Laboratory Supply Chain Frequently Asked Questions

Question	Answer
How do we prepare for supply chain issues?	Preparing for supply chain issues should be a proactive planning process and a community-wide effort. Become familiar with scenarios that could affect your laboratory supply chain, such as disruptions in manufacturing due to a public health emergency, and with ways to respond to such events. Develop a disaster plan and include expert input from multiple partners within the healthcare facility/system and community, either through a planning team, a coalition, or both. These resources can assist with planning for supply chain issues: Supply Chain Disaster Preparedness Manual | CDC COVID-19 Pandemic Planning Scenarios | CDC
How can I better forecast supply shortages?	Monitoring your laboratory's supply usage data for trends and using predictive modeling, if available, can help estimate current and future needs. Online resources include Conserving Supplies of Personal Protective Equipment in Healthcare Facilities during Shortages and Principles of Supply Chain Management in the Time of Crisis. Factors that influence supply shortages include: • Patient volume: Infection rates, hospital admissions, recovery times, discharges, etc., influence supply usage rates. • Labor shortages: A lack of skilled workers can slow the manufacturing or delivery of supplies. • Natural disasters: Hurricanes, floods, wildfires, snowstorms, etc., can hinder production and transportation. • Global and local policy changes during public health emergencies: For example, export restrictions of PPE by major suppliers and specific mandates (e.g., testing requirements before

Can we use expired kits/reagents for testing during supply chain shortages?	The Clinical Laboratory Improvement Amendments (CLIA) Interpretive Guidelines state that "when in-date reagents are unavailable, it may become necessary to frame written policies for their temporary use beyond their expiration dates until unexpired supplies become available. Under no circumstances, however, should a laboratory adopt policies allowing for the regular use of expired reagents." According to these guidelines, laboratories and testing sites may use expired supplies until unexpired supplies become available, provided that policies and procedures are in place to ensure the reagents are performing as expected. For example, expired supplies must pass quality control tests with each assay run. Always consult the test kit manufacturer to check whether expiration dates have been extended for specific lots. Also, notify manufacturers when testing has been interrupted because of expired test kits and supply shortages.
How do I coordinate personal protective equipment (PPE) within a laboratory?	Laboratories should perform site-specific and activity-specific risk assessments to determine the appropriate type and required supply of PPE for all laboratory procedures. To ensure the appropriate PPE is used for each laboratory procedure, incorporate mitigation processes that include engineering controls to provide additional physical barriers for reducing exposures, such as benchtop splash shields and certified Class II biosafety cabinets. In addition, create policies and procedures regarding the extended-use and decontamination of reusable PPE, quality monitoring, and inventory management to ensure the PPE used is justified and appropriate.

How can my laboratory optimize the supply of PPE, and is there guidance around reusing PPE?	To optimize PPE supplies, laboratories can use the Personal Protective Equipment Use Tracking Tools to calculate their average consumption rates and estimate how long their stock of PPE will last. Using the calculator can help your laboratory make order projections for future needs. For additional information, see general optimization strategies and Supply Chain Lessons Learned and Q&A. Reusing PPE designed for one-time use or disposal is not recommended. However, if you are considering the reuse of PPE, consult with infection prevention and occupational health teams on whether reuse is necessary and allowable. Multiuse PPE, e.g., powered air-purifying respirators, should be cleaned and disinfected after each use according to the manufacturer's instructions because not all disinfectants are compatible and some may degrade the PPE.
How much PPE should we keep on hand?	There is no clear-cut recommendation for how much PPE to keep on hand. However, consistent use of predictive models and digital tools can help laboratories prepare for unpredictable circumstances, including sudden infection surges, increased demands on health service units, and labor-related problems. When stocking PPE, laboratories should consider its useful life and shelf life and utilize strategies such as stock rotation to mitigate the stock loss caused by expiration or outdatedness. These resources provide information on and strategies for planning and optimizing future supply needs: Conserving Supplies of Personal Protective Equipment in Healthcare Facilities during Shortages Principles of Supply Chain Management in the Time of Crisis Personal Protective Equipment Use Tracking Tools

What is the Strategic National Stockpile (SNS), and who can request supplies?	The Strategic National Stockpile (SNS) is a national repository of medicines, vaccines, and other medical supplies in strategic locations nationwide. For example, the SNS has millions of masks, gloves, gowns, N-95 respirators, face shields, and other necessary PPE to minimize risks for healthcare and laboratory workers. These assets are designed to supplement state and local public health departments if a large-scale public health emergency causes local supplies to run out. Visit the SNS Products page. State or local public health departments may request federal assistance from the SNS to support response needs if states, tribal nations, territories, or large metropolitan areas deplete local supplies and commercial supplies are unavailable. Once federal and local authorities agree the SNS is needed, supplies will be delivered to any state in the U.S. and rapidly distributed to local communities.
What is the CDC's International Reagent Resource (IRR)?	The International Reagent Resource (IRR) provides registered users with reagents, tools, and information to detect and study influenza viruses and other pathogens, including SARS-CoV-2. The IRR is primarily a resource for procuring pathogen test components and for assembling, qualifying, and distributing these kits to public health laboratories for public health activities. In addition, the IRR helps users detect and characterize pathogens, which can help inform interventions. Centralizing these functions within the IRR supports access to and use of these materials in the scientific and public health communities and ensures quality control of the reagents. The American Type Culture Collection (ATCC) manages the IRR under a CDC contract.

What supplies does IRR distribute?	The IRR acquires, authenticates, produces, and distributes various materials with biosafety level 1 (BSL-1), BSL-2, and BSL-2+ designations. Over 1,220 different reagents are distributed to detect influenza, non-flu respiratory viruses, and bacterial diseases. For a complete list of the IRR's available items, view the IRR's catalog of reagents and materials and FAQs. The IRR also offers reagents for emergency responses, including CDC-manufactured kits and controls for COVID-19 testing. However, the distribution of these reagents is limited. For information on the specific kits/components offered for COVID-19 testing and their limitations for distribution, visit the IRR's COVID-19 FAQ.
Can I register my laboratory or hospital with IRR?	To register with IRR, you must be affiliated with a public, private, academic, nonprofit, or for-profit institution. Registrants must demonstrate that they work in an established institution with facilities and safety programs appropriate for the level of registration requested. For registrant eligibility and process details, visit the IRR's FAQs.
Should our laboratory outsource testing during a supply chain disruption?	Consider outsourcing if your laboratory cannot meet testing demands for various reasons, such as disruptions within the supply chain or surge testing. In these situations, the laboratory director, medical staff committees, clinicians, and other relevant groups must consider the acceptable turnaround times; available resources; federal, state, and local regulations (where applicable); etc., to determine which tests are suitable for outsourcing. Weigh each situation separately, if applicable.

Should smaller laboratories have a contract or memorandum of understanding (MOU) in place with larger laboratories for surge testing?	Laboratories should consider having a memorandum of understanding (MOU) in place with other laboratories as a contingency for surge testing. An MOU is a document that comprehensively describes the mutual understandings, concepts, goals, and plans shared by the laboratories and is not a legally binding agreement. In surge testing, the primary goal of an MOU between laboratories is to address the surge capacity. The MOU should describe, among other topics, the levels and shares of laboratory services, procedures, responsibilities, reimbursement for laboratory testing, training, and identification of infectious diseases and suspected bioterrorism select agents in surge testing.

This job aid is a component of the free laboratory job aids and resources produced by the CDC. Find more resources at the CDC Laboratory Training Job Aids webpage.