

Development of a nucleic acid-based amplification test as point-of-care rapid test detecting sexually-transmitted diseases for home-care

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BACKGROUND

In Europe, 350.000 new sexual transmitted diseases (STI) caused by Chlamydia types have been registered in 2009 [1]. Approximately 70 % of infections with *Chlamydia trachomatis* run an asymptomatic course and therefore remain undetected. This can result in severe complications such as chronic diseases, infertility, complications in pregnancy and cancer [2, 3].

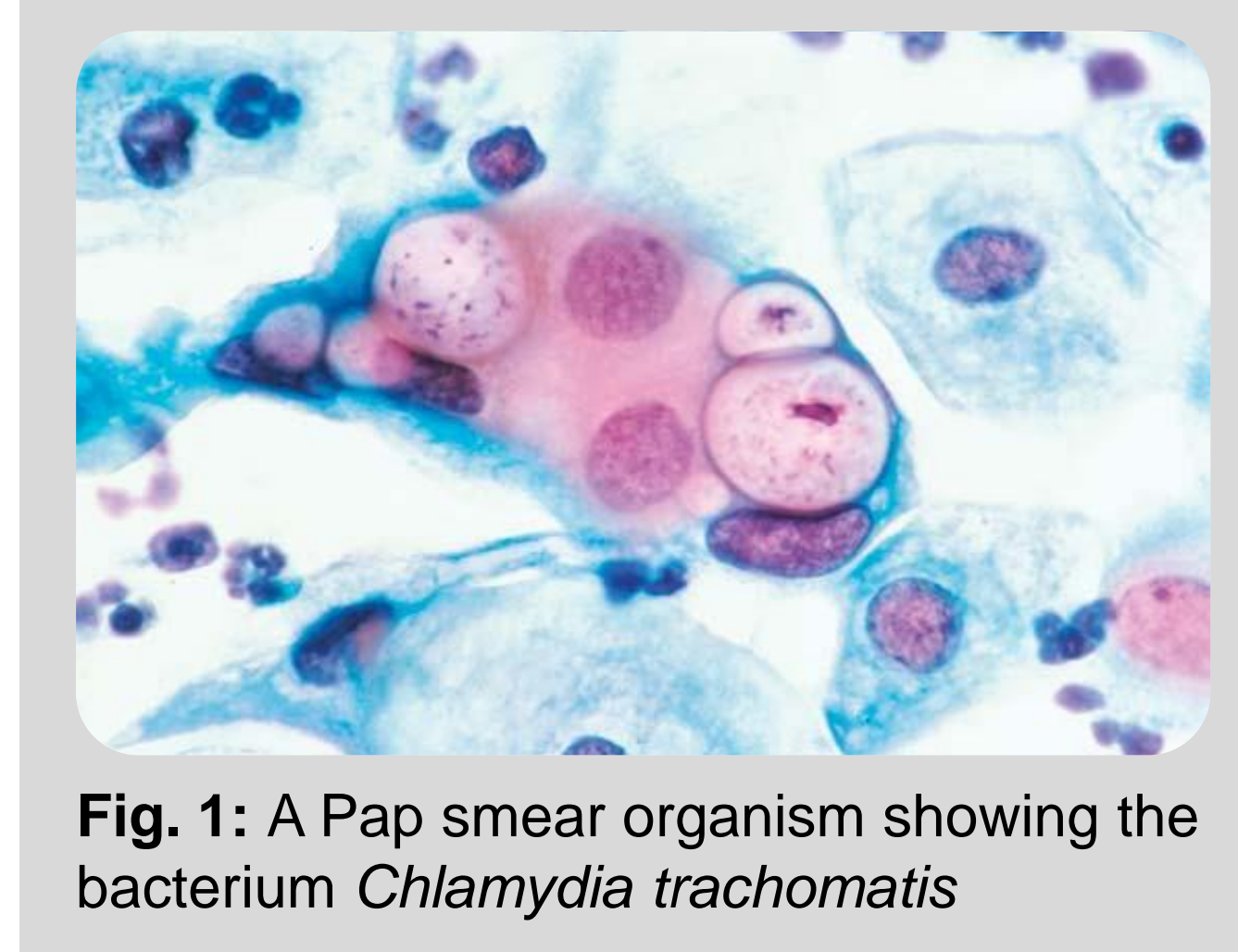


Fig. 1: A Pap smear organism showing the bacterium *Chlamydia trachomatis*

Current detection systems commercially available are based on **serological methods**. Drawbacks: high market price, diagnostics of infection in advanced stage not possible, false-negative results, main market focus lies in the clinical area.

