medicalnewstoday.com/articles/327284

3. Rohrman B.A., Leautaud V., Molyneux E., Richards–Kortum R.R. A lateral flow assay for quantitative detection of amplified HIV-1 RNA. *PLoS One.* 2012;7:e45611. doi: 10.1371/journal.pone.0045611. [PMC free article] [PubMed] [CrossRef] [Google Scholar]

4. Kamphee H., Chaiprasert A., Prammananan T., Wiriyachaiporn N., Kanchanatavee A., Dharakul T. Rapid molecular detection of multidrug-resistant tuberculosis by PCR-nucleic acid lateral flow immunoassay. *PLos One.* 2015;10:e0137791. doi: 10.1371/journal.pone.0137791. [PMC free article] [PubMed] [CrossRef] [Google Scholar]

5. Moreno M.L., Cebolla A., Munoz-Suano A., Carrillo–Carrion C., Comino I., Pizarro A., et al. Detection of gluten immunogenic peptides in the urine of patients with coeliac disease reveals transgressions in the gluten-free diet and incomplete mucosal healing. *Gut.* 2015 doi:10.1136/gutjnl-2015-310148. [PMC free article] [PubMed] [Google Scholar]

6. Carrio A., Sampedro C., Sanchez-Lopez J.L., Pimienta M., Campoy P. Automated low-cost smartphone-based lateral flow saliva test reader for drugs-of-abuse detection. *Sensors.* 2015;15:29569–29593. doi: 10.3390/s151129569. [PMC free article] [PubMed] [CrossRef] [Google Scholar]

7. Pacifici R., Farre M., Pichini S., Ortuno J., Roset P.N., Zuccaro P., et al. Sweat testing of MDMA with the Drugwipe analytical device: a controlled study with two volunteers. *J. Anal. Toxicol.* 2001;25:144–146. doi: 10.1093/jat/25.2.144. [PubMed] [CrossRef] [Google Scholar]

8. De Giovanni N., Fucci N. The current status of sweat testing for drugs of abuse: a review. *Curr. Med. Chem.* 2013;20:545–561. [PubMed] [Google Scholar]

9. Magambo K.A., Kalluvya S.E., Kapoor S.W., Seni J., Chofle A.A., Fitzgerald D.W., et al. Utility of urine and serum lateral flow assays to determine the prevalence and predictors of cryptococcal antigenemia in HIV-positive outpatients beginning antiretroviral therapy in Mwanza, Tanzania. *J. Int. AIDS Soc.* 2014;17:19040. doi: 10.7448/IAS.17.1.19040. [PMC free article] [PubMed] [CrossRef] [Google Scholar]

10. Schramm E.C., Staten N.R., Zhang Z., Bruce S.S., Kellner C., Atkinson J.P., et al. A quantitative lateral flow assay to detect complement activation in blood. *Anal. Biochem.* 2015;477:78–85. doi: 10.1016/j.ab.2015.01.024. [PMC free article] [PubMed] [CrossRef] [Google Scholar]

11. Ang S.H., Rambeli M., Thevarajah T.M., Alias Y.B., Khor S.M. Quantitative, single-step dual measurement of hemoglobin A1c and total hemoglobin in human whole blood using a gold sandwich immunochromatographic assay for personalized medicine. *Biosens. Bioelectron.* 2015;78:187–193. doi: 10.1016/j.bios.2015.11.045. [PubMed] [CrossRef] [Google Scholar]

12. Nielsen K., Yu W.L., Kelly L., Williams J., Dajer A., Gutierrez E., et al. Validation and field assessment of a rapid lateral flow assay for detection of bovine antibody to Anaplasma marginale. *J. Immunoassay Immunochem.* 2009;30:313–321. doi: 10.1080/15321810903084749. [PubMed] [CrossRef] [Google Scholar]

13. van Dam G.J., de Dood C.J., Lewis M., Deelder A.M., van Lieshout L., Tanke H.J., et al. A robust dry reagent lateral flow assay for diagnosis of active schistosomiasis by detection of Schistosoma circulating anodic antigen. *Exp. Parasitol.* 2013;135:274–282. doi: 10.1016/j.exppara.2013.06.017. [PMC free article] [PubMed] [CrossRef] [Google Scholar]

14. Ching K.H., He X., Stanker L.H., Lin A.V., McGarvey J.A., Hnasko R. Detection of shiga toxins by lateral flow assay. *Toxins.* 2015;7:1163–1173. doi: 10.3390/toxins7041163. [PMC free article] [PubMed] [CrossRef] [Google Scholar]

