

NVBL Advanced Manufacturing for Medical Supplies for COVID-19

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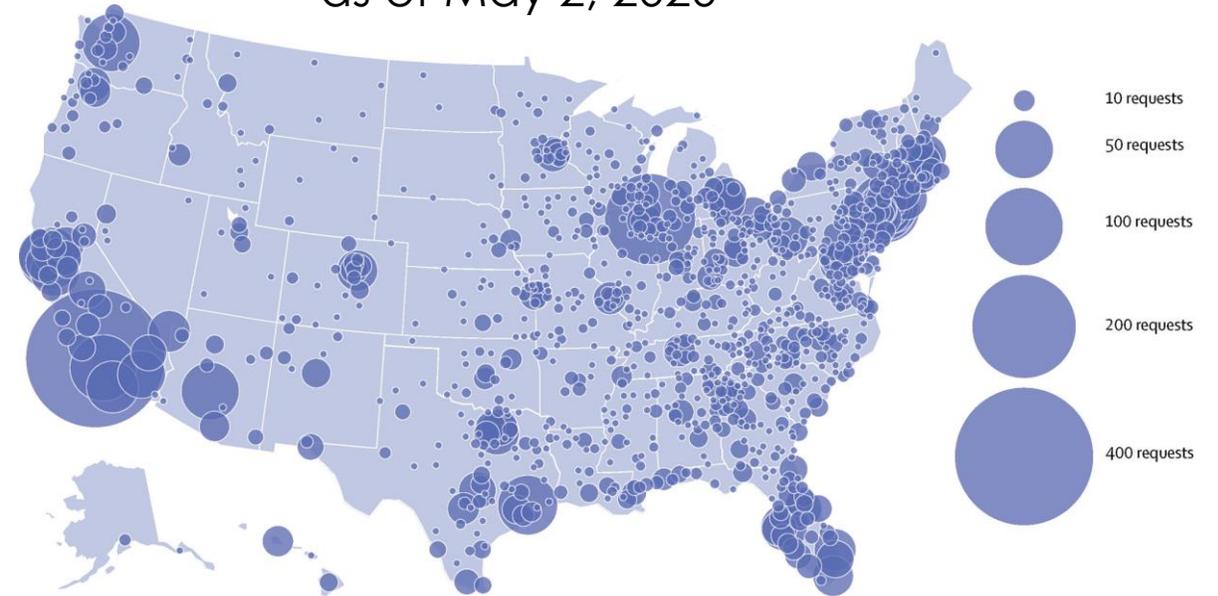


Advanced Manufacturing in Response to COVID-19

The rapid spread of COVID-19 has resulted in significant supply chain issues for critical medical supplies and medical equipment

- Personal protective equipment (PPE): Shortages in N95 respirators, face shields, and isolation gowns
- Ventilators: Projected demand for up to 740,000 ventilators
- Consumables: HHS targeting 20 million test per week and hundreds of millions of vaccine kit components

Requests for PPE by county,
as of May 2, 2020



S. Gondi et al.,
Lancet **395**,
e90–e91 (2020)

NVBL Manufacturing team focused on leveraging capabilities at DOE national labs to support US medical manufacturing industry

PPE: NVBL response

Used metal AM to rapidly make metal tooling

- For face shields, enabling DeRoyal to produce 40,000 face shields/day
- For reusable respirators

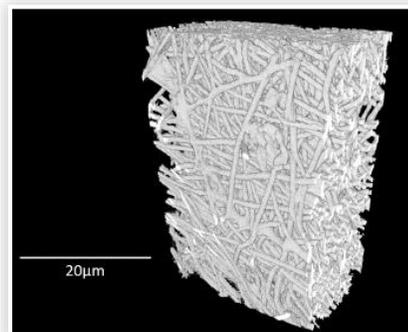


ORNL metal AM tooling for reusable N95 masks



SNL refined reusable designs, evaluated by Mayo Clinic

Developed electrospun and meltblown filter media for reusable respirators



NanoCT image of ANL N95 electrospun filter media acquired at APS

Collaborated with Dr. Peter Tsai on N95 filter material production

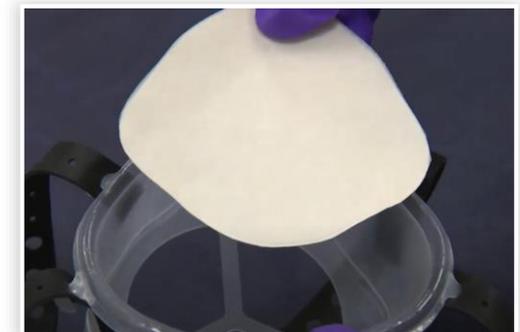
- 6 labs: Materials characterization
- SNL aerosol testing capabilities leveraged
- Technology transitioned to Cummins



N95 filter material production at ORNL

Additional activities

- Multiple labs: NextGen N95
- SLAC: Multi-scale characterization to understand viral fate and transport
- NREL: Examining effectiveness of home-made masks



