

## Sample Analysis for Novel Medical Applications

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**Abstract.** The sample preparation for biological and chemical probes involves following a strict workflow to eliminate any contamination to the sample beforehand. Furthermore, it is time consuming and must be carried out by trained personnel such as a nurse or other supervisors, making it therefore expensive. The development of novel sample preparation techniques paired with modern sample analysis systems is focused on improving the operability while keeping a constant quality of results. This is important to analyse samples, which cannot be determined with current screening conditions. The analysis of analytes is required to receive a more detailed picture of the patient and to fully understand its complexity. Possible samples for in-depth analysis of chemical origin can be cholesterol or glucose. More complex samples, such as blood or saliva, require a sophisticated system, which analyses the samples for their individual compounds.

### Introduction

Due to the proceeding of globalization, from time to time the epidemic rise of diseases occur all over the world. Tropical diseases, for example, are not anymore just a problem of the country of origin. [1] Combined with the problem, that more than half of the world population still do not have full essential medical care [2], the risk of a pandemic outbreak increases even further. In order to prevent such a disastrous event, it is essential to identify the spreading disease in a fast and reliable manner.

### Actual Situation

For the analysis of the medical conditions saliva and blood samples can be used, which should be regarded as samples of high complexity. This has the advantage, that more than one parameter could be determined. Well-equipped laboratories could prepare haemograms to get an overview about the medical status of the patient. [3] However, more than half of the world population have no access to essential medical care [2], therefore those complex medical analytics are not available in all regions of the world, especially in development countries.

Hence, simple analytical methods are needed. A simple method to perform specific blood analysis is the lateral flow assay (LFA) test. The LFA test has the advantage of low costs, as well as shorter execution time compared to other methods. It also has the benefit of not needing high special technical equipment. [4]. The LFA test also has disadvantages. The blood sampling and its analysis can only be performed by medical trained personal, since the blood sampling must follow an exact operating procedure. Not carrying out the procedure correctly could lead to an infection of the patient or contamination of the sample itself could be the consequence. Furthermore, a non-adherence of the operating procedure could influence the result of the test. False negative or false positive results lead to a faulty rehabilitation of the patient. Therefore, the procedure of the LFA test should generally be performed by medical trained personal. Although the LFA test is simpler and more cost-efficient compared to other methods, it still needs medical resources, execution time and

funds. That may be problematic in case of an upcoming epidemic. As medical care is not comprehensively assured, the necessary medical resources should be exported to the affected regions. For that reason, medical personal and tests are sent out with high expense. Following this, the need of medical trained persons, test, funds and execution time rise with the increasing patient count.

### **Requirements for New Medical Analytic System (MAS)**

The lack of the useful medical analytic systems is setting the requirements of prospective MAS. That way a new MAS should analyse more than one parameter to receive a better overview about the medical status of the patient. An improved usability provides a better reliability as well as improved overall performance. For this reason, funds could be reduced since medical trained personal is not necessary any more. Thereby, with the help of simpler and faster MAS a high number of patients could be tested in a short time, so that epidemic cases could be identified in an early stage. Such a novel MAS should be small in size and cost-efficient. Furthermore, the operation procedure of the MAS should be simple and intuitive. Another important requirement of the MAS is the functionality in case of extreme climatic conditions, so that it can be used in all regions of the world, especially in regions without essential medical care.

### **MAS as a Novel Medical Application**

The new MAS should unify the blood sampling procedure and the analytical part of the test in one system. After the blood sampling, the blood must be transferred to the test strip. For this part, a medical trained person is not necessary anymore. The output of the analysis should have a higher quality. That means potential errors will be minimized. The procedure of blood sampling should be automated and minimal invasive, whereby scars on the skin can be reduced and the risk of successive infections on sampling point will be minimized. The blood sampling procedure must be designed as single-use in order to prevent transmission of infections between several patients. A temperature, dust and humidity resistant case protects the test from detrimental effects from the environment, so that the assay can work under different climatic conditions. The structure of the MAS assures constant high-quality results because of the fully automated operating procedure. Such a system could be arranged in size and structure as an adhesive tape. [5]

### **Realization Strategy of the New MAS as a Novel Medical-Applications**

At first, the new MAS should be constructed with computer aided design. Afterwards the blood transfer from the blood sampling point to the analytical assay should be simulated to identify technical difficulties. Using the generated dataset, the system could be modified to optimize the test procedure. For the production process, rapid prototyping technologies could be used. The cost for the case should be kept low. At first, the prototype could be manufactured using 3D-printing. Later injection molding could be used for higher numbers of devices. The case could be made of bioinert material to minimize the risk of an allergic reaction of the patient to the patch.