➔ **Rising demand for new, innovative detection systems for home-care devices**

IDEA

- Development of a **point-of-care** rapid testing system for **home-use** that is able to detect *Chlamydia trachomatis* from **urine samples**
- Combination of a highly specific nucleic acid amplification with detection on a simple and disposable **test strip platform**



A

- Sample pretreatment (5 min, RT)
- Lysis of host and pathogen cells and extraction of genomic material

B

- Loop-mediated isothermal amplification** (Fig. 2)
- No cycling of temperature, high specific and sensitive
- 60 °C for 25 minutes

C

- Qualitative immunochromatographic detection
- Lateral flow strip system** (Fig. 3)
- 5 minutes at RT

STRATEGY

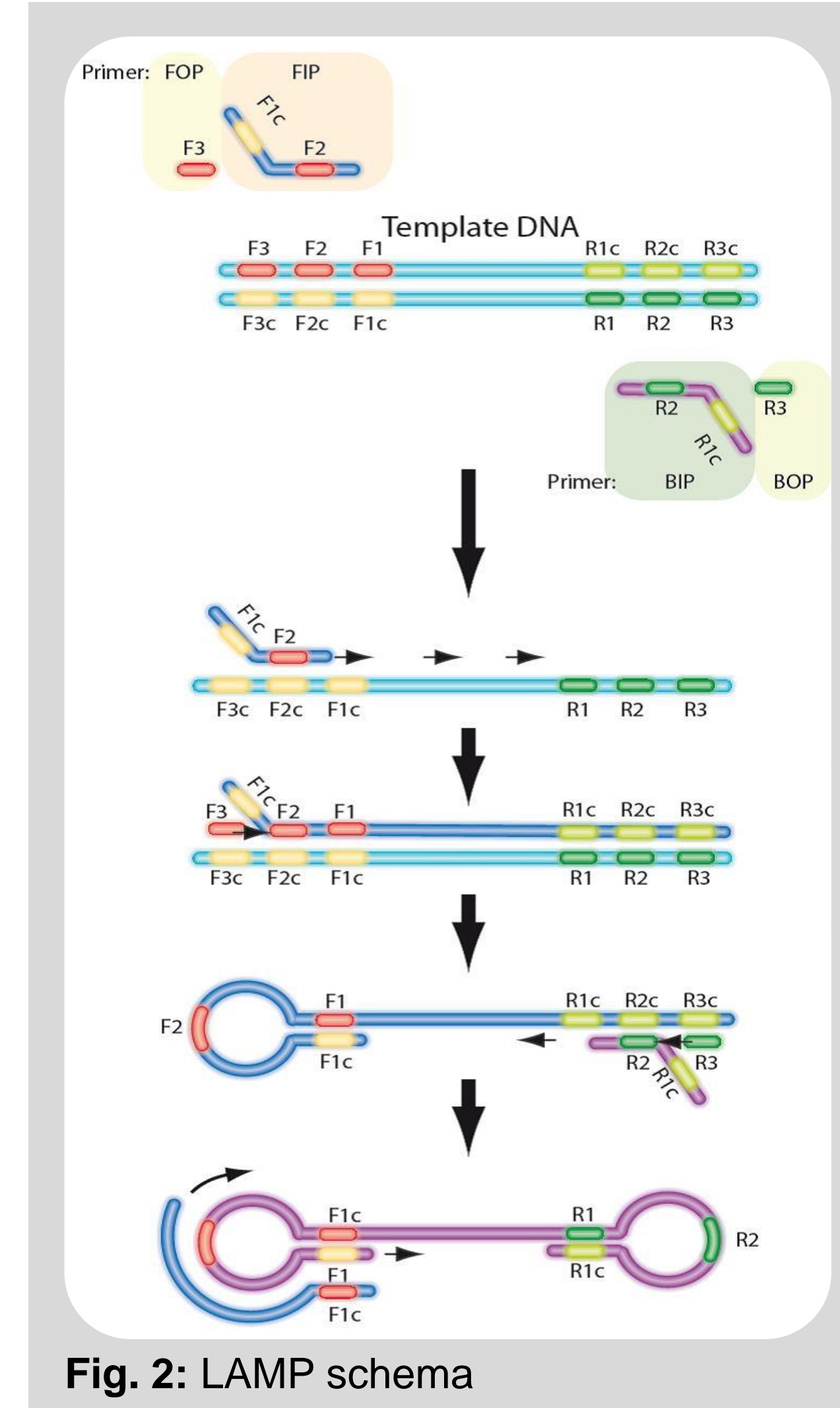
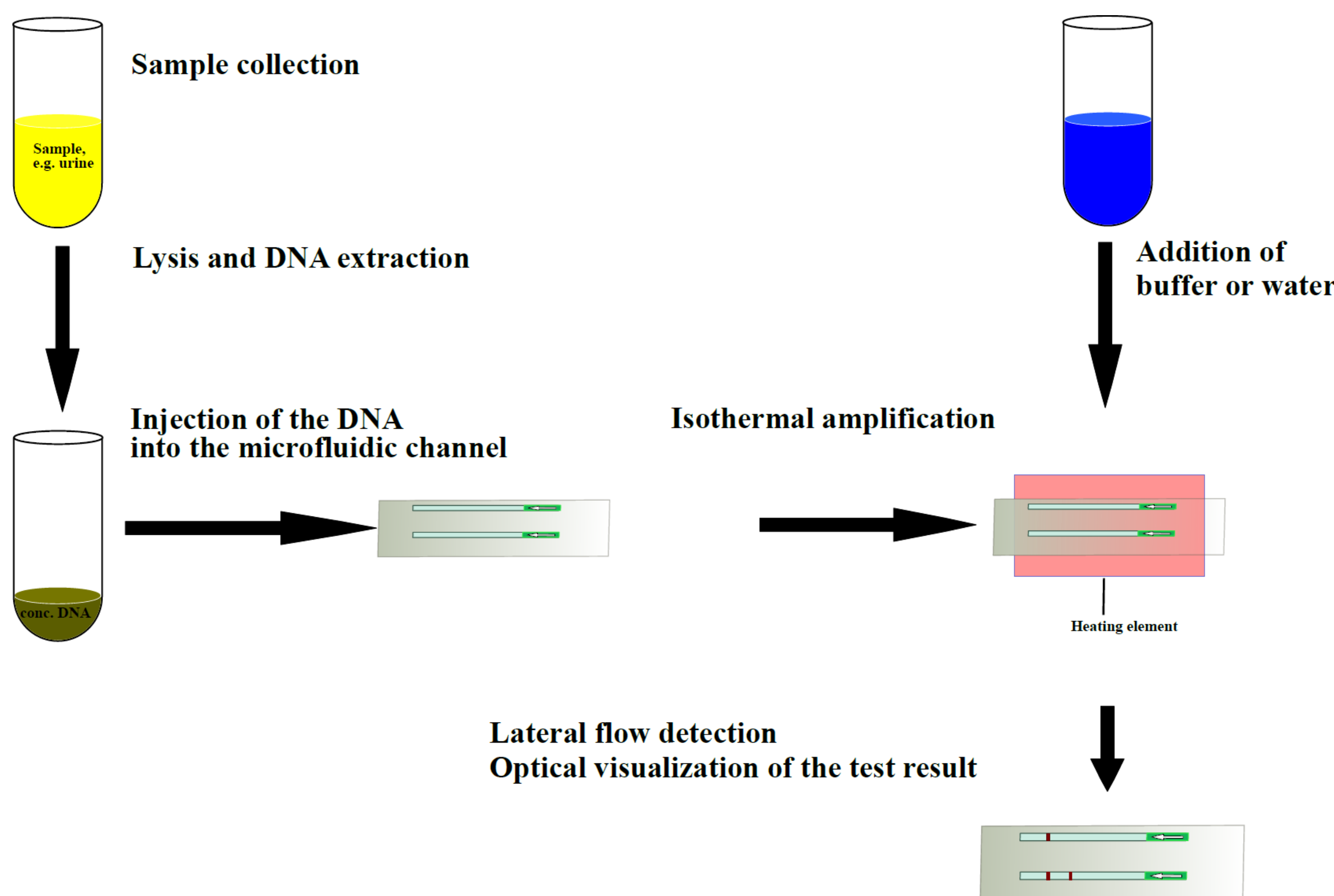


