

## Identified Resource Specifications

Ventilators .....	2
N95 Respirators (Disposable).....	2
Surgical Masks .....	5
Coveralls (Hospitals and EMS).....	5
Surgical or Examination Gowns .....	6
Face Shields (Disposable) .....	8
Goggles.....	8
Examination Gloves.....	9
Hand Sanitizers .....	9
Wipes .....	10
Test Kits .....	10
Swabs .....	10
Viral Testing Media .....	11

## Ventilators

Language: English

Mode Capabilities:

- Assist Control Ventilation
- Synchronized Intermittent Mandatory Ventilation
- Pressure Control Ventilation
- Volume Control Ventilation
- Positive End Expiratory Pressure
- Pressure Support
- Blending of Oxygen and Air
- CPAP mode – continuous positive airway pressure

Lead Time: Total order must be available within 4 weeks with at least 25% of the order delivered each week.

## N95 Respirators (Disposable)

Must have NIOSH Certification TC-xxx-xxxx.

- a. Verify that the brand of respirator is listed either in NIOSH's list of manufacturers or as a private label company.  
[https://www.cdc.gov/niosh/nppt/topics/respirators/disp\\_part/default.html](https://www.cdc.gov/niosh/nppt/topics/respirators/disp_part/default.html).
- b. Check that the approval number matches the respirator considered.
- c. See information about counterfeits. NIOSH publication 2013-138 "Respirator Awareness: Your Health May Depend on It" provides additional information to look for when verifying a respirator is truly NIOSH-approved.

**CDC Crisis Capacity** (if NIOSH-certified respirators are not available): Consider respirators certified in other countries. See "Use of respirators approved under standards used in other countries that are similar to NIOSH-approved N95 respirators" at <https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/crisis-alternate-strategies.html>.

### **3-28-2020: Guidance from NIOSH/CDC on purchase of respirators from other countries**

NIOSH has confidence that devices supplied by current NIOSH-approval holders producing respirators under the various standards authorized in other countries are expected to provide the protection indicated, given that a proper fit is achieved.

## State of California COVID-19 Medical Supply Contributions

### Identified Resource Specifications

Non-NIOSH-approved products developed by manufacturers who are not NIOSH approval holders, those approved by and received from China, should only be used in crisis situations when no other NIOSH-approved N95 respirator or a listed device from one of the other recognized countries is available. Furthermore, these respirators should not be used during aerosol-generating medical procedures unless the alternative is a facemask or improvised device.

To support this effort and relieve concerns about filtration performance of respirators received from other countries, NIOSH will offer testing to assess whether a small sample of the product meets NIOSH's filtration performance requirements. NIOSH will begin sampling respirators received from other countries, from stockpiles, and respirators that have gone through decontamination cycles (without the respirator being contaminated) to provide users a preliminary assessment of whether the products meet similar filtration performance requirements as those for NIOSH-approved N95 respirators. Please contact [PPEConcerns@cdc.gov](mailto:PPEConcerns@cdc.gov) if you are interested in participating in this effort. The preliminary testing will not result in a NIOSH approval, rather it will provide an initial assessment to provide a preliminary level of assurance that the products will provide the intended protection to support workers during the COVID-19 response.

### **3/24/2020: Guidance from FDA on purchase of respirators from other countries**

FDA issued an Emergency Use Authorization (EUA) that permits imported respiratory protective devices from other countries to be used in healthcare settings but does not authorize respirators from China:

<https://www.fda.gov/media/136403/download>.

