

COVID-19 Testing Program

Example:

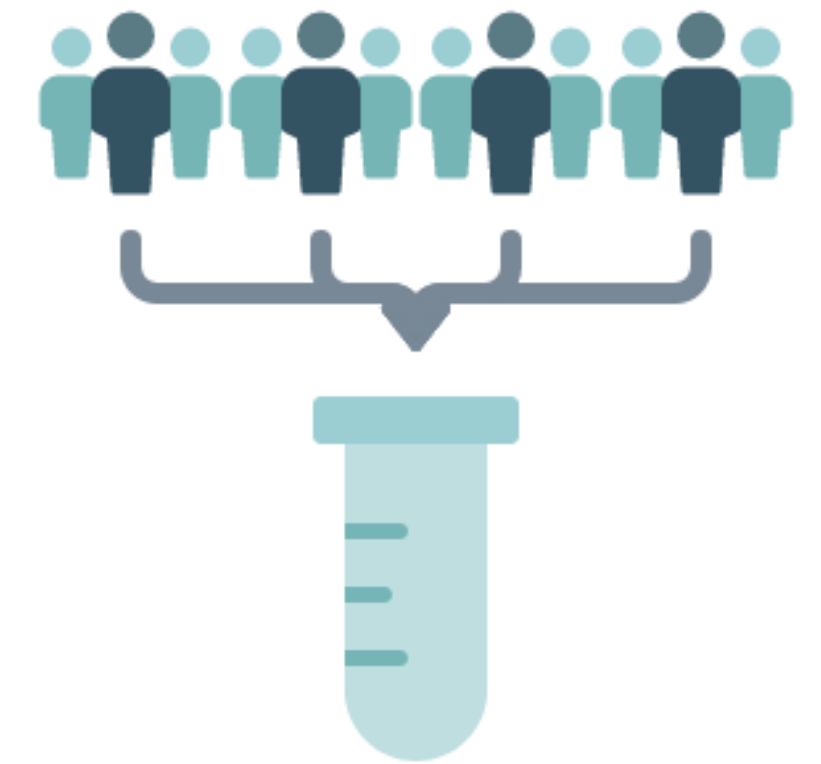
ddPCR and Group Testing

Group Sense Solutions Inc.

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Combine High Volume with High Sensitivity

- **Droplet Digital PCR (ddPCR)** is 25-50x more sensitive for detecting COVID-19 RNA than standard RT-PCR.
- **Group testing:** combine many samples into one test.
- ddPCR offers the **sensitivity** needed for detection of low viral load positives pooled with many negatives
- Screens a high volume of samples in one round of ddPCR.
- Saves 80%+ of tests compared to individual testing.



Overview of Scientific Concepts

1. Sensitivity advantage of ddPCR.
2. A basic example of group testing.
3. Optimal group testing with overlapping groups.

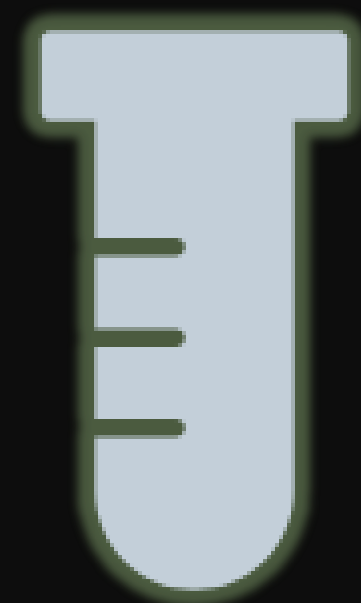
ddPCR: Highest Sensitivity COVID-19 RNA Test

RT-PCR:

- Low viral load -> weak signal + unacceptable false negative rate

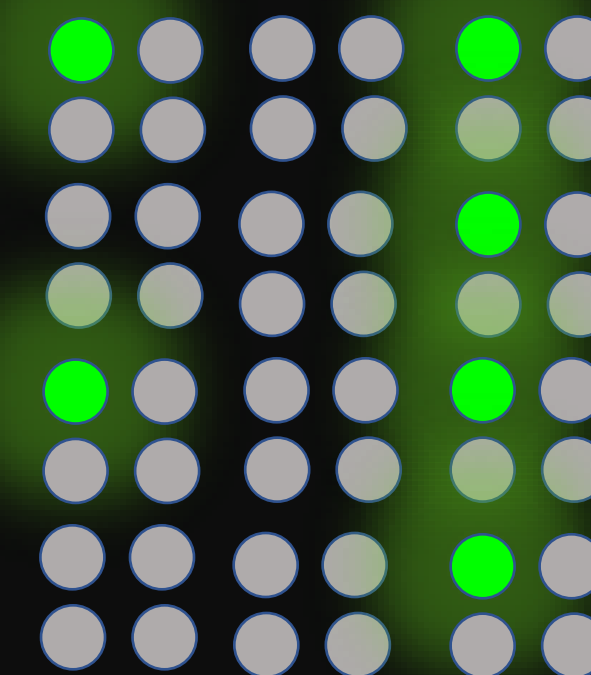
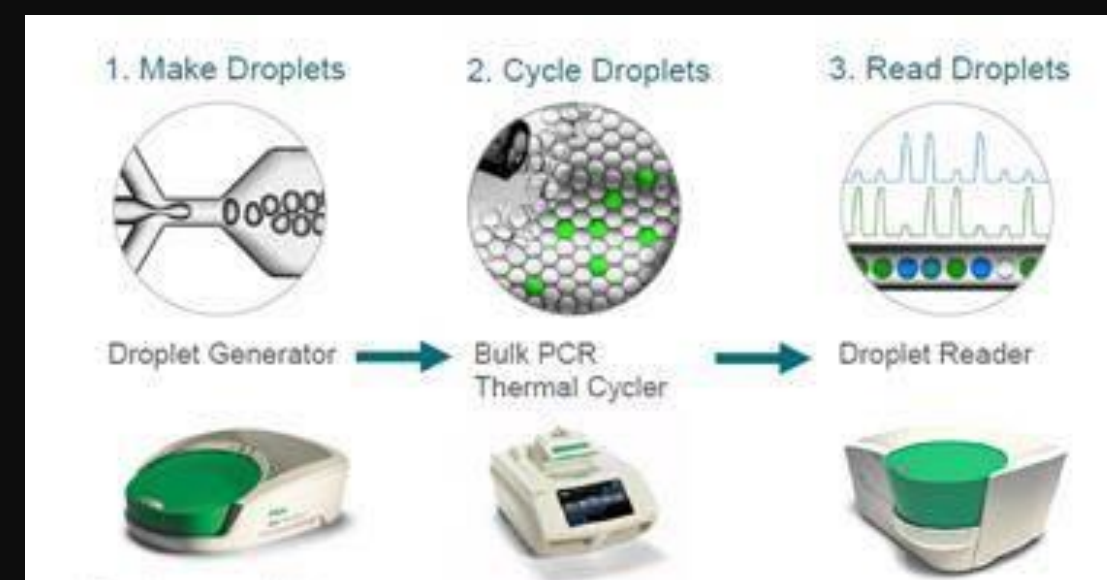
ddPCR:

- Partition sample into ~20,000 droplets for 20,000 tests
- 1 weak signal is concentrated into many strong signals
- Direct quantification of viral load: good for measuring kinetics.



