

In vitro diagnostics medical devices to respond to **urgent** needs

Author: David Nauwelaers
15 May 2022

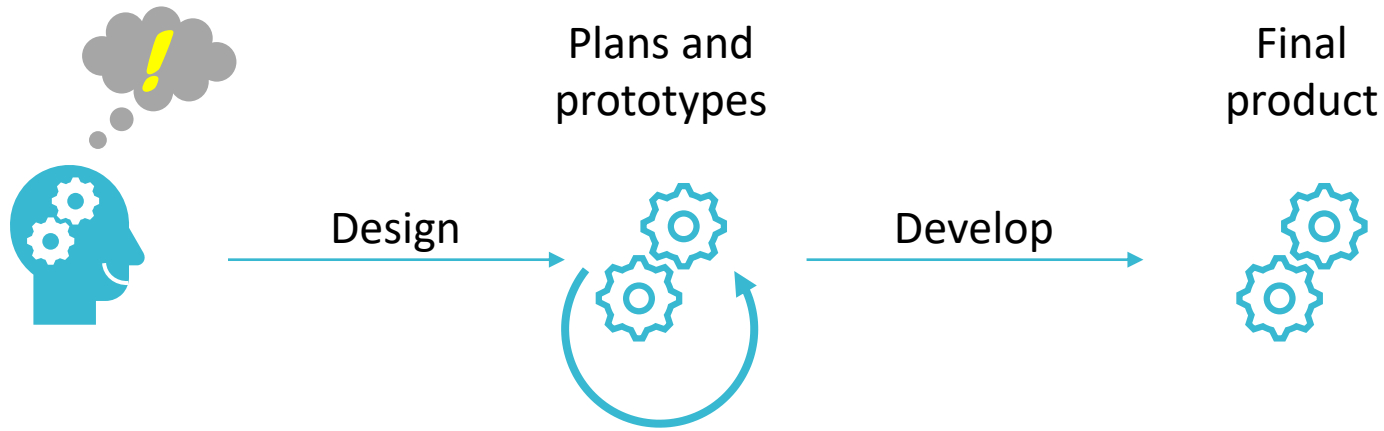
*mi*DIAGNOSTICS

**Challenges in
product
development
from an
operational
standpoint**

Product

Production process

Logistics



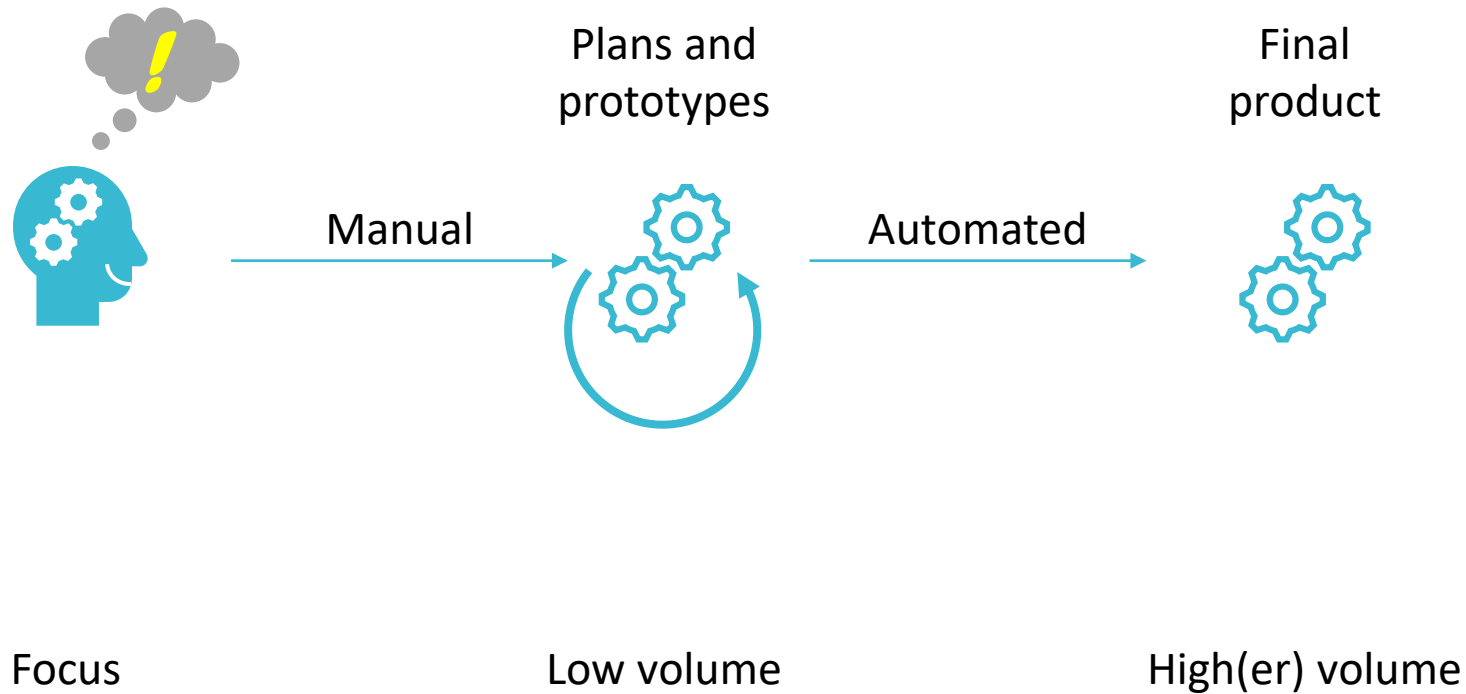
Focus

This thing
needs to work

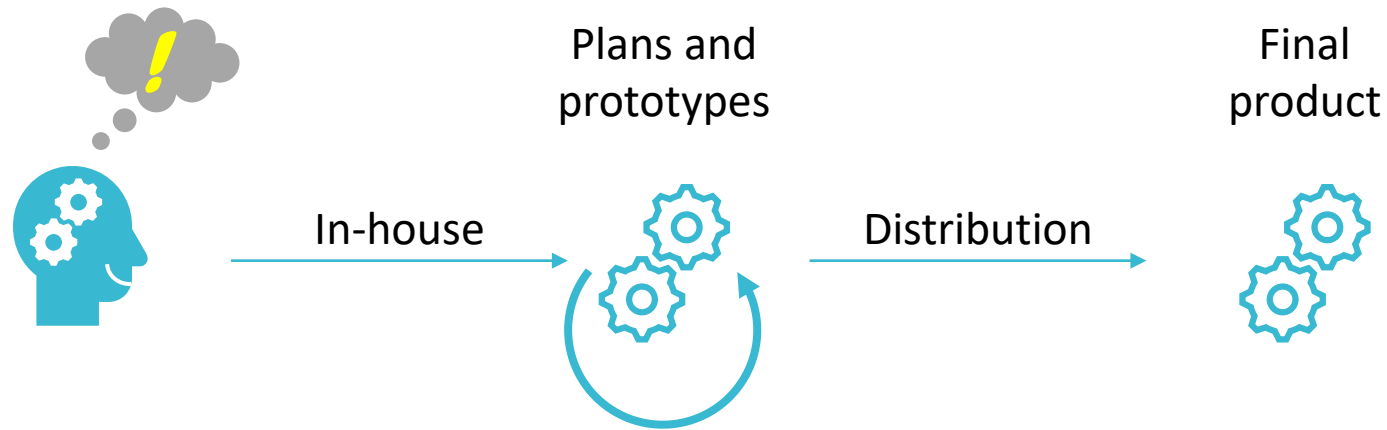
Cheaper
Better
Smaller



Challenge #1: **Product** – Make in function of performance vs make in function of cost



Challenge #2: **Production process** – Optimize for Quality and Scalability



Focus

In-house
local

We need to reach
all the customers
(worldwide)

Challenge #3: **Logistics** – Optimize for Quality and Stability

Idea: A quick PCR test

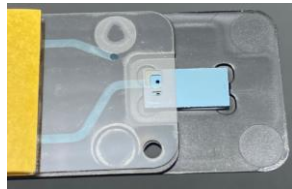