Respirators meeting the criteria in the following two categories are eligible for authorization under this EUA as described in this section (Scope of Authorization (section II)). Respirators that satisfy the eligibility criteria in numerals 1 and/or 2, and that meet the terms and conditions (Conditions of Authorization (section IV)) of this EUA will be listed in Exhibit 1 pursuant to the procedure outlined below. The categories of eligibility are as follows:

- A. Disposable FFRs that have been designed, evaluated, and validated to meet a given performance standard and have corresponding acceptable product classifications, as follows (Table 1):

## State of California COVID-19 Medical Supply Contributions

### Identified Resource Specifications

Jurisdiction	Performance Standard	Acceptable Product Classifications	Standards/ Guidance Documents	Protection Factor $\geq 10$
<b>Australia</b>	AS/NZS 1716:2012	P3, P2	AS/NZS 1715:2009	YES
<b>Brazil</b>	ABNT/NBR 13698:2011	PFF3, PFF2	Fundacentro CDU 614.894	YES
<b>Europe</b>	EN 149-2001	FFP3, FFP2	EN 529:2005	YES
<b>Japan</b>	JMHLW-2000	DS/DL3 DS/DL2	JIS T8150: 2006	YES
<b>Korea</b>	KMOEL-2017-64	Special 1 <sup>st</sup>	KOSHA GUIDE H-82- 2015	YES
<b>Mexico</b>	NOM-116-2009	N100, P100, R100, N99, P99, R99, N95, P95, R95	NOM-116	YES

## State of California COVID-19 Medical Supply Contributions

### Identified Resource Specifications

- B. Disposable FFRs which have a marketing authorization in one of the following regulatory jurisdictions:
- European CE Mark
  - Australian Register of Therapeutic Goods (ARTG) Certificate of Inclusion
  - Health Canada License
  - Japan Pharmaceuticals and Medical Device (PMDA)/Ministry of Health Labour and Welfare (MHLW)

## Surgical Masks

Must have evidence of U.S. Food and Drug Administration (FDA) clearance. Should have device name “surgical mask” and product code “FXX” or device name “Face Mask” and Product Code “QKR” or have an Emergency Use Authorization.

- Establishment Registration & Device Listing:  
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm>
- List of FDA Emergency Use Authorizations:  
<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov>

Provide information on ASTM certification that surgical masks are classified in, depending on the level of protection they provide to the person wearing them:

- Minimum protection face masks are meant for short procedures or exams that won't involve fluid, spray, or aerosol.
- Level 1 face masks often feature ear loops and are the general standard for both surgical and procedural applications, with a fluid resistance of 80 mmHg. They're meant for low-risk situations where there will be no fluid, spray, or aerosol.
- Level 2 masks, with 120 mmHg fluid resistance, provide a barrier against light or moderate aerosol, fluid, and spray.
- Level 3 face masks are for heavy possible exposure to aerosol, fluid and spray, with 160 mmHg fluid resistance.

## Coveralls (Hospitals and EMS)

**Coveralls for EMS providers** must meet [NFPA 1999](#) which is primarily intended for emergency medical first responders, but its scope also covers medical first receivers.

**Coveralls for hospitals:** Coveralls may be used if there is a gown shortage. For anticipated exposure to blood and body fluids, to prevent penetration of blood

## State of California COVID-19 Medical Supply Contributions

### Identified Resource Specifications

or other potentially infectious materials, the PPE must meet or exceed the following testing standards published by the American Society for Testing and Materials (ASTM): F1670 (blood or bloody fluid penetration) and F1671 (bloodborne pathogens penetration).

## Surgical or Examination Gowns

Most of the time, nonsterile, disposable patient isolation gowns, which are used for routine patient care in healthcare settings, are appropriate for use by healthcare personnel when caring for patients with suspected or confirmed COVID-19. <https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/isolation-gowns.html>

ANSI/AAMI PB70 classifies the garments used in the healthcare industry, such as surgical and isolation gowns as meeting ANSI/AAMI PB70 Level 1, 2, 3, or 4 standards: [ANSI/AAMI PB70External](#).

### Isolation gowns

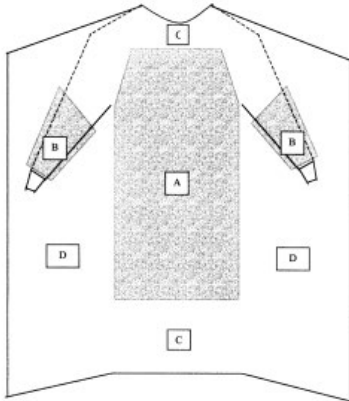
Isolation gowns should demonstrate they meet the performance standards established by the American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI), ANSI/AAMI PB70.