For the analytical assay, a commercial sandwich LFA test could be used. The fundamental functionality of a sandwich LFA test is shown in Fig. 1. If the blood sample is positive, in the test are two visible lines (the test and the control line). If the blood sample is negative the test only shows the control line. LFA tests are usually invalid when no line or only the test line is visible. [4]

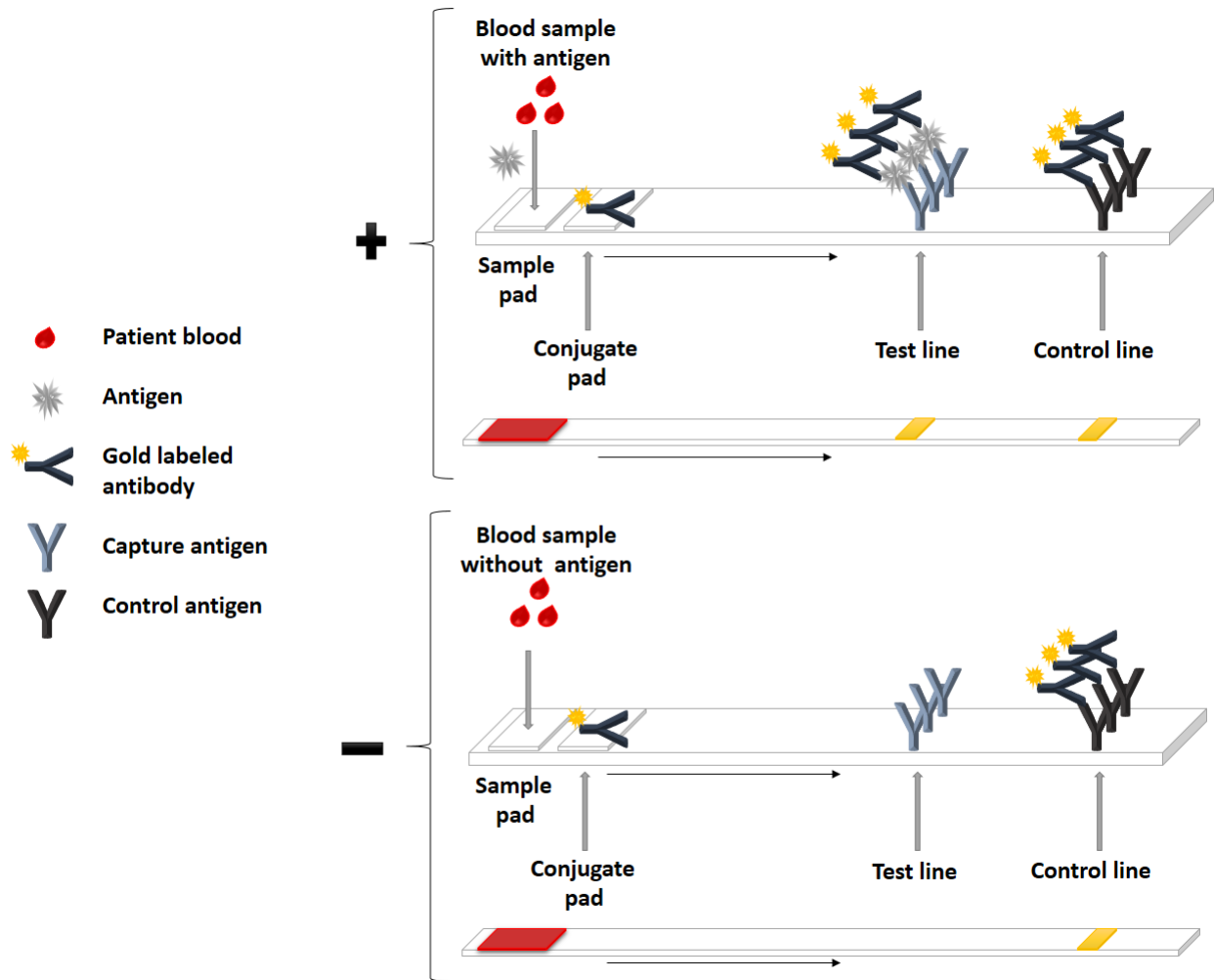


Figure 1: Schematic representation of a sandwich lateral flow assay (LFA). The first LFA shows two lines (the test and the control line) and is positive (+). The second test shows only one line (the control line) and it is negative (-).

Using a universal case, several commercial LFA could be installed. The MAS could be modified for different requirements and medical applications. Thereby, the research and development expenses are minimized, and the final product could be produced cost-efficient. Fig. 2 shows a potential patch structure. Fig. 2a illustrates the top view of the MAS with patient identity, test identity and the test line as well as a control line. The lateral view of the universal case with the integrated test system is illustrated in Fig. 2b.

The blood sampling procedure and the integrated safety mechanism could be implemented in a mechanical manner, whereby an internal or external power supply should not be necessary. That is important for the utilization in regions without stable electrical power supply.