Reusable N95 mask: ANL electrospun filter media and ORBIS BioAID mask shell

NVBL collaboration with Cummins enables domestic production of N95 filter media for millions of masks/day

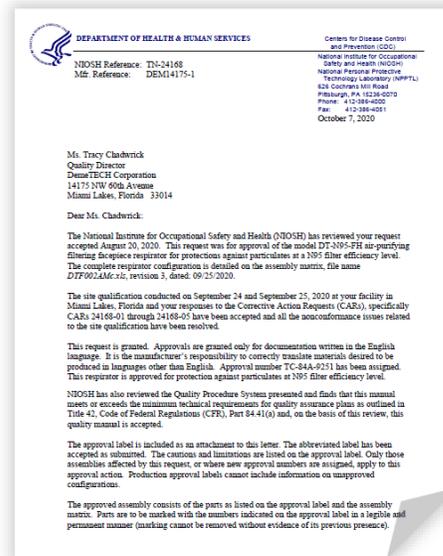
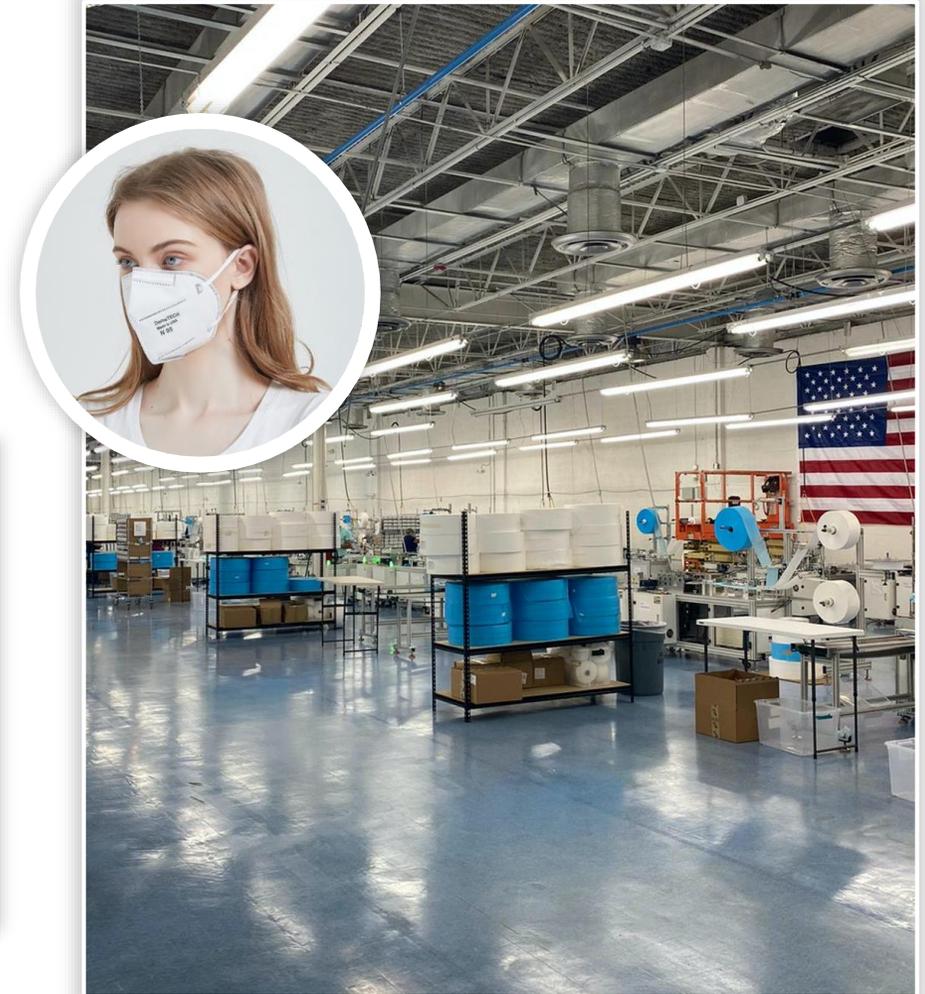
Focus: Developing electrostatic charging process (“the recipe”) for N95 production

- Collaborated with the inventor of N95 filter media, Dr. Peter Tsai, to develop the novel in-line charging device that could be placed on a precursor production line to electrostatically charge the meltblown material (polypropylene or PP)
- Designed, manufactured, and assisted in installation of a custom electrostatic charging device at Cummins facility in Cookeville, Tennessee



NVBL-DemeTECH collaboration adds 500 jobs in Miami

- DemeTECH: Only producer of high-quality N95 masks in the state of Florida
- NVBL contributions:
 - Characterization of N95 material (6 user facilities)
 - Advice on solving production issues
- Outcomes for DemeTECH:
 - 2 additional production facilities
 - 600 additional jobs expected by end of year
 - NIOSH certification, October 7, 2020