RT-PCR: 1 Weak signal
= COVID-19 (-)

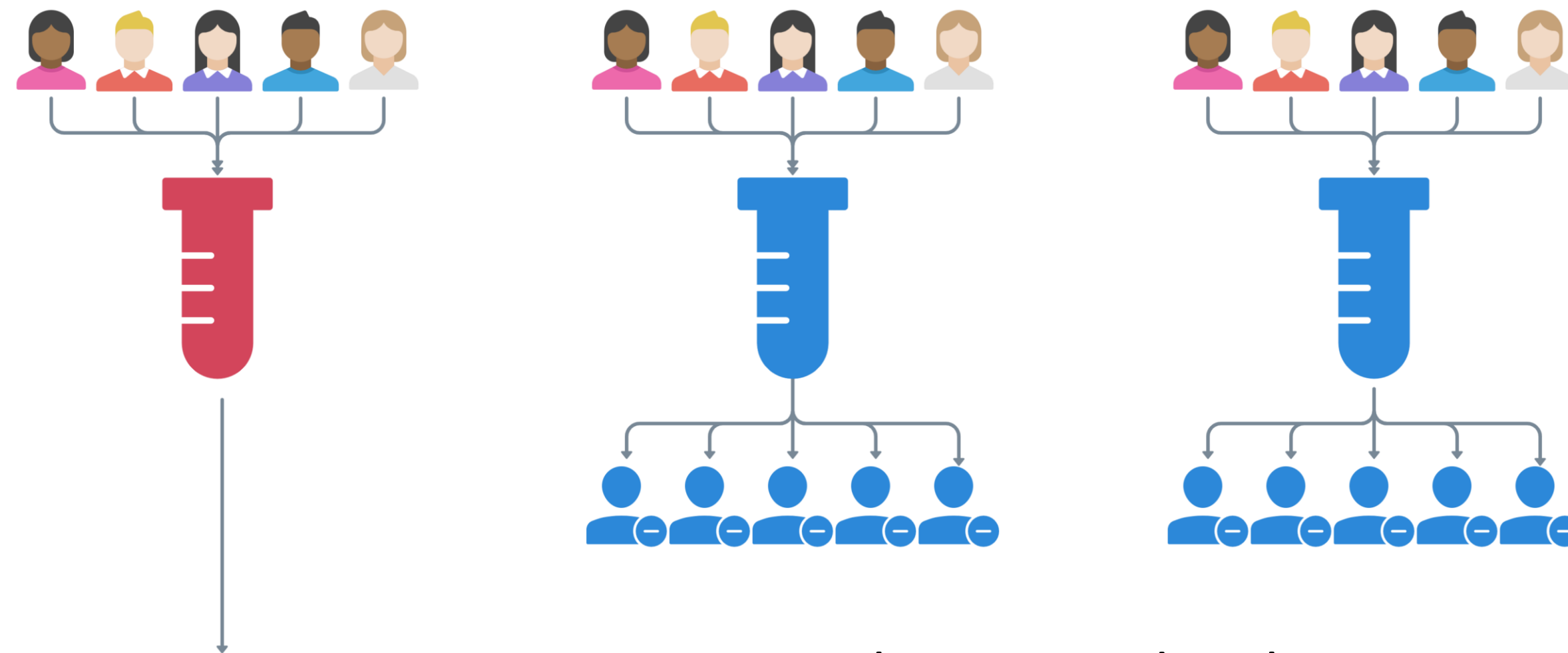
Partition, PCR, read droplets



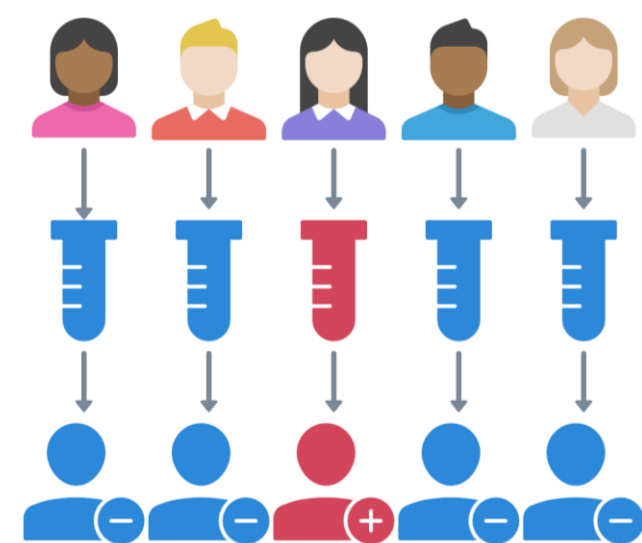
ddPCR: Several strong
signals

and mostly negative
signals.
= COVID-19 (+)

Basic Group Test Example



15 people screened with 3 tests
(Round 1)



5 people evaluated with 5 tests
(Round 2)