- If the risk of bodily fluid exposure is low or minimal, gowns that claim minimal or low levels of barrier protection (ANSI/AAMI PB70 Level 1 or 2) can be used. These gowns should not be worn during surgical or invasive procedures, or for medium to high risk contamination patient care activities.
- If there is a medium to high risk of contamination and need for a large critical zone, isolation gowns that claim moderate to high barrier protection (ANSI/AAMI PB70 Level 3 or 4) can be used. For fluid resistance of the whole gown (except cuffs) only level 4 isolation gowns are required to be fluid resistant.

## State of California COVID-19 Medical Supply Contributions

### Identified Resource Specifications

NOTE: The entire isolation gown (areas A, B, and C), including seams but excluding cuffs, hems, and bindings, is required to have a barrier performance of at least Level 1.



Activities with medium to high risk contamination that can result in exposure to bodily fluids include suctioning, nebulizer treatments, and other respiratory treatments or procedures, care activities where splashes and sprays are anticipated, and high-contact patient care activities that provide opportunities for transfer of pathogens to the hands and clothing of healthcare providers. Examples of high-contact patient care activities requiring gown use include: dressing, bathing/showering, transferring, providing hygiene, changing linens, changing briefs or assisting with toileting, device care or use, or wound care.

- **Contingency Capacity Strategies:** Shift gown use towards cloth isolation gowns. Use reusable (i.e. washable gowns).

FDA: Surgical Mask and Gown Conservation Strategies - Letter to Healthcare Providers

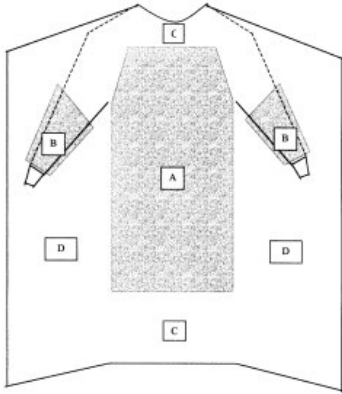
<https://www.fda.gov/medical-devices/letters-health-care-providers/surgical-mask-and-gown-conservation-strategies-letter-healthcare-providers>

### Surgical gowns

- For healthcare activities with low, medium, or high risk of contamination, **surgical gowns** can be used. These gowns are intended to be worn by healthcare personnel during surgical procedures. Surgical gowns are only required to be protective in the front and on the sleeves, not on upper arm or back.

## State of California COVID-19 Medical Supply Contributions Identified Resource Specifications

NOTE: The back of the surgical gown (area D) may be non-protective.



Surgical gowns meet ASTM F2407 Standard Specification for Surgical Gowns intended for Use in Healthcare Facilities

FDA: <https://www.fda.gov/medical-devices/letters-health-care-providers/surgical-mask-and-gown-conservation-strategies-letter-healthcare-providers>

CDC: Frequently Asked Questions about Personal Protective Equipment: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html>

## Face Shields (Disposable)

- Visors manufactured from acetate, propionate, and polycarbonate.
- Visors treated for anti-glare, anti-static, and anti-fogging properties are best.
- Face shields must be, at a minimum, full-face length with outer edges of the face shield reaching at least to the point of the ear, include chin and forehead protectors, and cover the forehead.
- Brow caps or forehead cushions should be of enough dimensions to ensure that there is adequate space between the wearer's face and the inner surface of the visor to allow for the use of N95 respirator and eyewear.
- Face shields with single Velcro or elastic straps.

## Goggles

- Indirectly vented.
- Have manufacturer's anti-fog coating.
- Have marking "D3" for splash or droplet protection.



## Examination Gloves

Nonsterile disposable patient examination gloves, which are used for routine patient care in healthcare settings, are appropriate for the care of patients with suspected or confirmed COVID-19 (CDC).