miDiagnostics employees

Imec – chip manufacturer

Plans and Prototypes

Foil manufacturer

Final product



Challenge #1: **Product** – Traditional development path

Idea: A quick PCR test

miDiagnostics employees

Imec – chip manufacturer

Plans and Prototypes

Final product

Foil manufacturer



Our required yearly consumption of chips >>>> than the production capacity of Imec



Challenge #2: Production process – Traditional development path

Idea: A quick PCR test

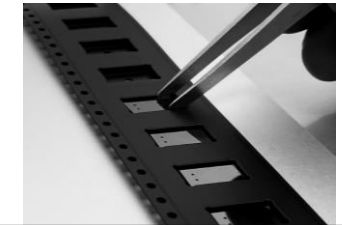
miDiagnostics employees

Imec – chip manufacturer

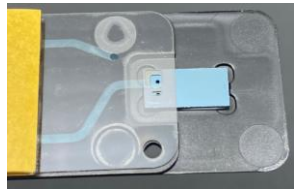
Plans and Prototypes

Final product

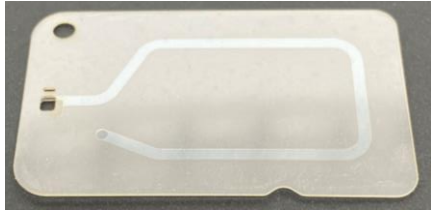
Foil manufacturer



Our required yearly consumption of chips >>>> than the production capacity of Imec



