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Emergency Use Authorization

Emergency Use Authorization (EUA) information, and list of all current EUAs

Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved, and available alternatives.
Coronavirus Disease 2019 (COVID-19) Emergency Use Authorizations for Medical Devices

On February 4, 2020, the Secretary of the Department of Health and Human Services (HHS) determined, pursuant to section 564 of the Federal Food, Drug and Cosmetic (FD&C) Act, that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019-nCoV). The virus is now named severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which causes the disease COVID-19.

On the basis of this determination, the Secretary of HHS has subsequently declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for the detection and/or diagnosis of COVID-19 (February 4, 2020), personal respiratory protective devices (March 2, 2020), and other medical devices, including alternative products used as medical devices (March 24, 2020), for use during the COVID-19 outbreak pursuant to section 564 of the Act and subject to the terms of any authorization issued under that section.
FDA EUAs (9/17/20)

- Blood Purification
- CRRT and HD Devices
- In Vitro Diagnostics
- Decontamination Systems for PPE
- Infusion Pump
- PPE
- Remote or Wearable Patient Monitoring Devices EUAs
- Respiratory Assist Devices EUAs
- Ventilators and Ventilator Accessories EUAs
- Other Medical Device EUAs

PPE Selection

Acceptable Alternative PPE – Use Facemask

Face shield or goggles

Facemask

N95 or higher respirators are preferred but facemasks are an acceptable alternative.

One pair of clean, non-sterile gloves

Isolation gown

N95 or higher respirator

When respirators are not available, use the best available alternative, like a facemask.

One pair of clean, non-sterile gloves

Isolation gown

AGPs

cdc.gov/COVID19
# PPE Selection: Risk = Resources Needed

## Table: PPE Selection

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<tbody>
<tr>
<td>Yes</td>
<td>Yes</td>
<td>Any level</td>
<td>FFR, face/eye protection, gloves, gown</td>
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<td>Moderate or substantial</td>
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<td>Mask and eye protection *</td>
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<td>Minimal or Limited</td>
<td>Mask or cloth covering (source control) *</td>
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</table>

* Additional PPE as required by Standard and Transmission based Precautions

**FFR: Filtering Facepiece Respirator**
Room Turnover Time

- Considerations
  - Size of room?
  - Number of air exchanges/hour?
  - Length of time patient was in room?
  - Patient coughing/sneezing?
  - Patient wearing face covering?
  - PPE worn?
  - Aerosol generating procedure?

<table>
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https://www.cdc.gov/infectioncontrol/guidelines/environmental/appendix/air.html#tableb1

Searching Health Departments

Thank You

We support your efforts in response to the COVID-19 pandemic and hope to provide helpful resources.
COVID-19 resources

What Your Organization Needs to Know About the Coronavirus

Trusted Guidance. Trusted Resources.

View resources
Resources

- COVID Resources
  - https://www.jointcommission.org/covid-19/

- Standards Interpretation
  - https://www.jointcommission.org/standards/standard-faqs/