

Update on U.S. Testing & Vaccine Supply

PrEP4All's M-Pox Alert is a weekly bulletin containing key information for activists, advocates and impacted communities on the evolving response to the monkeypox in the United States and worldwide.

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PrEP4All M-Pox Community Monitoring

PrEP4All has a community monitoring project focused on access to monkeypox testing, vaccines, and treatments in the United States; we encourage activists and impacted people in diverse communities in the US and in other countries to reach out to share tools, information and updates as we track this outbreak.

<https://prep4all.org/monkeypox>

Testing Update

On July 6, the testing company Labcorp became the first commercial national laboratory to offer testing for monkeypox. Quest Laboratories began testing on July 15th. Labcorp says that it will be able to conduct up to 10,000 tests per week, doubling the current capacity reported by the CDC's Laboratory Response Network. This is a crucial step because it dramatically simplifies the process for providers, who no longer have to call a public health authority to request a test. It should also speed turnaround time for test results from the current wait time of more than ten days in many metropolitan areas to two to three days from specimen pick up. The CDC reports that as additional commercial laboratories join Labcorp and Quest in offering testing, the capacity could reach up to 60,000 tests per week. PrEP4All began pushing for the involvement of commercial laboratories within days of the initial reports of the monkeypox outbreak in May 2022. We welcome this progress and also believe that the six-week lag in scaling up commercial testing was preventable and exacerbated the outbreak.

Testing: Key Points on Access and Activism

ACCESS

- ▶ Health providers can now order monkeypox test as part of routine lab work. Labcorp has said it will run all tests. Insurance status and ability to pay should not be a barrier to seeking or ordering tests.
- ▶ Lab capacity is increasing. These tests should not be rationed. Routine STI screening for all at-risk populations should include monkeypox testing. At-risk populations includes people of all genders and sexual identities with a large number of sexual partners, particularly gay men and other men who have sex with men, and transgender women should now also include monkeypox testing.
- ▶ It is very important to include monkeypox as part of routine screening because of data suggesting that asymptomatic infection is possible. A person can have and pass on monkeypox without experiencing symptoms. Stopping the outbreak depends on accessible, routine screening. City health departments are urging health providers to request the monkeypox test right away for clients with lesions, sores or other symptoms—and not after ruling out other possible infections.

ACTIVISM

- ▶ The CDC, the US government and Labcorp have yet to launch large-scale provider- and patient-oriented information campaigns about when and how to order monkeypox testing. This is leading to confusion, delays, and, in instances reported directly to PrEP4All, refusals of tests to symptomatic individuals. Activists demand federal government investment in communication about monkeypox testing, treatment and vaccine availability now.
- ▶ Labcorp has said that it is willing to share broad, top-line data on monkeypox testing—such as how many tests are performed per week. It has stated that it will not be sharing more detailed data on where these tests were conducted, in which populations (race, gender, sexual orientation/risk factor). These detailed demographic data must be routinely reported by LabCorp and other commercial laboratories. They are an important source of information about how successful efforts are to monitor where the virus is and how it is spreading.
- ▶ Labcorp has said it will run all of the tests requested; it will also bill for these tests, including un- and underinsured people. This is unacceptable. The US government, state and local governments should ensure that monkeypox testing is covered for all people, and that no un- or underinsured individuals will receive a bill for this test.

Vaccine Update

Demand for monkeypox vaccine in the United States far exceeds supply in the country at present. PrEP4All has identified and pushed for action on major challenges with the US government's readiness to deploy the safest and most effective monkeypox vaccine, known as Jynneos. The US government owns more than 17 million Jynneos doses, all manufactured by a company called Bavarian Nordic. Since 2007, the US government has invested \$2.5 billion in research, development, manufacturing and stockpiling of Jynneos. Nearly a million US-owned doses are ready to be administered today—including more than 300,000 which have all of the FDA certification required for immediate shipment. The other ready-to-administer doses are delayed because, until very recently, the US Food and Drug Administration had not inspected a new addition to the Bavarian Nordic facility where the doses were produced, even though the facility was completed in March 2021, and the vaccine in question is part of the United States' biosecurity stockpile. (The European Medicines Agency has certified the facility and the fill-finish lines used for the doses in question but the FDA will not recognize the EMA's certification for vaccines as it does for small molecule therapeutics.) The 300,000-plus doses should have been in the United States within days of the outbreak, with the certification finished and additional doses delivered shortly thereafter. These delays are causing physical suffering and allowing the outbreak to spread. The White House must step in and ensure all available doses arrive in the US immediately.

Vaccines: Key Points on Access and Activism

ACCESS

- ▶ People seeking monkeypox vaccines are being turned away from clinics and unable to get appointments in on-line systems, where all available slots are taken within minutes. This is a crisis and must be addressed.
- ▶ The supply is slowly increasing. US government reports roughly approximately 300,000 doses will be arriving in the coming weeks, with an additional 800,000 doses by the end of the year. Vaccine allocations are tied to test positivity rates; equity provisions for access for Black, Indigenous and People of Color (BIPOC) communities, under- and uninsured individuals, and for jurisdictions with high spread and low testing must be in place.

ACTIVISM

- ▶ The US FDA has finally and belatedly completed its certification of the Bavarian Nordic facility. Now it must ensure all doses arrive immediately and share the expected date publicly. A flight from Copenhagen to New York takes less than 8 hours.
- ▶ The US government should proactively and transparently revise its need estimates to anticipate spread beyond MSM and transgender communities, including spread in cis women at risk of and living with HIV and in incarcerated populations. Our next **M-Pox Alert** will share updates on treatment and look at US government, global and activists' own need estimates.

Three Steps to Increase the JYNNEOS Vaccine Supply in the United States — and Worldwide

SHORT TERM

NEED

Transport approximately 800,000-1 million already filled and finished doses to US from Denmark

PROBLEM

US FDA certification of Bavarian Nordic facility was not completed in a timely manner.

SOLUTION

US FDA must ensure all doses arrive immediately and share the expected date publicly.

MEDIUM TERM

NEED

The US government must by July 31 share a plan for turning 15.2 million BN doses of raw vaccine substance into vaccination-ready vials

PROBLEM

BN appears not to have the “fill and finish” capacity to rapidly convert this quantity of drug substance into vaccines: in addition the US government has asked BN to freeze dry 13 mn of the 15.2 mn doses, a time-consuming process.

SOLUTION

Pause freeze-drying and work with Bavarian Nordic and/or the Fill-Finish Manufacturing Network or other contract manufacturer to produce 15.2 million doses by August 31

LONG TERM

NEED

WHO, CEPI and GAVI by July 31 publish estimated global need and vaccine coverage plan for JYNNEOS

PROBLEM

Monkeypox is proving readiness for pandemic preparedness has not improved during COVID-19 vaccine apartheid, poor forecasting and communication persist

SOLUTION

Global leadership centered on pandemic preparedness must use monkeypox as opportunity to prove swift, equitable outbreak response is possible