MicroBioDx
MOLECULAR LAB SERVICES

Turnkey Laboratory for Covid-19

RT-PCR Testing • Same Day Results

Keep Lab Revenues In-House

www.covidpcrlab.com

Phone: 800-848-7240 • Email: info@microbiodx.com

Phone: 800-848-7240

- We have installed and currently oversee over 50 PCR labs across the country

- We handle licensing, equipment installation, personnel training, ongoing compliance

- Designed for labs running 200+ PCR Covid/day

Options for Covid PCR Testing

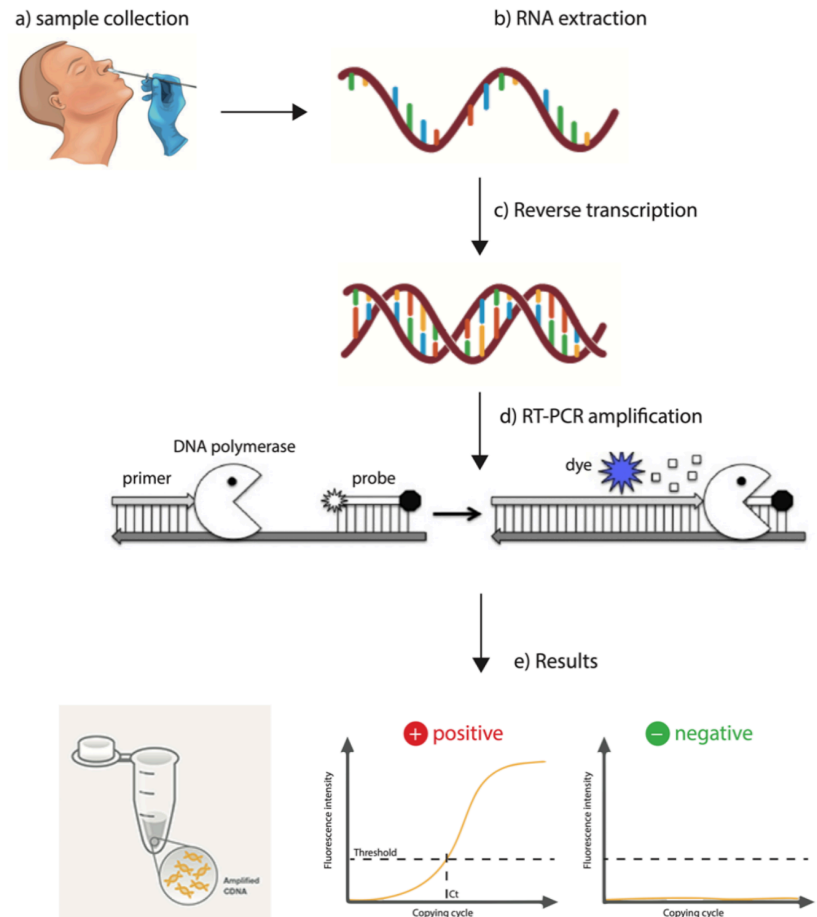## Send Covid PCR samples to reference lab:

- Subject to long turnaround times when demand is high and/or testing supplies are limited.
  - Can exceed 4 days for Covid PCR testing
  - Long turnaround times can hinder effective contact tracing and lead to further spread of Covid
  - Ultimately poses health risks and increases costs as Covid outbreaks are not contained

- Opportunity cost: loss of revenue opportunity from testing reimbursement.

Set up turnkey CLIA lab for Covid PCR testing:

- Same or Next-day turnaround time.
  - Facilitates contact tracing
  - Mitigates health risks of Covid by lowering infections
  - Save costs associated with long turnaround times.

- Significant source of revenue as reimbursement for the performed tests
  - Projected net profit of ~$8.5M in first year on 500 tests per working day (detailed slides to follow)

Background: RT-PCR testing

- RT-PCR: Reverse Transcriptase Polymerase Chain Reaction.
  - It is the molecular diagnostic assay that detects viral RNA during an active infection.
  - It is the gold standard for detecting viral infections, including SARS-CoV-2 infection.

- Antigen "Rapid" tests are sometimes used, but confirmation of negative results by RT-PCR is recommended.
  - Antigen tests, especially negative results, are less reliable than RT-PCR.
    - Per CMS: "Negative results should generally be treated as presumptive, do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions."

a) sample collection

b) RNA extraction

c) Reverse transcription

d) RT-PCR amplification

DNA polymerase

primer   probe   dye

e) Results

Amplified cDNA

+ positive

− negative

Fluorescence intensity

Threshold

Ct

Copying cycle

Fluorescence intensity

Copying cycle

Services Provided by MicroBioDx

Turnkey – We provide reagents, equipment, training, validation support

No sourcing needed – ALL items included in per test charge (swab, plastics, solutions, reagent mixture)

Easy – No extraction. Premixed plates. Sample to result in 1.5 hr.

High-throughput – 752 samples in eight runs on one RT-PCR machine

RT-PCR – The PLATINUM standard for Covid testing

No supply issues – Can produce 100,000 or more assays per order

Covid RT-PCR Test Developed by MicroBioDx

Saline Swab (provided)
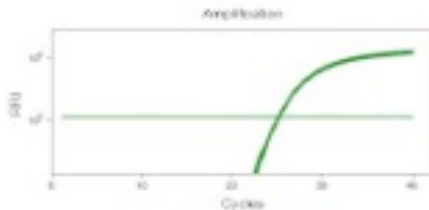
Mix sample with solution Heat 5 min

Add heated sample directly to premixed reaction mixture in 96 well plate

94 samples per run

Load PCR plate into RT-PCR machine

1 hour run time RT-PCR reaction (not isothermal)

Amplification

Review data

Covid RT-PCR Test Developed by MicroBioDx

Assay performance

- For sensitivity and specificity we have seen 100%. We do not typically see false positives or negatives for this assay. For precision, we try to shoot for a %CV of 2.5 or below, preferably 2.

Here is the data from our LOD experiment for our no extraction molecular Covid:

- We achieved 20/20 positives at 3.46 TCID50/mL, or 2160 genome equivalents/mL, with a mean Ct 34.64, SD 0.67. This corresponds to 5.4 genome equivalents/reaction.

This is likely what we would see onsite at your facility during validations.

- For comparison, the LabCorp COVID-19 RT-PCR EUA LOD is 6250 copies/mL or 31.25 copies/reaction. Here is the FDA link for Labcorp's EUA: https://www.fda.gov/media/136151/download

Projected Annual Revenue

	Medicare Rate	# of Samples			
Covid Molecular	$ 100.00	132000		$ 13,200,000.00	*500 samples per day
Total Reimbursement (1 year)				$ 13,200,000.00	*22 working days/month

- Projected annual revenue from testing reimbursement is $13,200,000
  - Based on an estimated 500 samples per working day (132,000 tests per year).

Proforma – 500 samples/day

Projected Net Profit (first year)

- Reimbursement – Cost = Net Profit

- $13,200,000 – $4,710,000 = **$8,490,000**

  *500 samples per working day

  *22 working days per month

  *CMS reimbursement rate of $100 per test

Process and Timeline for CLIA Lab

- Lab setup process
  - PCR machines installation (we have these available to install; both are currently difficult to get), assay validations, personnel training.
  - One of our Principals will serve as the technical supervisor
  - Validation is 2-3 days onsite with technicians
- Total setup will take 1-2 months to begin testing. Depends on when contracts are signed and personnel availability at hospital.