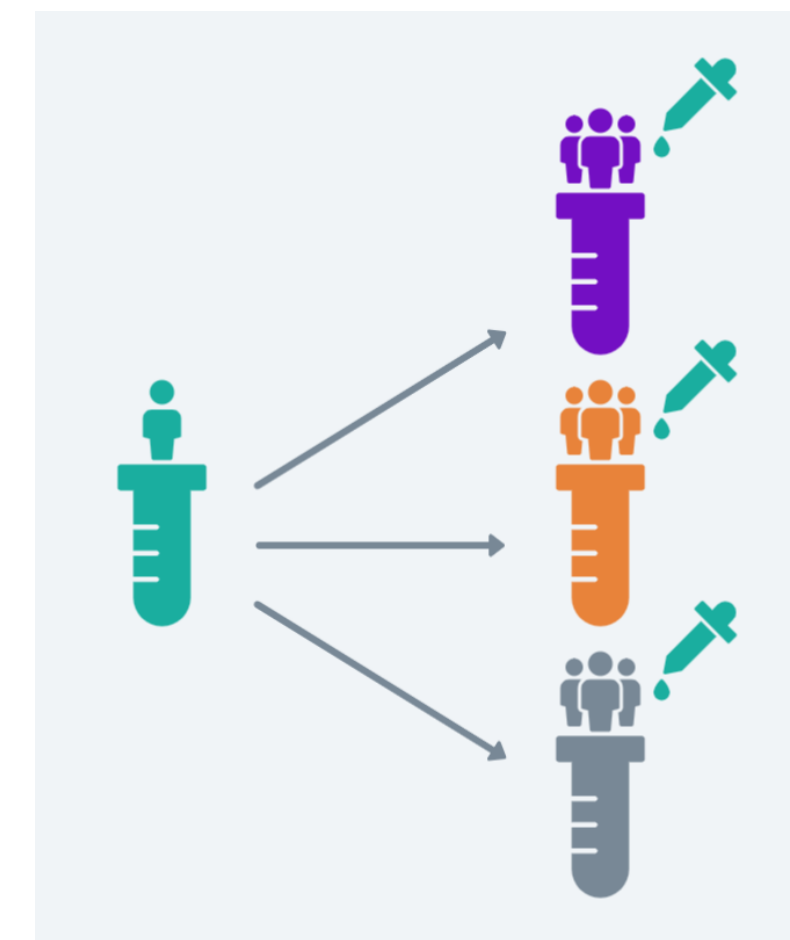
Group Testing Details

ddPCR tests 92 pools/samples in a ~5 hour round.

Screening round: Pipette each sample into 3-4 **overlapping** pools.
Pools are of size 20-25.

Pools overlap for maximum screening.

Instructions described by app.



Round 2: Test all potentially positive samples individually.

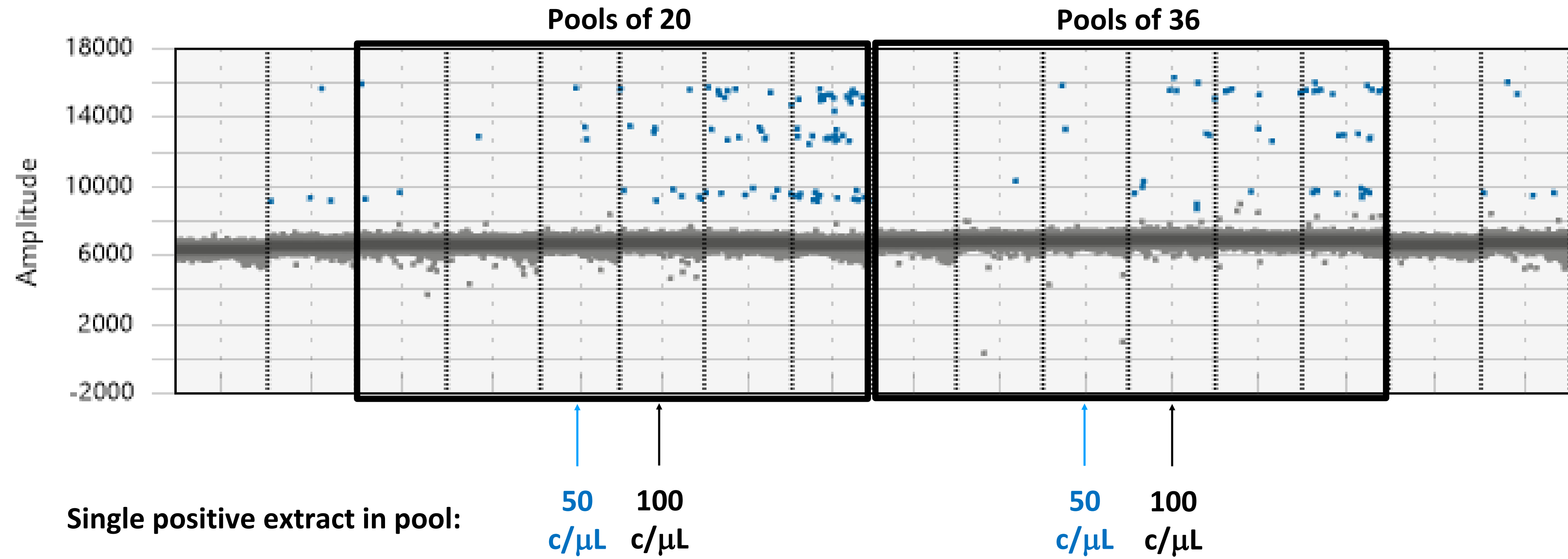
- Group testing makes screening 900 samples on one ddPCR in one day possible.