The evaluation of one or multiple tests could also be performed for example by one non-medical trained person utilizing an additional supporting mobile application.

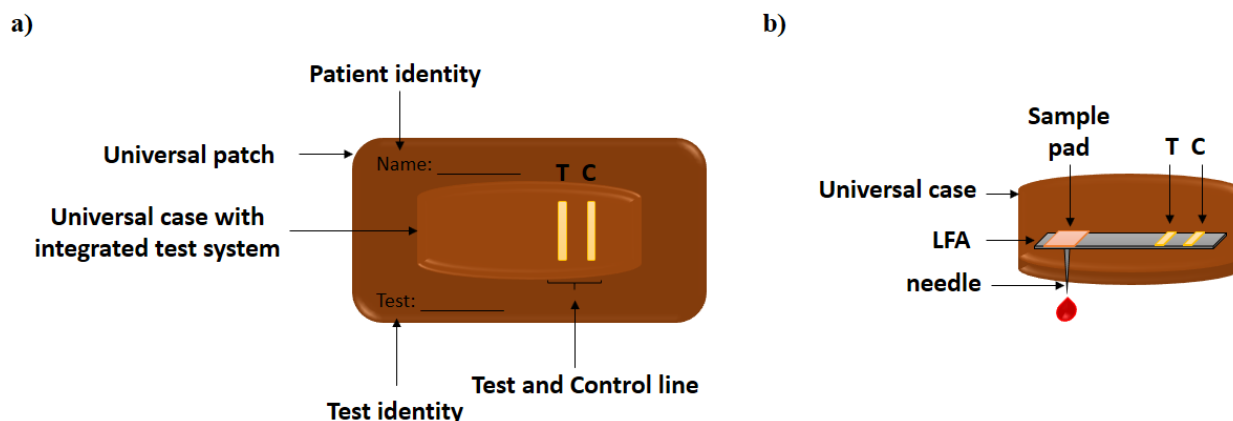


Figure 2: Schematically patch structure, a) topview of the potential MAS, b) functional unit of the MAS with integrated LFA test and blood sampling needle [5]

## Summary

A combination of preparation techniques and novel analysis systems could improve the overall process of blood sampling. This is especially important when considering the situation of sample analysis in case of pandemic prediction or other catastrophic events. As one very potential sample blood is the focus of various strategies. However, the sample preparation for blood samples follows a strict workflow to eliminate any contamination of the sample beforehand.

With a new medical analytic system (MAS) the risk of contamination for the patient and medical personnel could be reduced. Furthermore, MAS are less time consuming and medical trained personnel such as a nurse or other supervisors are not necessary. A theoretical approach utilizing a LFA test has been drafted and can be used as strategic guideline. With simpler and faster MAS, a high number of patients could be tested in a much shorter period of time, which enables to identify epidemics in an early stage. Such MAS could be used in all regions of the world, especially in regions without essential medical care.

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