Ventilators

Industry partnerships to develop low-cost, transformative technologies

INL led NVBL teams in addressing ventilator supply chain issues

- Applying advanced manufacturing to improve performance and reduce machining cost
- Leveraging advanced modeling and simulation for ventilator performance
 - LANL: Understand breakup of mucus using intrapulmonary percussive ventilation (IPV)
 - INL: Oxygenation/scrubbing of CO₂ in advanced liquid IPV ventilators
 - Machine learning algorithm to harness complex CFD modeling and experimental data to assess aerosol transport, mucus breakup, and lung performance of COVID-19 patients
- Developed aerosol monitoring system to track flow of gases into lung structures



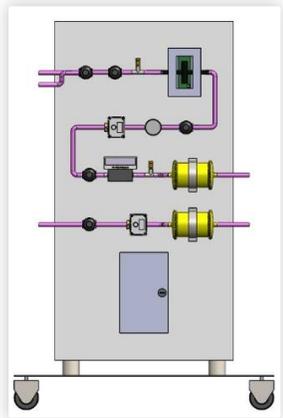
SNL pathogen management kit for converting BiPAP to ventilator (100 kits distributed to Albuquerque hospitals)



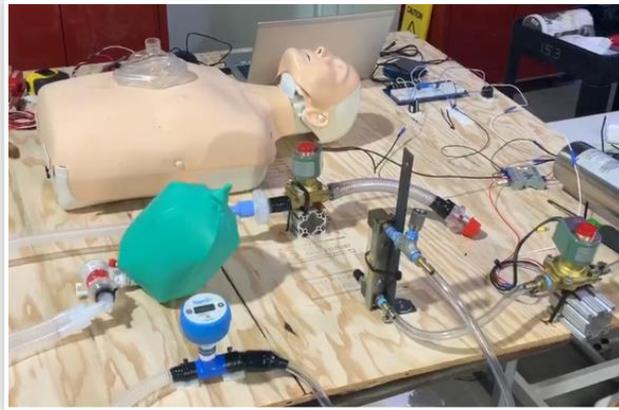
INL IPV ventilator sensor and measurement electronics for Percussionaire Inc.

FDA-EUA approved ventilator (components sourced outside commercial ventilator company supply chains) in 12 weeks

- March 16: Bay Area shelter in place order
- March 19: Assembly of LLNL team
- March 31: Conceptual design review
- April 23: EUA submission to FDA
- May 6: CRADA signed with partner
- June 8: FDA granted EUA
- Currently: Alternate therapies



Day 3:
Conceptual design



Day 8:
Component test



Day 25:
Full functionality testing in cased machine



Today:
Production-level build with CRADA partner BioMedInnovations LLC for use in hospital setting

Assisting Thermo Fisher in development of tooling to enable production of 8M automated test kits/week

- NVBL contributions:
 - LLNL and ORNL proved out design and low-volume tooling for viral transport media (VTM) for COVID-19 samples
 - LLNL validated use of 3D printing for swabs, enabling production of up to 250k/day
 - ORNL and SNL worked with HHS to validate sterilization procedures for Coke preforms for test kits, enabling 2 million tests/week
 - Transition to Thermo Fisher Scientific for production



Outcome

- New \$40M factory in Lenexa, KS
- 300 new employees

Impact: Rapid innovation to support US industrial base for health, economic, and national security

This is what national labs were created to do

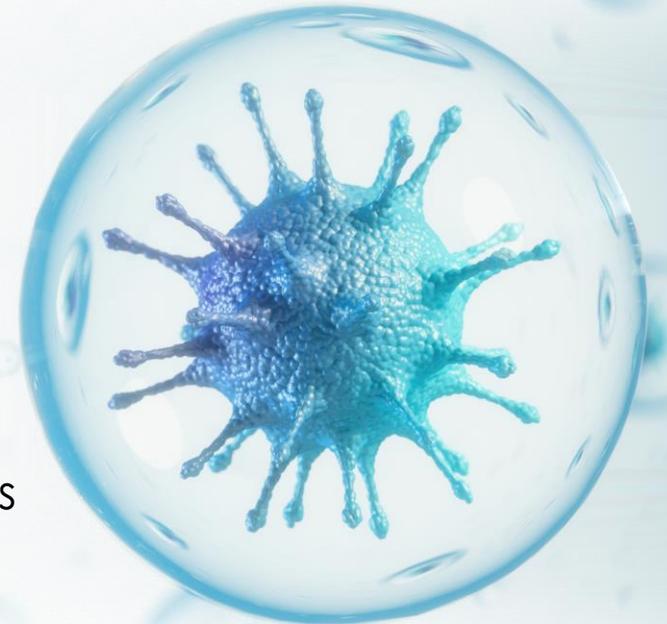
Enabled production of up to 10 million test kits/week

Expanded N95 production to enable >3 million masks/day

Validated AM swabs, enabling production of up to 250,000 swabs per day

Supported commercialization of BioMed Innovations ventilator and securing of FDA EUA approval

Participated in creating >1,000 new jobs in US medical manufacturing sector





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