Experiments with ddPCR Group

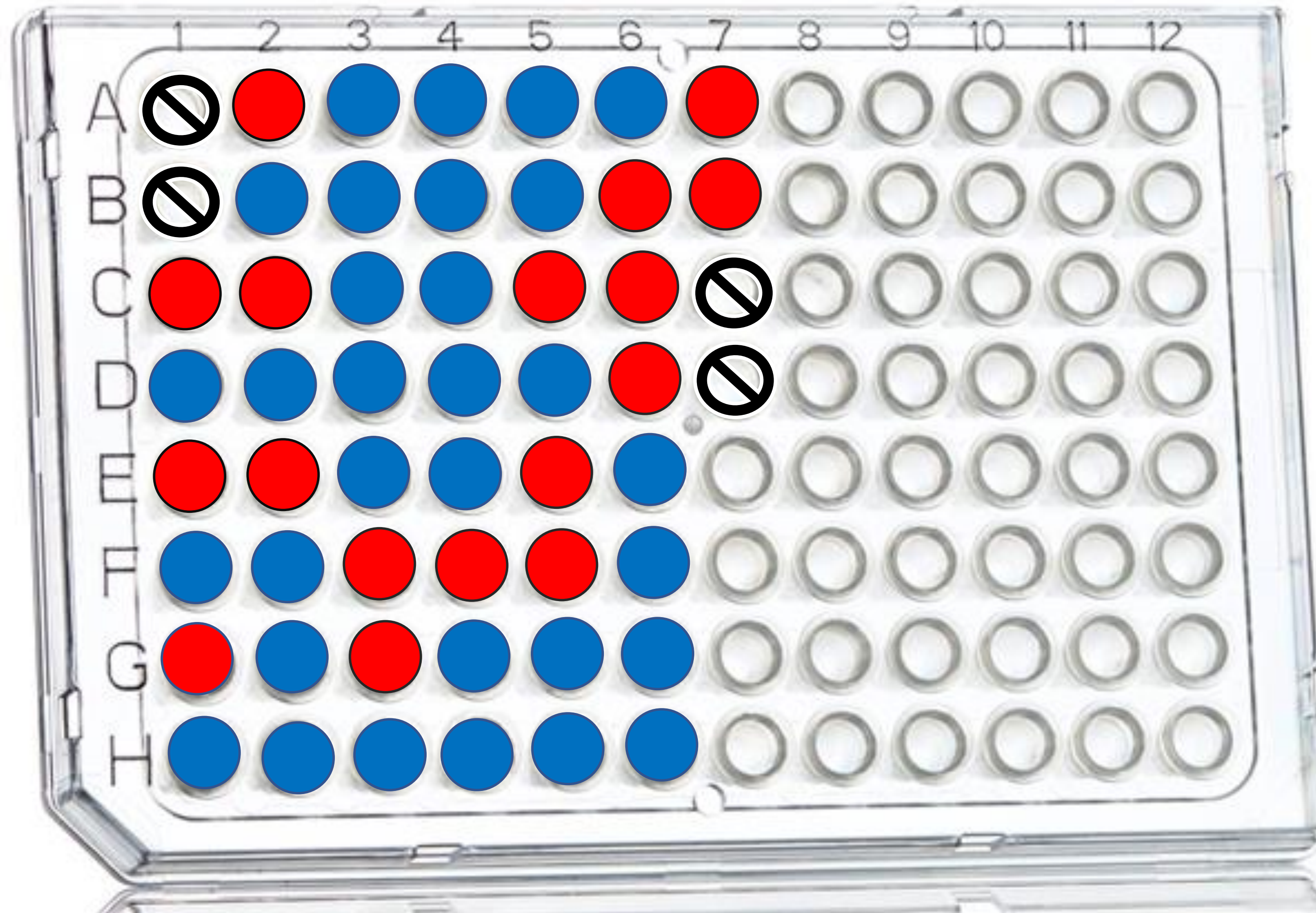
Testing on Saliva

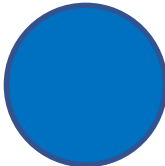
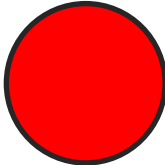
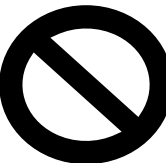
1. Test the sensitivity of detecting single +ive sample with different viral loads in pools of different sizes. 2. Run-through on 240 samples using Group Well app.

ddPCR Group Test Proof of Concept: Sensitivity Analysis



Screening Round: Pooled Tests for 240 People

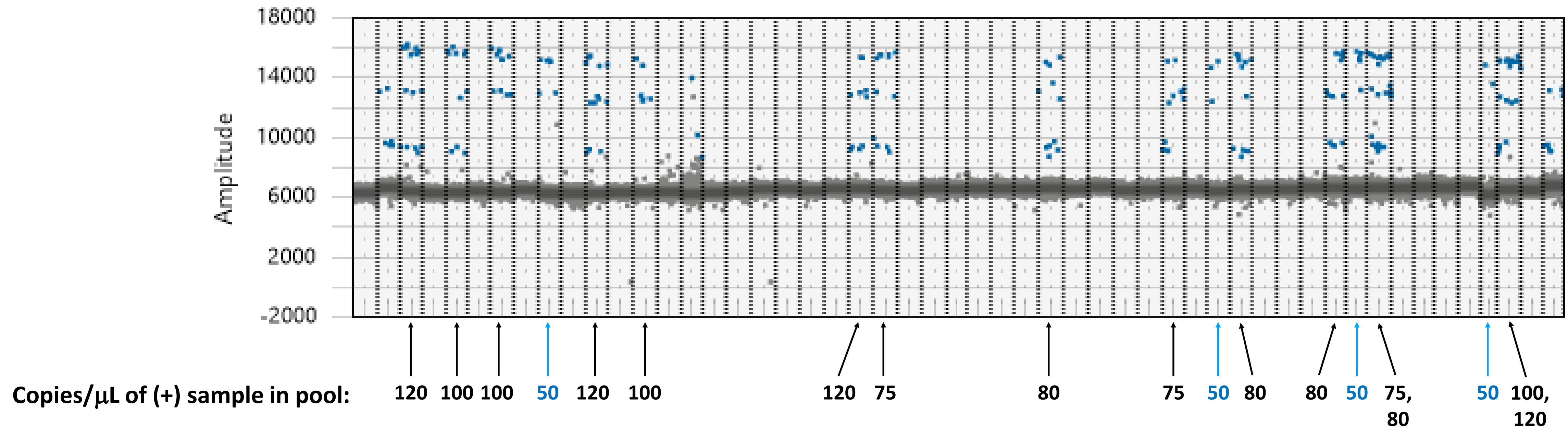


-  - Pooled test (-) result
-  - Pooled test (+) result
-  - Well occupied by control