Challenge #2: Production process – Traditional development path



Production process

4 different layers



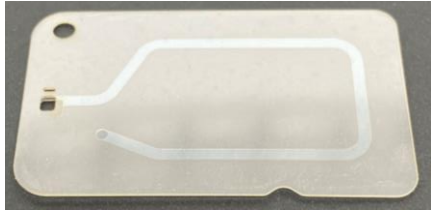
Complex laser cutting technology

3-step assembly process

12-36 at a time

750 pieces/week (24/7!)

Challenge #2: **Production process** – Traditional development path



Production process

Assembly process

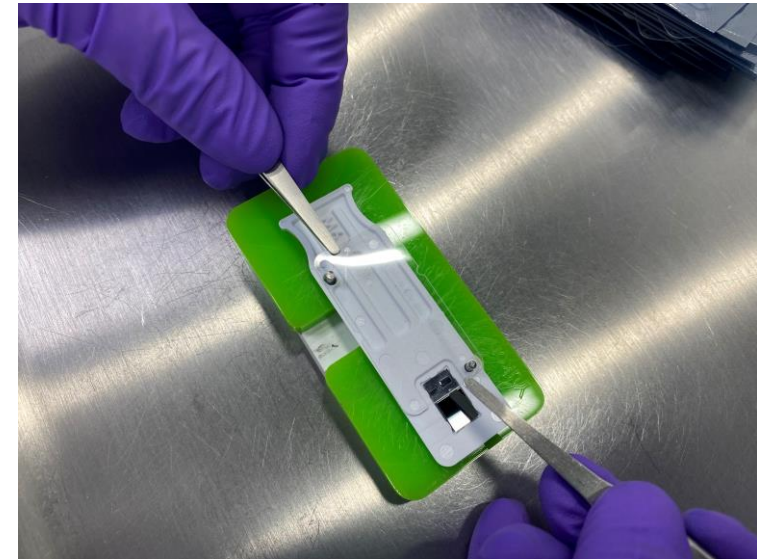
Manual

Extremely precise positioning required

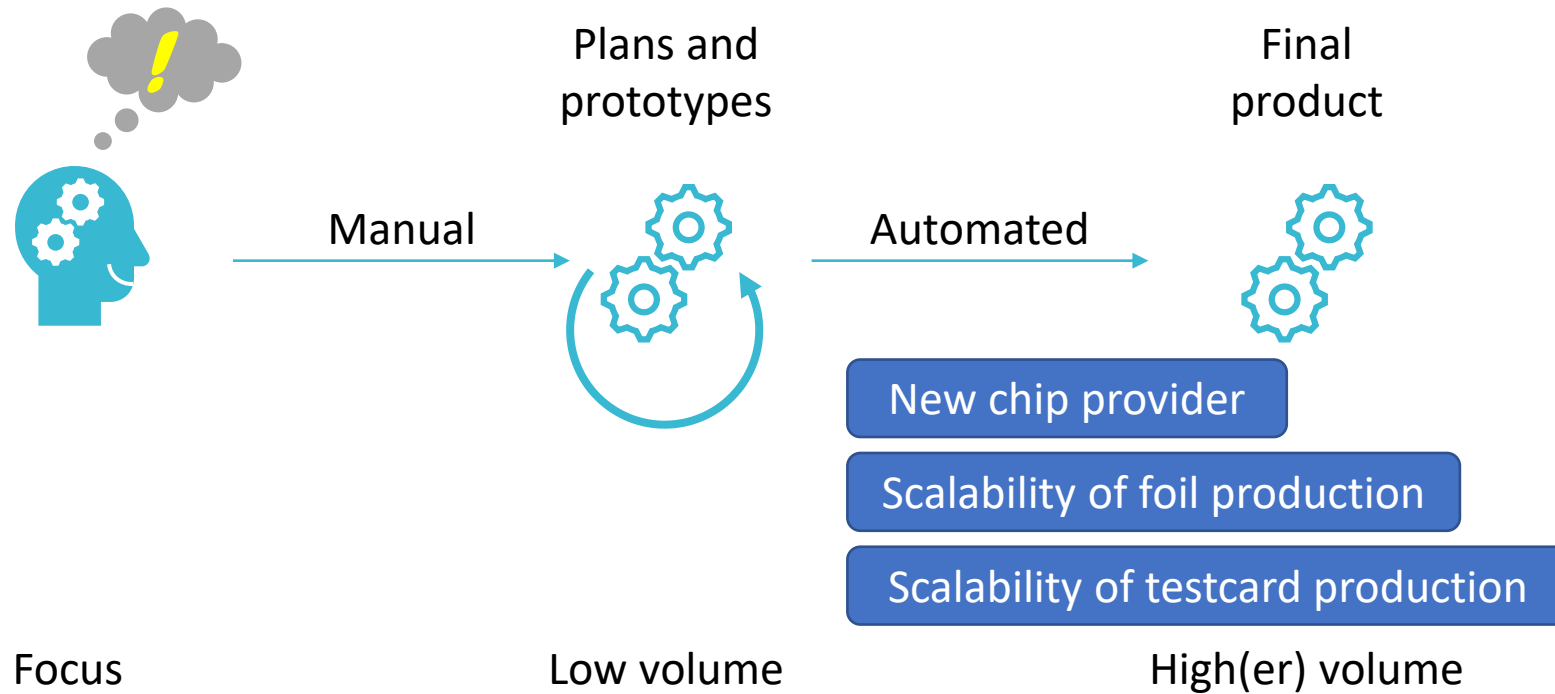
One at a time

1000 testcards a day is feasible (labor)