Fig. 2: LAMP schema

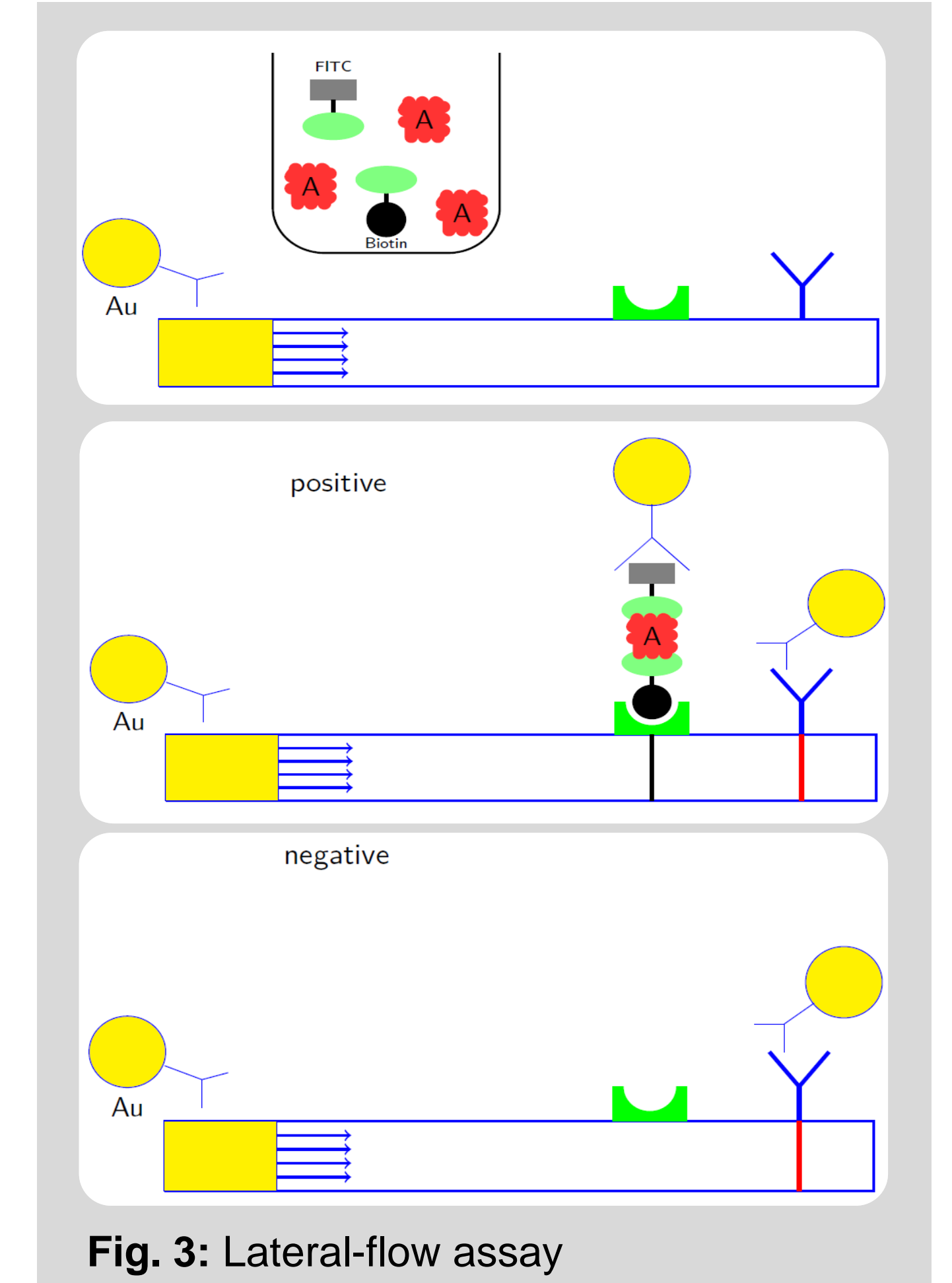


Fig. 3: Lateral-flow assay

MUTITESTING SYSTEM (COC CHIP)

- Fabrication by injection molding
- Bonding with double-adhesive tape
- Platform integrated **two detection systems on one COC chip** (Fig. 4)



Fig. 4: COC device – functional model

INITIAL CLINICAL TESTING

Result in functional model	Number of patient samples
Positive	7
Negative	10
False-positive	0
False-negative	1
Total	18

Fig. 5: Results of tested urine samples from patient; performed in device

MICROHEATING SOLUTION

- Requirements: Non-toxic, disposable in household waste
 - Prototype: **PMMA case** (milled) with cavity for chemicals
 - Exothermic chemical reaction
 - Result: Temperature range between 57 °C and 63 °C over a period of > 40 min
- ➔ **Suitable for LAMP on chip**