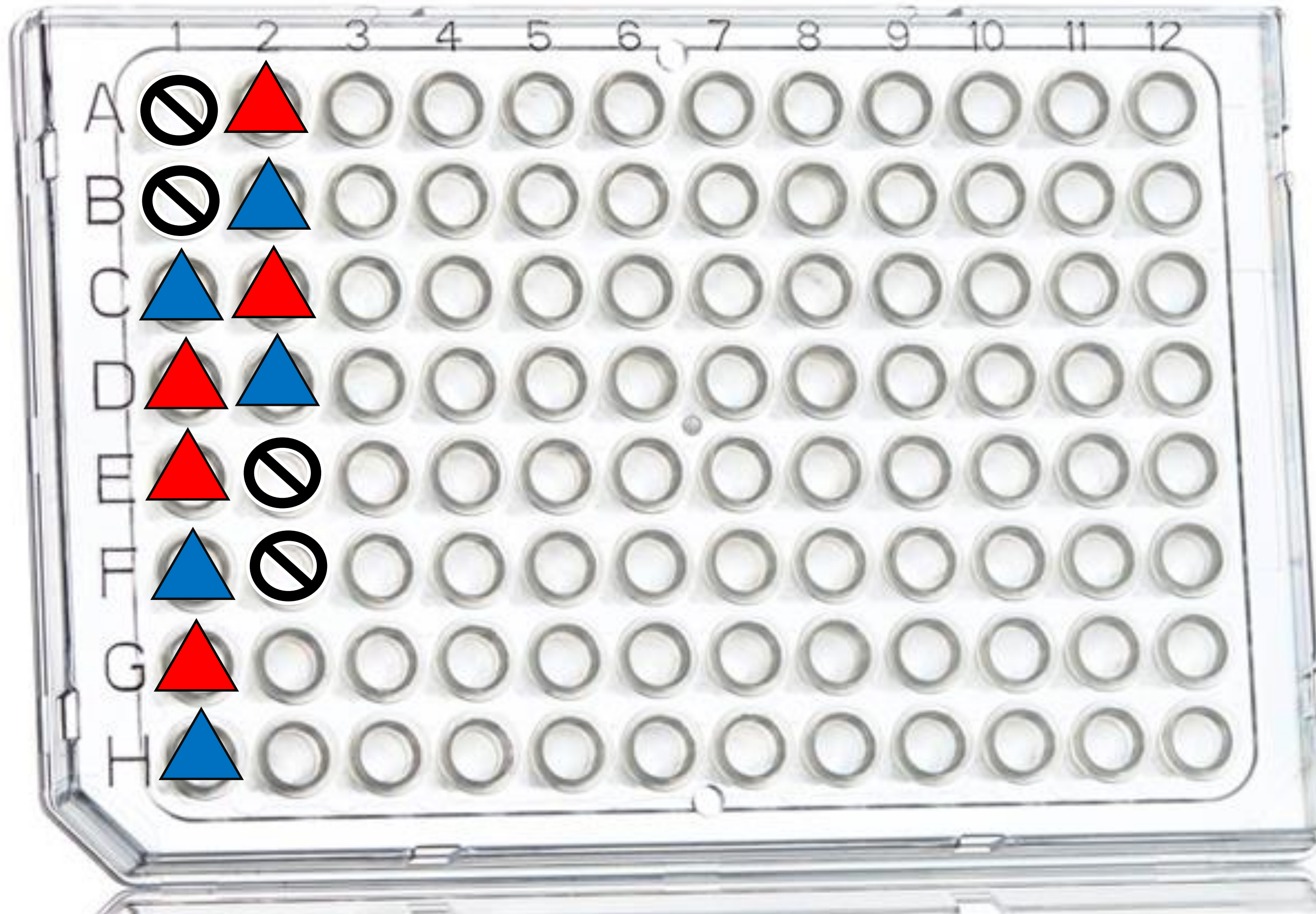
- 48 pooled tests for 240 people.
- Max possible savings = 80%
- Each round is 5-7 hours depending on lab capabilities.

ddPCR Group Test in Practice

- 240 deidentified remnant extracts - clinical NP swabs
- 48 pools of 15-20 samples each
- 5 positives ranging from 50 – 120 copies/ μ L



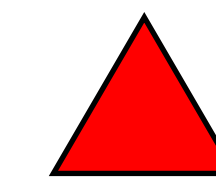
Round 2: Test Potential Positive Samples



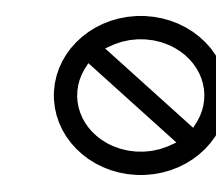
- After 48 tests, 230 individuals cleared as negative (~96%)
- Only 10 individuals are left undetermined



- COVID-19 (-)
individual sample

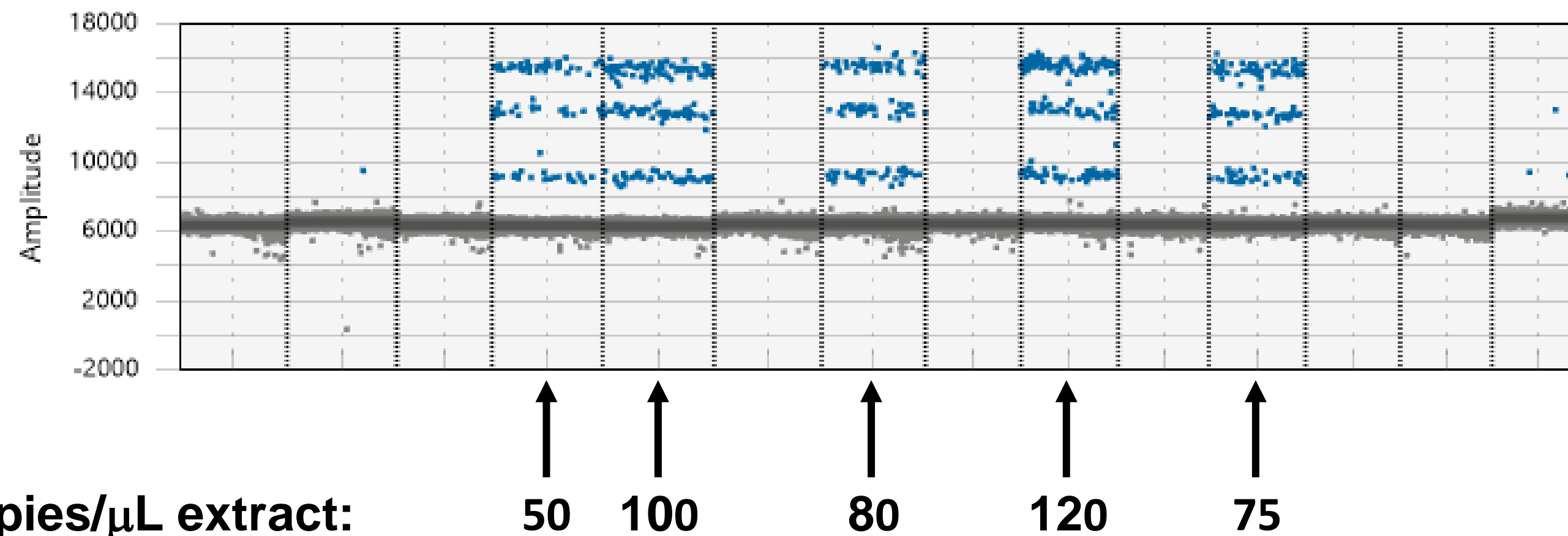


- COVID-19 (+) individual
sample



- Well occupied by control

Individual Test Results (round 2)



Stratification is caused by use of 2 probes N1,N2 for improved detection.