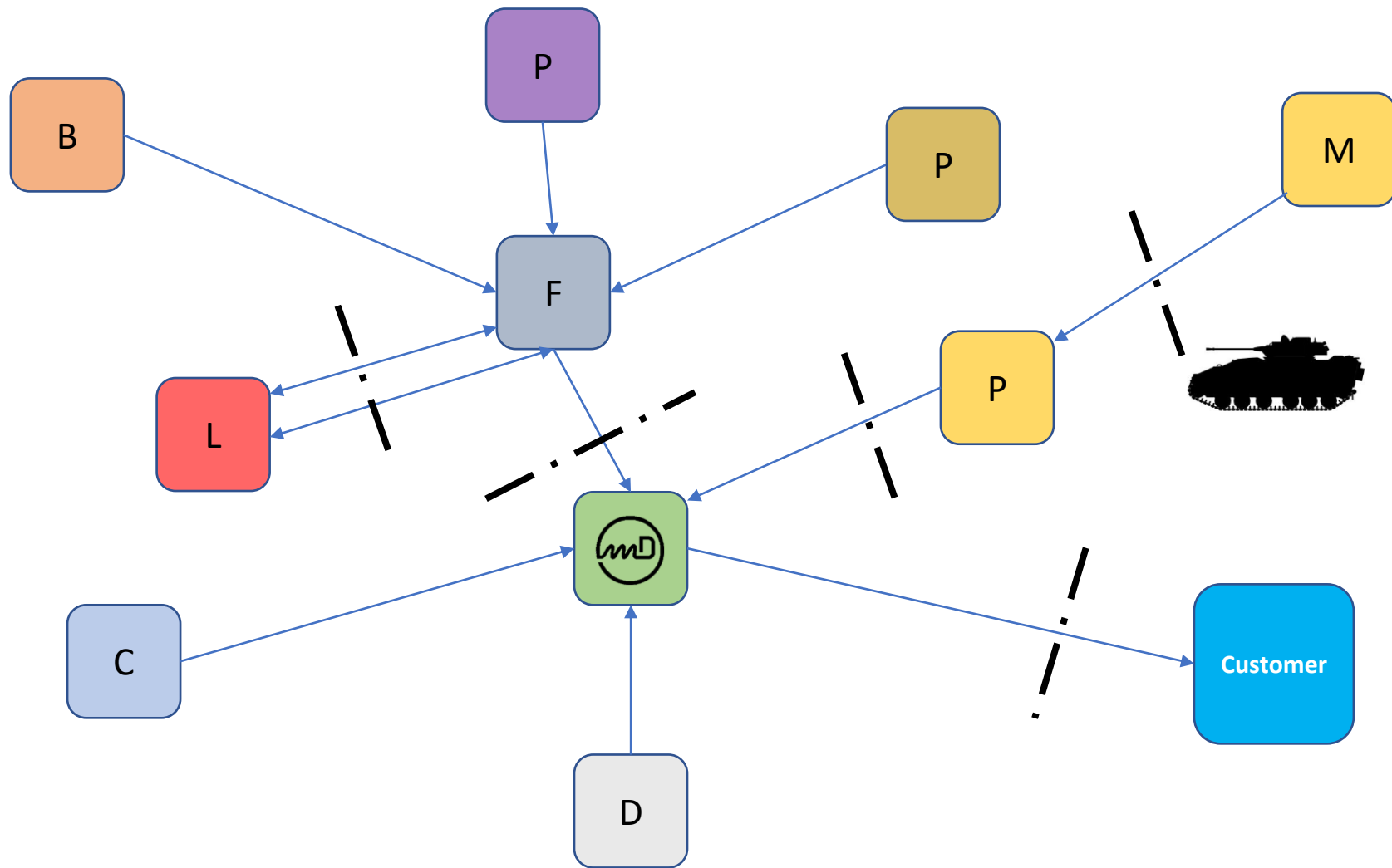
4 different layers



Challenge #2: **Production process** – Traditional development path



Challenge #2: **Production process** – Optimize for Quality and Scalability



Challenge #3: **Logistics** – Optimize for Quality and Stability

A faint, blue-tinted image of a microfluidic chip is visible in the background of the left sidebar. The chip features a grid of small rectangular wells and various channels and structures.

**IVD medical
devices to
respond to
urgent needs**

As a company you need to be able to respond quickly to a (global) need

- (Rapid development of) a suitable sample collection, sample prep
- Rapid development time (PCR)
- Generic system
- Rapid, scalable production
- (Global) distribution channels

New approach

Production process

Product

Logistics

Production process

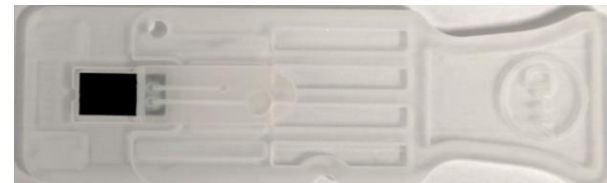
10 Million / 360 days / 24 hours / 60 minutes = 20 pieces per minute or
3 seconds per testcard

1-step assembly (3 parts)



