

Lateral Flow Test - Questionnaire

A	General information	
1	Name	<input style="width: 95%;" type="text"/>
2	Company	<input style="width: 95%;" type="text"/>
3	E-Mail address	<input style="width: 95%;" type="text"/>
4	Phone number	<input style="width: 95%;" type="text"/>
5	Website	<input style="width: 95%;" type="text"/>
B	This request is regarding...	<input type="checkbox"/> New development <input type="checkbox"/> Transfer / optimization of development <input type="checkbox"/> Scale-up <input type="checkbox"/> Production
C	Information about the (planned) lateral flow test	
1	Target analyte(s)	<input style="width: 95%;" type="text"/>
2	Intended use of the lateral flow test, sample matrix	<input style="width: 95%; height: 100%;" type="text"/>
3	Required limit(s) of detection	<input style="width: 95%;" type="text"/>
4	Qualitative or (semi-)quantitative	<input style="width: 95%;" type="text"/>
5	Test design	<input style="width: 95%; height: 100%;" type="text"/>

6	Regulations	
7	Availability of reagents	
8	Concept of kit needed	
9	Number of tests per year	<input type="checkbox"/> ≤ 10 000 <input type="checkbox"/> ≤ 100 000 <input type="checkbox"/> ≤ 1 000 000 <input type="checkbox"/> > 1 000 000
10	Lot size	
11	Target transfer price	
12	Target time frame to product launch	

D	Comments	
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Explanations

A General information

Please fill in your contact data with E-Mail address and phone number here, so we can answer your request. After receiving your request we will answer within 3 business days.

B This request is about...

MC offers a wide range of services regarding lateral flow business. Everything from sampling and sample preparation to analyte detection, lateral flow test and kit design. We will work out the details of your product idea with you. If you already did some pre-work on the assay we can transfer your prototype to our laboratories, regardless of the current stage of development. Furthermore, we offer small scale production (as low as 1.000 tests per lot) as well as large scale production (> 100.000 tests per lot). We can also assist in scale up procedures.

C Information about the (planned) lateral flow test

In this part of the request you can fill in all necessary and important information that you want to share with us. The more details you can provide, the easier it is for us to understand your needs, and provide you with the optimal solution for your assay. If you are not sure about some details, don't hesitate to contact us. We will gladly provide any support required! If needed, a CDA can be exchanged beforehand.

C1 Target analyte(s)

What is (are) the target analyte(s) you want to detect? If there is more than one target analyte, do you want to have a multiplex lateral flow test for all analytes together or single lateral flow tests for each analyte?

C2 Intended use of the lateral flow test, sample matrix

What kind of personnel (trained, untrained) will use this test? In which location (e.g., special companies or institutes, in the lab, in the field, on-site, in other countries with different climatic conditions) will the test be performed? How is the sampling done and what is the resulting sample matrix for the test strip (e.g., aqueous, extract of liquid or solid material, a swab)?

C3 Required limit(s) of detection

What concentration/content of target analyte do you want to detect (e.g., ng/mL, ppb)? Are there any legal requirements concerning the analyte?

C4 Qualitative or (semi-)quantitative

Is your desired test concept a qualitative, a semi-quantitative or a quantitative test? What is the desired readout of the test – visual or by some kind of reader? For quantitative tests a reader is mandatory. For qualitative and semi-quantitative tests the readout can be accomplished visually or by reader depending on preference.

C5 Test design

The test design correlates with the intended use of the lateral flow test. Do you prefer a dipstick format, a test strip in a cassette or a different format? Do you have a preference how to apply the detection particles (e.g., particle conjugate pad on strip, particles in suspension, particles dried or lyophilized in tubes)?

C6 Regulations

Are there any regulations to take into account? This of course depends on the intended use of your lateral flow test. As an OEM manufacturer, we can also support you during an IVD certification if required.

C7 Availability of reagents

Dependent on the lateral flow test you want us to develop/produce, will you supply us with all or some reagents needed (e.g., target analyte, appropriate antibodies, polyhapten, sample matrix)? If not, are the reagents that are not supplied commercially available?

C8 Kit concept needed

Are you solely interested in the lateral flow strip (with the strip design you specified in C5) or in a kit containing lateral flow strips and other necessary components, such as pipettes or swabs? MC offers assistance in selecting suitable packing materials for kits with respect to boxes, inlays, bottles, caps and labels and a full-scale kit manufacturing with lot sizes of up to 5000 kits per batch. If you want a kit concept, how many tests should be contained in one kit?

C9 Number of tests per year

If you decide on requesting a production of the lateral flow test, what will be your estimated number of tests per year (lateral flow tests or kits)?

C10 Lot size

With regard to the number of tests per year, what would be your preferred lot size (tests per lot or kits per lot)?

C11 Target transfer price

What would be your target transfer price per strip or kit?

C12 Target time frame

What would be your preferred time frame for development/production transfer/product launch?

D Comments

In this box, you can fill in any additional information you think is necessary for us to know.