Droplets then contain:
{N1},{N2} or
{N1,N2}

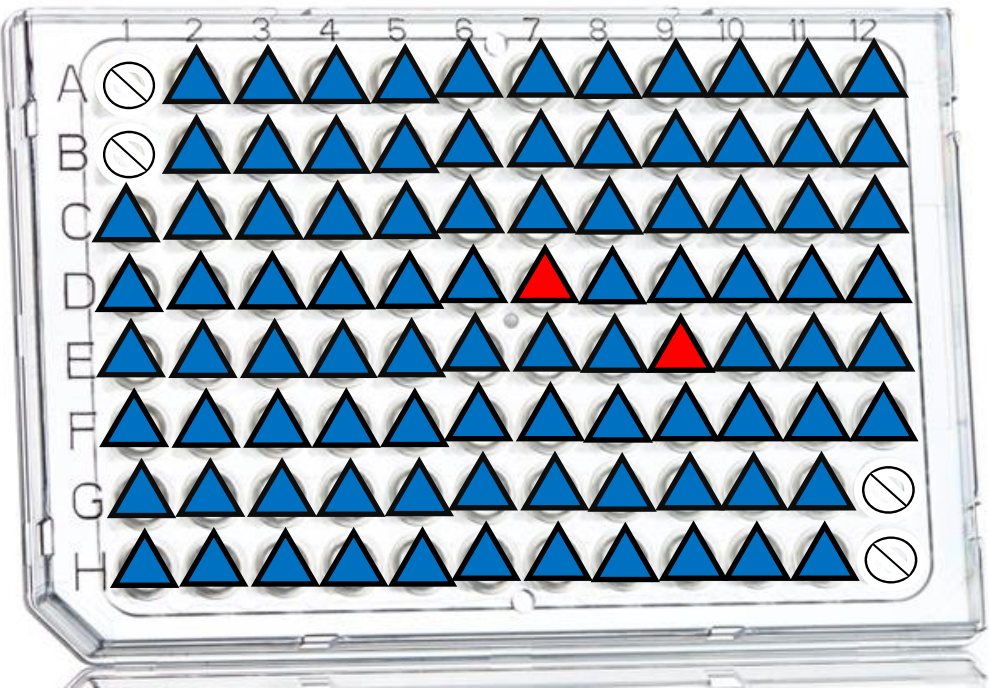
- 5 individual positives identified – ~2% prevalence.
- Total tests used for 240 people = 48+10 = 58 (~76% savings)

Timing and logistics

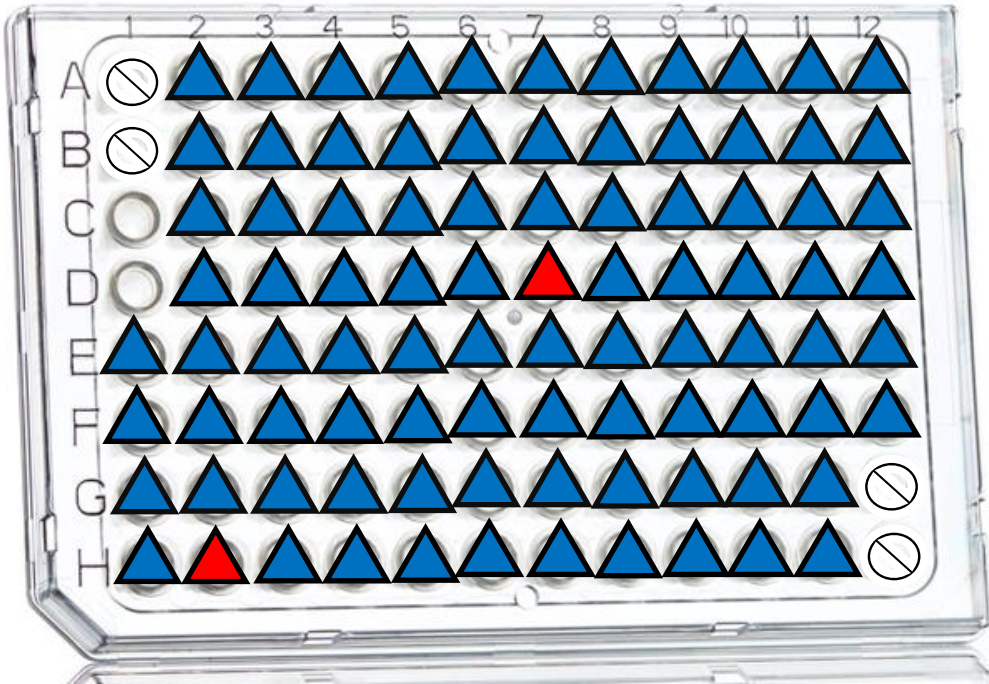
1. Compare group with 1:1 testing. 2. Example of testing work flow.