Minimal labor

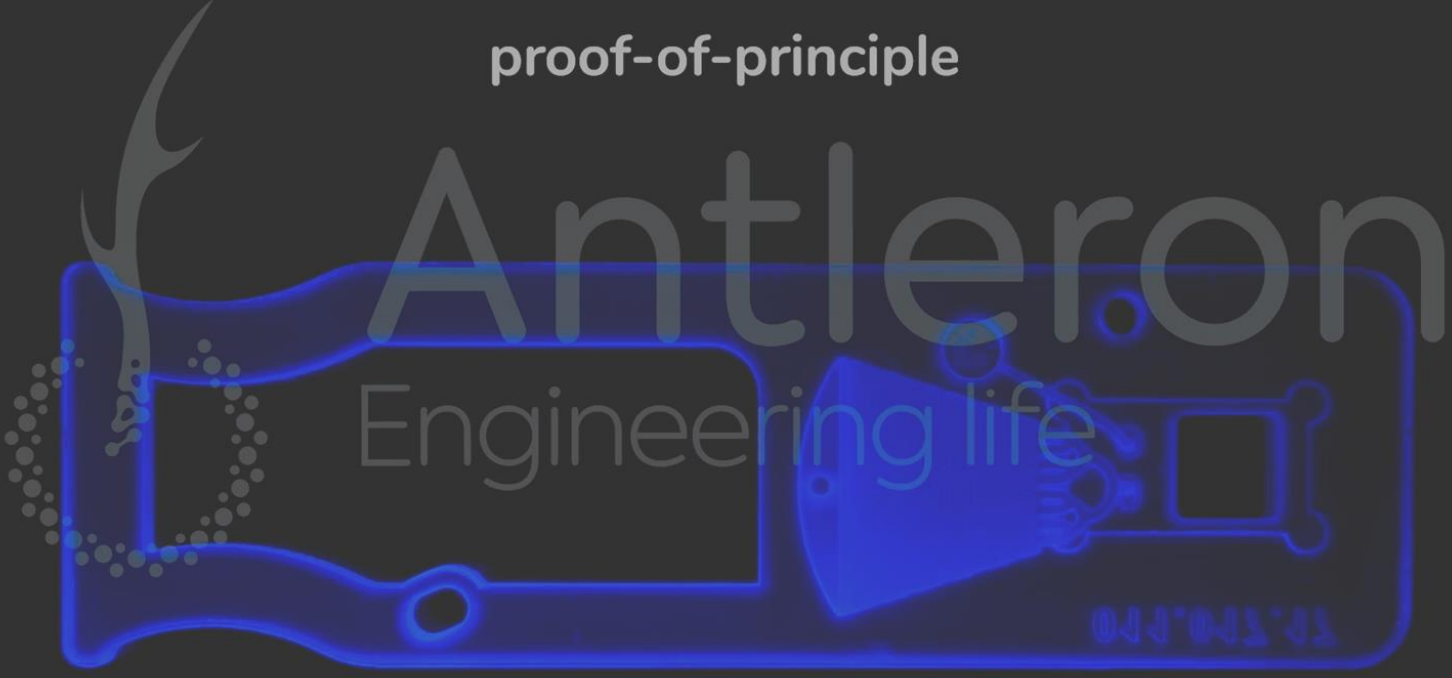
Local



Key requirements

Proof of principle

PCR chip integrated into card
proof-of-principle



The logo for Antleron Engineering life features a stylized antler on the left, a central rectangular frame containing a magnifying glass, and a circular arrangement of dots on the left side of the frame. The text 'Antleron' is written in a large, light blue font across the top, and 'Engineering life' is written in a smaller, light blue font across the middle. The entire logo is set against a dark blue background.

Confidential Antleron 2021

Start small

Learn

Improve

Go big

Research Assembly Tool (RAT)
(Focus on assembly, manual feed)



Commercial Assembly Tool (CAT)
(RAT x 2, fully automated)