15. Mei Z., Qu W., Deng Y., Chu H., Cao J., Xue F., et al. One-step signal amplified lateral flow strip biosensor for ultrasensitive and on-site detection of bisphenol A (BPA) in aqueous samples. *Biosens. Bioelectron.* 2013;49:457–461. doi: 10.1016/j.bios.2013.06.006. [PubMed] [CrossRef] [Google Scholar]

16. Kim Y.K., Lim S.I., Cho I.S., Cheong K.M., Lee E.J., Lee S.O., et al. A novel diagnostic approach to detecting porcine epidemic diarrhea virus: the lateral immunochromatography assay. *J. Virol. Methods.* 2015;225:4–8. doi: 10.1016/j.jviromet.2015.08.024. [PMC free article] [PubMed] [CrossRef] [Google Scholar]

17. Shukla S., Leem H., Lee J.S., Kim M. Immunochromatographic strip assay for the rapid and sensitive detection of *Salmonella* Typhimurium in artificially contaminated

tomato samples. *Can. J. Microbiol.* 2014;60:399–406. doi: 10.1139/cjm-2014-0223. [PubMed] [CrossRef] [Google Scholar]

18. Morales-Narvaez E., Naghdi T., Zor E., Merkoci A. Photoluminescent lateral-flow immunoassay revealed by graphene oxide: highly sensitive paper-based pathogen detection. *Anal. Chem.* 2015;87:8573–8577. doi: 10.1021/acs.analchem.5b02383. [PubMed] [CrossRef] [Google Scholar]

19. Ngom B., Guo Y., Wang X., Bi D. Development and application of lateral flow test strip technology for detection of infectious agents and chemical contaminants: a review. *Anal. Bioanal. Chem.* 2010;397:1113–1135. doi: 10.1007/s00216-010-3661-4. [PubMed] [CrossRef] [Google Scholar]

20. Shyu R.H., Shyu H.F., Liu H.W., Tang S.S. Colloidal gold-based immunochromatographic assay for detection of ricin. *Toxicon.* 2002;40:255–258. doi: 10.1016/S0041-0101(01)00193-3. [PubMed] [CrossRef] [Google Scholar]

21. Kuang H., Xing C., Hao C., Liu L., Wang L., Xu C. Rapid and highly sensitive detection of lead ions in drinking water based on a strip immunosensor. *Sensors.* 2013;13:4214–4224. doi: 10.3390/s130404214. [PMC free article] [PubMed] [CrossRef] [Google Scholar]

22. Lopez Marzo A.M., Pons J., Blake D.A., Merkoci A. High sensitive gold-nanoparticle based lateral flow Immunodevice for Cd^{2+} detection in drinking waters. *Biosens. Bioelectron.* 2013;47:190–198. doi: 10.1016/j.bios.2013.02.031. [PubMed] [CrossRef] [Google Scholar]

23. Connelly J.T., Nugen S.R., Borejsza-Wysocki W., Durst R.A., Montagna R.A., Baeumner A.J. Human pathogenic Cryptosporidium species bioanalytical detection method with single oocyst detection capability. *Anal. Bioanal. Chem.* 2008;391:487–495. doi: 10.1007/s00216-008-1967-2. [PubMed] [CrossRef] [Google Scholar]

24. Xu Y., Liu Y., Wu Y., Xia X., Liao Y., Li Q. Fluorescent probe-based lateral flow assay for multiplex nucleic acid detection. *Anal. Chem.* 2014;86:5611–5614. doi: 10.1021/ac5010458. [PubMed] [CrossRef] [Google Scholar]

25. Yen C.W., de Puig H., Tam J.O., Gomez-Marquez J., Bosch I., Hamad-Schifferli K., et al. Multicolored silver nanoparticles for multiplexed disease diagnostics: distinguishing Dengue, yellow fever, and Ebola viruses. *Lab Chip.* 2015;15:1638–1641. doi: 10.1039/C5LC00055F. [PMC free article] [PubMed] [CrossRef] [Google Scholar]

26. Fung K.K., Chan C.P., Renneberg R. Development of enzyme-based bar code-style lateral-flow assay for hydrogen peroxide determination. *Anal. Chim. Acta.* 2009;634:89–95. doi: 10.1016/j.aca.2008.11.064. [PubMed] [CrossRef] [Google Scholar]

27. Fang C., Chen Z., Li L., Xia J. Barcode lateral flow immunochromatographic strip for prostate acid phosphatase determination. *J. Pharm. Biomed. Anal.* 2011;56:1035–1040. doi: 10.1016/j.jpba.2011.08.008. [PubMed] [CrossRef] [Google Scholar]