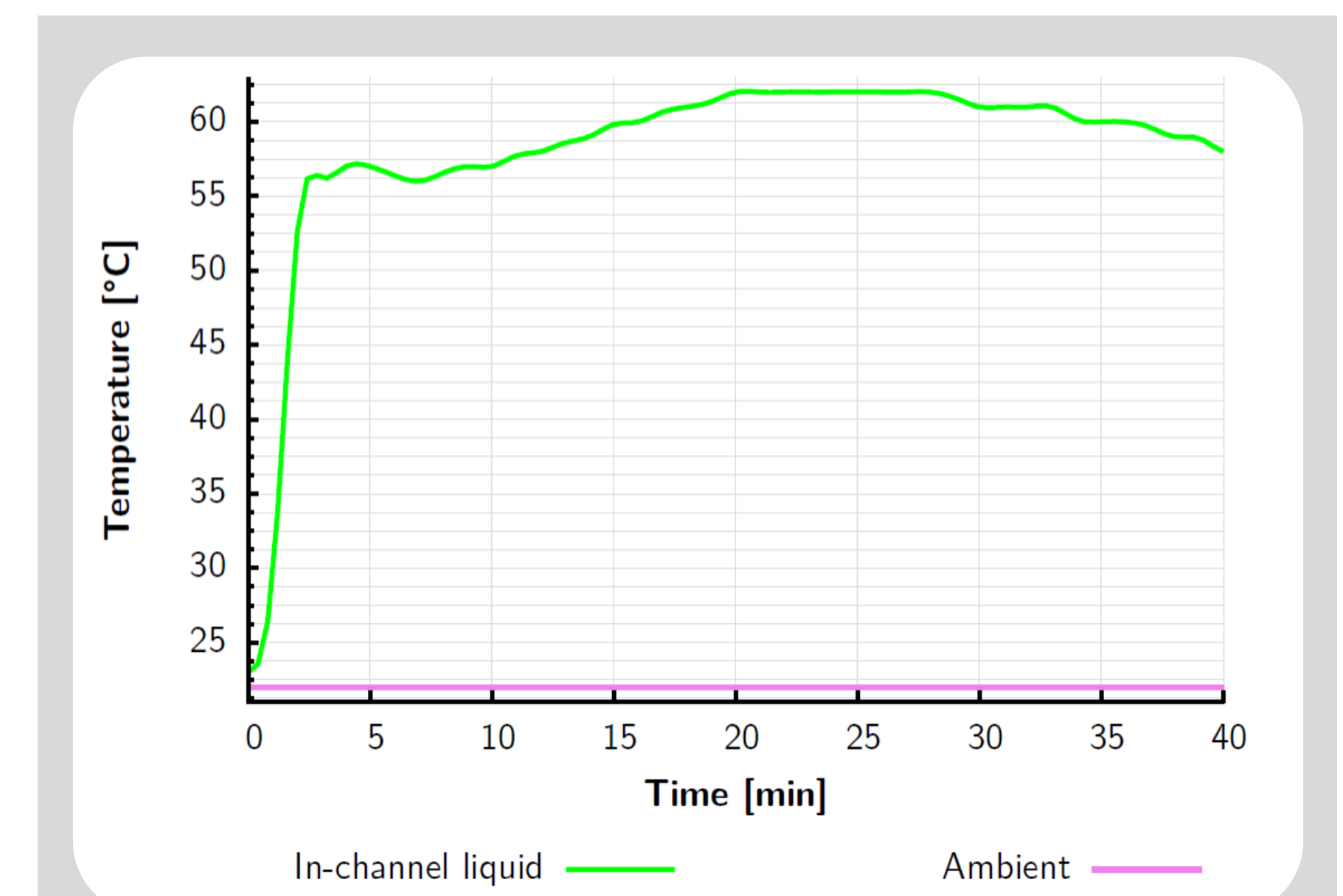


Fig. 6: Temperature profile of the chemical exothermal reaction; performed in the PMMA case

LITERATURE

- [1] World Health Organization: Global incidence and prevalence of selected curable sexually transmitted infections – 2009. WHO 2012.
- [2] European Centre for Disease Prevention and Control: Sexually transmitted infections in Europe, 1990-2009. Stockholm: ECDC, 2011.
- [3] World Health Organization: Sexually Transmitted Infections (STIs) as a Public Health Issue, Fact Sheet 2004.