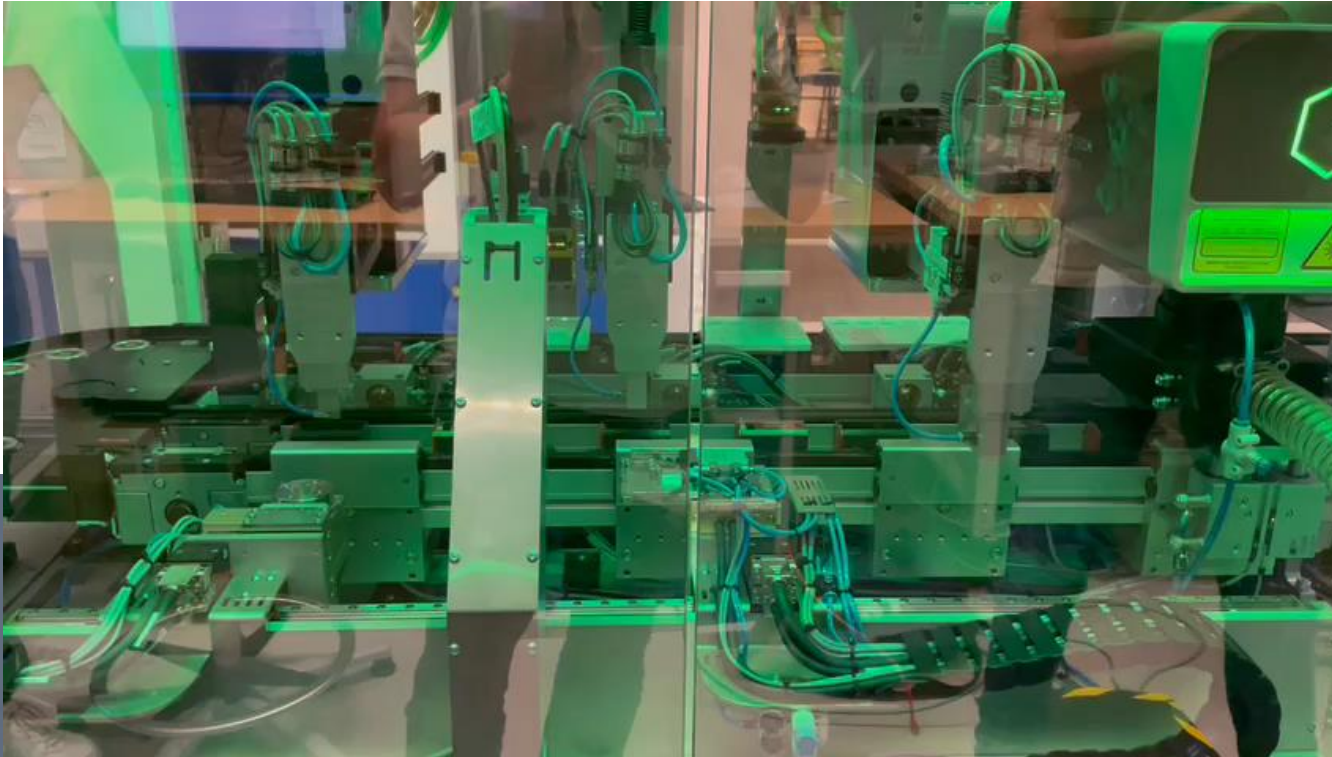
RAT

4 operators

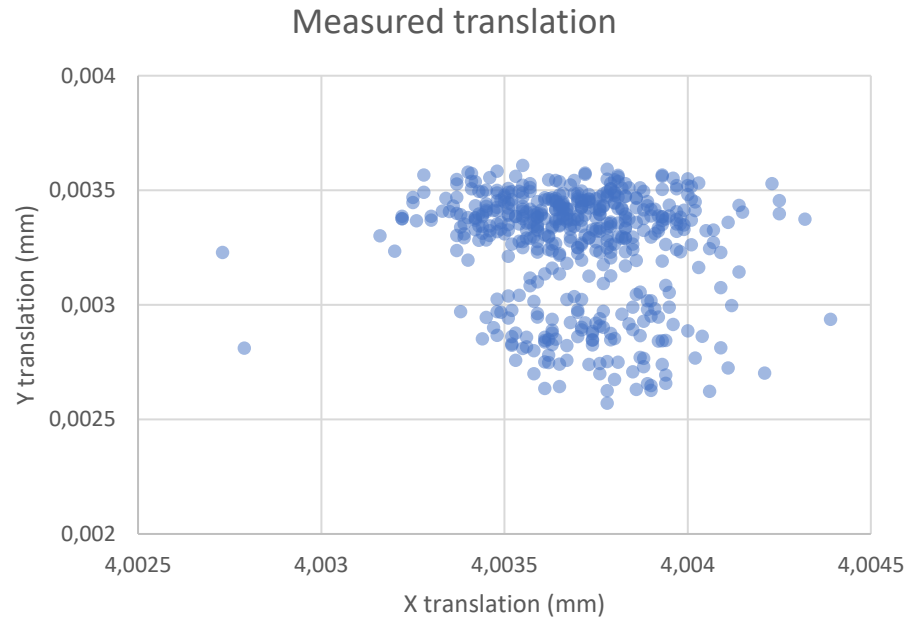