Individual vs Group Testing

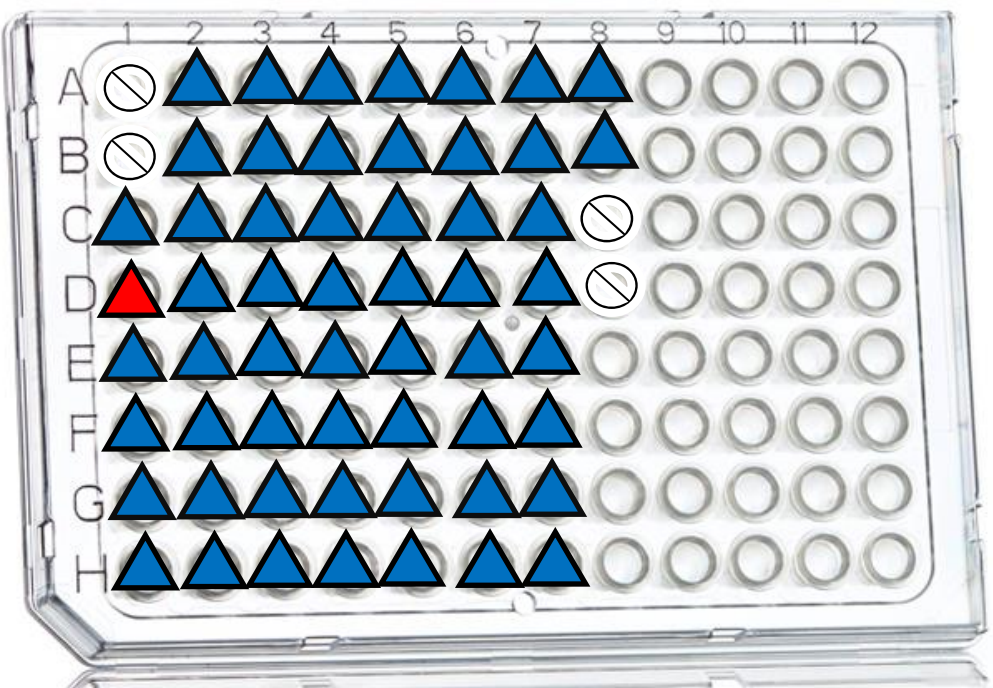
~ 5 hrs: 92
people tested



~ 10 hrs: 184
tested

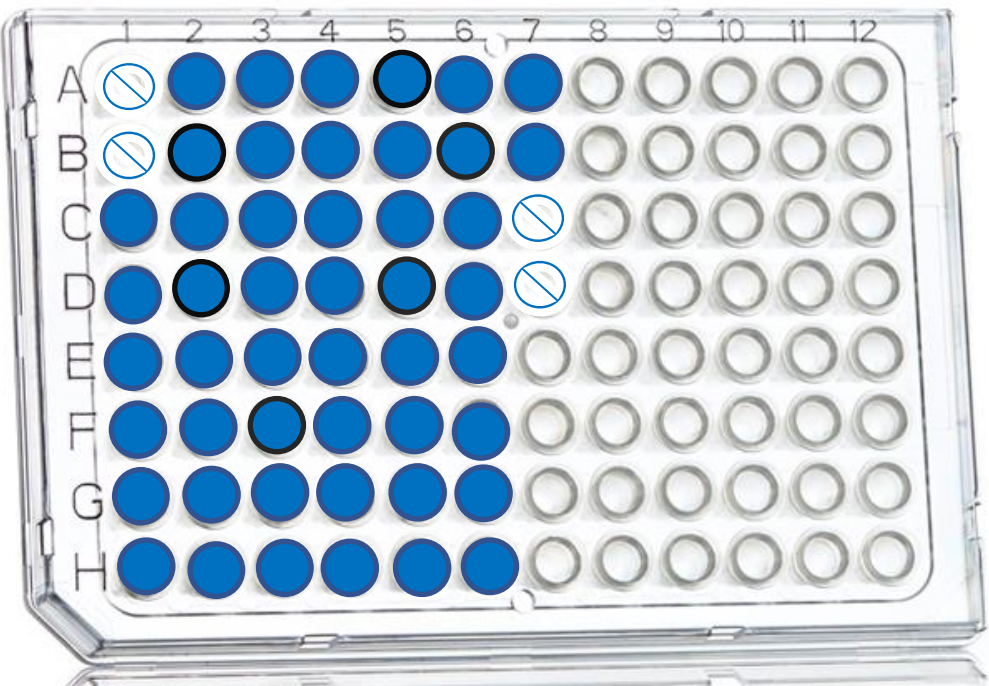


~ 15 Hours

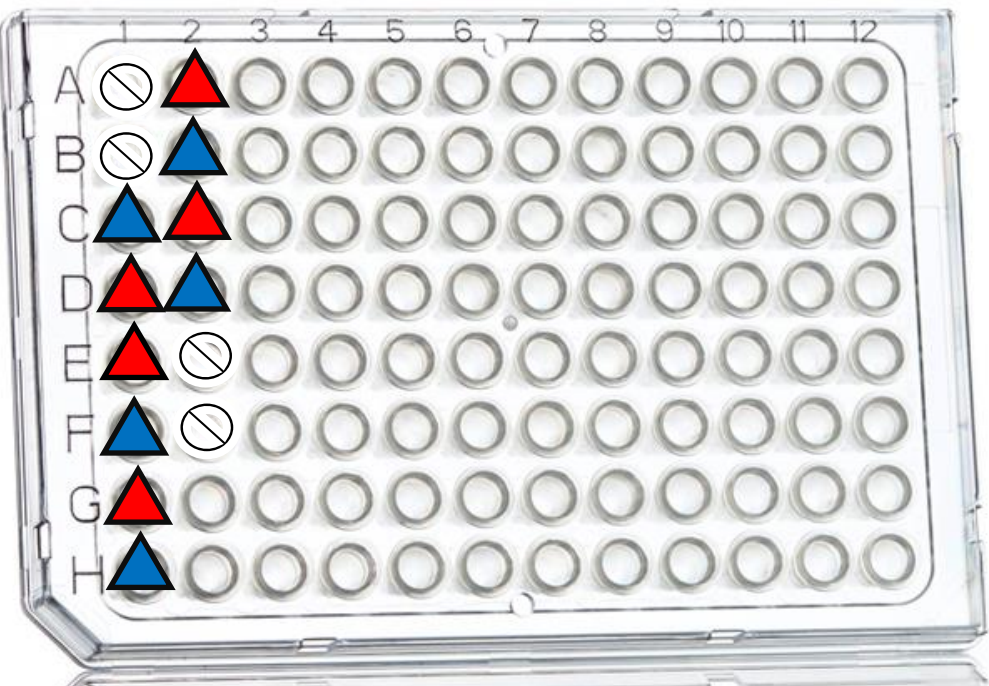


1 test per
sample
**240 assays
performed**

~ 5 hrs:
~240 people screened



~ 10 hrs:
Test potential (+)