Specifications include:

- Prioritize medical grade gloves
- Latex-free
- Powder-free
- Available in sizes: S-XXL
- Length requirements for patient exam gloves must be a minimum of 220mm-230mm depending on glove size and material type.
- The American Society for Testing and Materials (ASTM) has developed standards for patient examination gloves.
  - ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application
  - ASTM D3578-19 Standard Specification for Rubber Examination Gloves
  - ASTM D5250-19 Standard Specification for Poly(vinyl chloride) Gloves for Medical Application
  - ASTM D6977-19 Standard Specification for Polychloroprene Examination Gloves for Medical Application

FDA Guidance: "Medical Glove Conservation Strategies: Letter to Health Care Providers": <https://www.fda.gov/medical-devices/letters-health-care-providers/medical-glove-conservation-strategies-letter-health-care-providers>

## Hand Sanitizers

CDC recommends the use of alcohol-based hand sanitizers with greater than 60% ethanol or 70% isopropanol: <https://www.cdc.gov/coronavirus/2019-ncov/infection-control/hcp-hand-sanitizer.html>

For manufacturing requirements, see FDA: Coronavirus (COVID-19) Update: FDA provides guidance on production of alcohol-based hand sanitizer to help boost supply, protect public health.

<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-guidance-production-alcohol-based-hand-sanitizer-help-boost>

## State of California COVID-19 Medical Supply Contributions

### Identified Resource Specifications

American Society for Testing and Materials (ASTM) standards:

- ASTM E2755-15 Standard Test Method for Determining the Bacteria-Eliminating Effectiveness of Healthcare Personnel Hand Rub Formulations Using Hands of Adults
- ASTM E1174-13 Standard Test Method for Evaluation of the Effectiveness of Health Care Personnel Handwash Formulations
- ASTM E3058-16 Standard Test Method for Determining the Residual Kill Activity of Hand Antiseptic Formulations

## Wipes

Suppliers with these resources will be followed up with individually to identify specifications.

## Test Kits

Suppliers with these resources will be followed up with individually to identify specifications.

## Swabs

FDA approved swabs:

- Puritan Nasopharyngeal swabs: 25-3317-H, 25-1406 1PF 50f, 25-800 1PD 50\*\*, 25-3320-U, 25-3320-H EMB 80, 25-3320-U EMB 80, 25-3320-H EMB 100 and 25-3320-U EMB 100
- Copan Nasopharyngeal swabs: 503CS01, 518CS01, and 501CS01, 502CS01
- BD Nasopharyngeal swabs: 220252 and 220251
- DHI/Quidel Nasopharyngeal swabs: 503CS01.DHI
- Fisher Healthcare Nasopharyngeal swabs: 23600952, 23600956 and 23600950 Puritan Oropharyngeal swabs: 25-1506 1PF SOLIDf, 25-1506 1PF 100f, 25-3206-H, 25-3206-U, 25-3706-H, 25-806 1PD\*\* and 25-806 1PD BT\*\*
- Copan Oropharyngeal swabs: 502CS01, 519CS01, 164KS01\*\*, 167KS01\*\*, 170KS01\*\* and 175KS01\*\*
- BD Oropharyngeal swabs: 220250
- Fisher Healthcare Oropharyngeal swabs: 23600950, 23600957, 1490641\*\*, 1490640\*\* and 1490650\*\*
- Additional sterile flocked swabs from Puritan that may be used: 25-3316-U, 25-3316-H, 25-3317-U, 25-3318-U, 25-3318-H, 25-3320-U, 25-3320-H and 25-3319-H

## **Viral Testing Media**

Viral Transport Media (VTM) / Universal Transport Media Kits (Complete Sample Collection Kits with both swab & media):

- FYI: nasopharyngeal (NP) preferred, other types acceptable; should be shelf-stable (i.e., no refrigeration requirements); volume of media could be in the 1-3 mL range depending on product.
- Examples of product SKUs:
  - BD Brand: 220222, 220526, 220527, 220529, 220531 (all are described as UVT kits)
  - Puritan: UT-367; UT-316; UT-317

VTM / Universal Transport only

- Examples of product SKUs:
  - BD Brand: 220220
  - Puritan: UT-300;
  - Remel: R12506, R12505