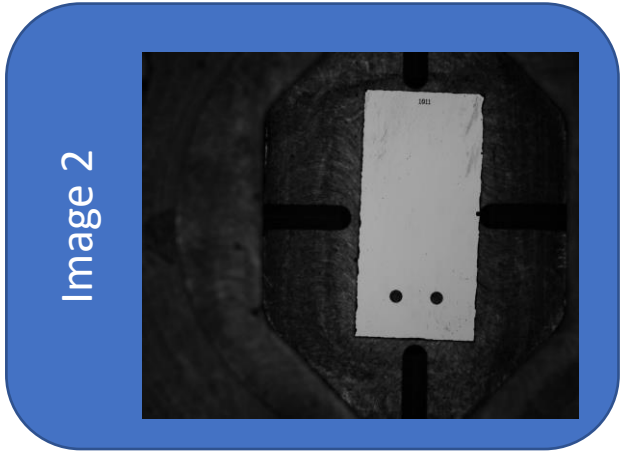
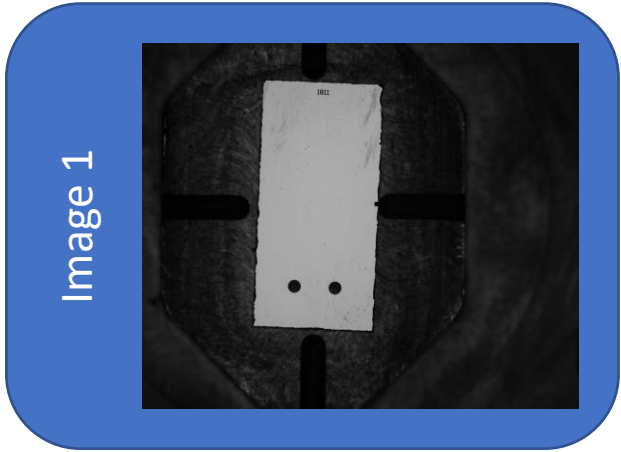
3 parts