28. Leung W., Chan C.P., Rainer T.H., Ip M., Cautherley G.W., Renneberg R. InfectCheck CRP barcode-style lateral flow assay for semi-quantitative detection of C-reactive protein in distinguishing between bacterial and viral infections. *J. Immunol. Methods.* 2008;336:30–36. doi: 10.1016/j.jim.2008.03.009. [PubMed] [CrossRef] [Google Scholar]

29. Workman S., Wells S.K., Pau C.P., Owen S.M., Dong X.F., LaBorde R., et al. Rapid detection of HIV-1 p24 antigen using magnetic immuno-chromatography (MICT) *J. Virol. Methods.* 2009;160:14–21. doi: 10.1016/j.jviromet.2009.04.003. [PubMed] [CrossRef] [Google Scholar]

30. Butler S.A., Khanlian S.A., Cole L.A. Detection of early pregnancy forms of human chorionic gonadotropin by home pregnancy test devices. *Clin. Chem.* 2001;47:2131–2136. [PubMed] [Google Scholar]

31. Mao X., Ma Y., Zhang A., Zhang L., Zeng L., Liu G. Disposable nucleic acid biosensors based on gold nanoparticle probes and lateral flow strip. *Anal. Chem.* 2009;81:1660–1668. doi: 10.1021/ac8024653. [PubMed] [CrossRef] [Google Scholar]

32. Parolo C., de la Escosura-Muniz A., Merkoci A. Enhanced lateral flow immunoassay using gold nanoparticles loaded with enzymes. *Biosens. Bioelectron.* 2013;40:412–416. doi: 10.1016/j.bios.2012.06.049. [PubMed] [CrossRef] [Google Scholar]

33. Qiu W., Xu H., Takalkar S., Gurung A.S., Liu B., Zheng Y., et al. Carbon nanotube-based lateral flow biosensor for sensitive and rapid detection of DNA sequence. *Biosens. Bioelectron.* 2015;64:367–372. doi: 10.1016/j.bios.2014.09.028. [PubMed] [CrossRef] [Google Scholar]

34. Ren M., Xu H., Huang X., Kuang M., Xiong Y., Xu H., et al. Immunochromatographic assay for ultrasensitive detection of aflatoxin B(1) in maize by highly luminescent quantum dot beads. *ACS Appl. Mater. Interfaces.* 2014;6:14215–14222. doi: 10.1021/am503517s. [PMC free article] [PubMed] [CrossRef] [Google Scholar]

35. Huang C., Jones B.J., Bivragh M., Jans K., Lagae L., Peumans P. A capillary-driven microfluidic device for rapid DNA detection with extremely low sample consumption; 17th International Conference on Miniaturized Systems for Chemistry and Life Sciences; Freiburg, Germany: 2013. 27–31 October 2013. [Google Scholar]

36. Anon . *Rapid Lateral Flow Test Strips: Considerations for Product Development.* Billerica: Merck Millipore; 2008. [Google Scholar]

37. Anfossi L., Di Nardo F., Giovannoli C., Passini C., Baggiani C. Increased sensitivity of lateral flow immunoassay for ochratoxin A through silver enhancement. *Anal. Bioanal. Chem.* 2013;405:9859–9867. doi: 10.1007/s00216-013-7428-6. [PubMed] [CrossRef] [Google Scholar]

38. https://www.yashodahospitals.com/diagnostics/dengue-ns1-test/

39.https://www.google.com/search?q=covid+test+results&tbm=isch&ved=2ahUKEwiOr_TQjpf-AhVJIbcAHVSyDNoQ2-cCegQIABAA&oq=covi+test+results&gs_lcp=CgNpbWcQARgAMgYIABAHEB4yBggAEAcQHjIGCAAQBxAeMgYIABAHEB4yBggAEAcQHjIGCAAQBxAeMgYIABAHEB4yBggAEAcQHjIGCAAQBxAeMgYIABAHEB46BAgjECc6BQgAEIAEOgcIABCKBRBDUMMGWLEdYIc9aAFwAHgAgAGhAogBwA-SAQUwLjYuNJgBAKABAaoBC2d3cy13aXotaW1nwAEB&sclient=img&ei=YLQvZI7_PMnC3LUP1OSy0A0&bih=569&biw=1280&rlz=1C1RXQR_enIN976IN976#imgrc=IwXpvISd32OQRM&imgdii=cqLHDCW7WTXIIM