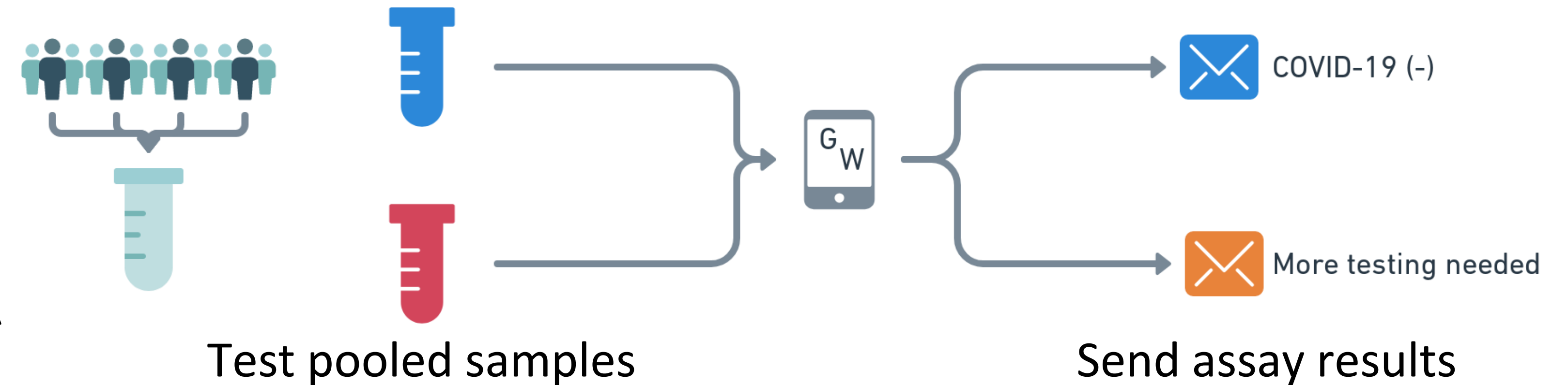
Group testing
**58 assays
performed**

Person/Workforce Scale Logistics

Sample Prep Phase

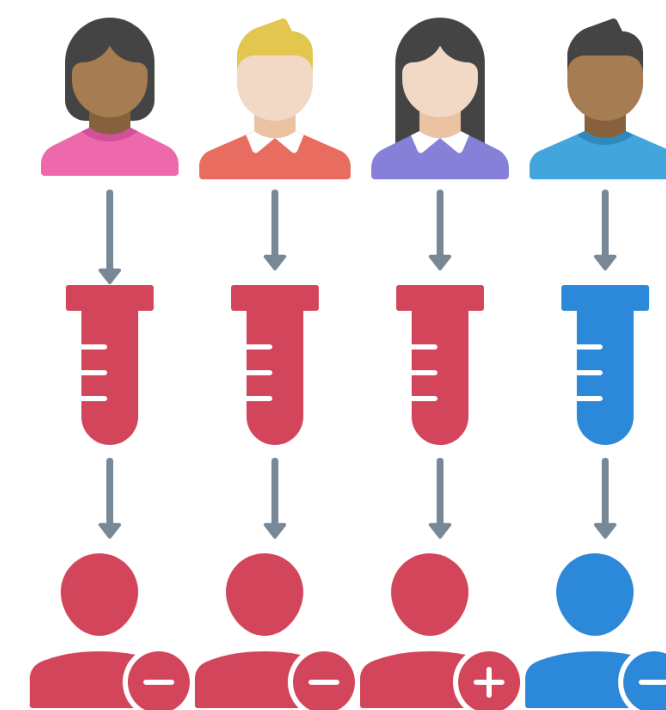


Group test assay w/ddPCR



Test potential (+) samples

COVID-19 (-) resume normal activity



COVID-19 (-) people safe to work

Example Daily COVID-19 Test: Prep Phase Workflow

Collect specimen from every person. (15 minutes)



Transport samples to lab (30 min)



Prepare samples for testing (2hr 15 min)

- RNA extraction
- Reverse transcription etc



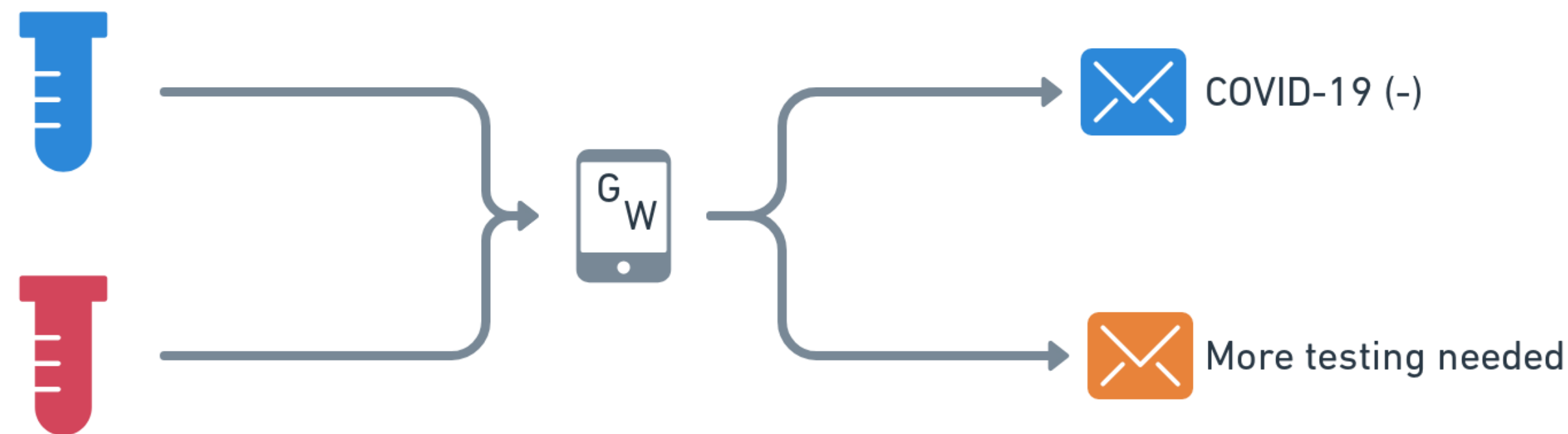
All necessary sample collection+ prep completed.

Daily COVID-19: Assay Phase Workflow

Test pooled samples using ddPCR (4-5 hours)

1. Determine all 200 people are (-)
2. Determine 95%-99.5% to be (-) if there are some COVID-19 (+)

- Lab personnel sends out test-results using Group-Well app



Test potential (+) while quarantined (4-5 hours). COVID-19 (-) safe to work.

Cost and savings

1. Costs and savings of 1:1 to group testing method. 2. Breakdown of costs.

Cost

		Per person	Per 400 persons Daily
PCR test market price	1:1 Standard Testing Technique	\$100-200/test	\$40000
Group Sense Solutions	1:1 Testing	\$70/test	\$28000
	Group testing with ddPCR	\$44/test	\$17600

Cost-Keep it Simple

- \$35 prep cost for all specimens
- \$35 assay cost
- With group testing we can generate on average 200 individual test results with 35-50 assay costs.
- For a typical group of 200, if 50 tests are priced at \$70 (\$35 prep+\$35 prep), remaining 150 priced at \$35 just for prep
- Some runs may require less assay runs and we pass the savings on to the NFL.
- We charge a small commission on each test saved.
- Both parties incentivized to maximize algorithm efficiency but most important priority is sensitivity

Group Sense Solutions Inc Program Meets Business Testing Needs

- Most sensitive COVID-19 assay
- High throughput
- Quick turn-around
- Cost/resource efficient
- Designed specifically for each population's needs