2.8 seconds assembly time

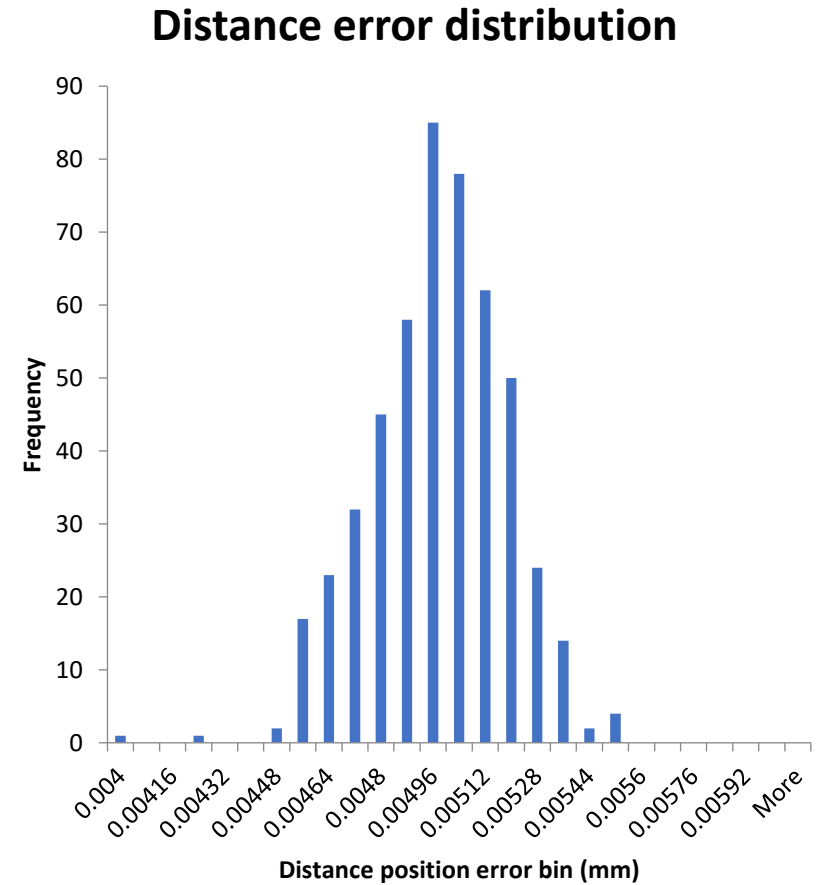
1285 testcards/hour



500 image pairs (stage @ 0mm, 4mm)



	mean	stdev
X translation (mm)	4.003695	0.000208
Y translation (mm)	0.003264	0.000246
Distance error (mm)	0.004936	0.000206



- Estimate the error between vision and alignment stage
 - Calibrate vision to stage
 - Compare relative movement of die-holes with known stage translation
 - Move stage to position #1[x,y] - Take image - Move stage to position #2[x,y] - Take image (Repeat multiple times)
 - Subtract stage values from vision values - Analyze spread

Average measurement
inaccuracy is about 5 μ m

New approach

Product

1-step assembly (3 parts)



Next-day adaptable
Rapid prototyping
No mold or machinery development

New approach

Logistics

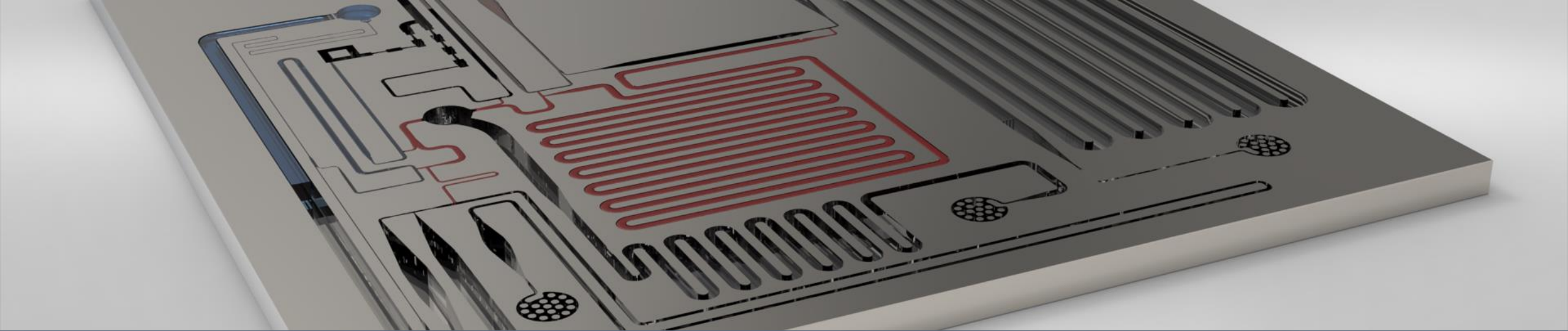
Limited logistics (Leuven area)

Print entity 1,5M€ / 10,000 printed parts

Scalable as demands requires, setup in 3 months time

Local production possible (Leuven or elsewhere)

Distributed manufacturing if desired – no “valuable” logistics



Thank you!

Questions?

*mi*DIAGNOSTICS