

## Why GAO Did This Study

Widespread diagnostic testing for diseases with pandemic potential can help reduce potential death rates. Diseases with pandemic potential are highly transmissible and virulent. During the COVID-19 public health emergency, HHS faced several challenges developing accurate tests quickly, deploying tests, developing clear guidance for test use, and collecting complete testing data. GAO placed HHS's leadership and coordination of public health emergencies on its High-Risk List in January 2022, in part, due to HHS's handling of COVID-19 testing.

The CARES Act includes a provision for GAO to monitor and report on the federal pandemic response. This report identifies actions suggested by experts for HHS to improve diagnostic testing for infectious diseases with pandemic potential, and steps HHS has taken related to these actions.

GAO convened a roundtable of 19 experts to discuss actions HHS should take to improve diagnostic testing. GAO contracted with the National Academies of Sciences, Engineering, and Medicine to help identify experts representing a range of perspectives. GAO also reviewed HHS documents and interviewed HHS officials.

## What GAO Recommends

GAO is making four recommendations to HHS related to developing a national diagnostic testing strategy and establishing a national testing forum. HHS noted it is committed to carefully reviewing the recommendations and providing a future update.

View [GAO-25-106980](#). For more information, contact Mary Denigan-Macauley at [deniganmacauleym@gao.gov](mailto:deniganmacauleym@gao.gov).

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## PUBLIC HEALTH PREPAREDNESS

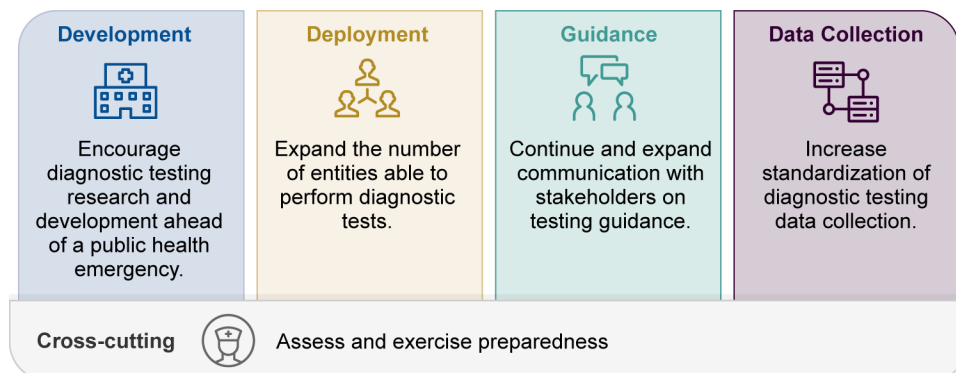
### HHS Needs a Coordinated National Approach for Diagnostic Testing for Pandemic Threats

## What GAO Found

Infectious diseases with pandemic potential—such as avian influenza—pose a threat to American lives, national security, and economic interests. The Department of Health and Human Services (HHS) leads federal diagnostic testing efforts related to such diseases. It must work with public and private stakeholders who, among other things, administer tests and collect data.

An expert roundtable GAO convened suggested nearly 100 actions HHS should take to improve diagnostic testing development, deployment, guidance, and data collection for the future. Several actions also cut across these areas. HHS officials said they are taking some steps to improve diagnostic testing related to the actions suggested by experts. For example, to help expand the number of entities able to test during an emergency, HHS has developed guidance for non-traditional laboratories seeking approval to perform testing.

#### Examples of Actions Experts Suggested to Improve Diagnostic Testing



Source: GAO analysis of statements made by a roundtable of 19 experts; RaulAlmu/stock.adobe.com (illustrations). | GAO-25-106980

Note: The actions in this report are not listed in any specific rank or order, and their inclusion should not be interpreted as GAO endorsing any of them. Implementing any one action or a combination of actions listed in this report might require considerations such as implementation feasibility, resource and legal constraints, and tradeoffs between actions or taking no action at all.

Experts coalesced around two of the suggested actions. These actions could guide a coordinated approach to testing, according to GAO's prior work, and help alleviate challenges. Specifically:

- A national diagnostic testing strategy would establish clear roles and responsibilities to improve collaboration during future public health threats. It would also help manage risks, such as conflicts arising from variation in jurisdictional resources and cooperation.
- A diagnostic testing coordinating group (forum) that includes all relevant partners would help coordinate diagnostic testing in preparation for, and in response to, public health threats. It would also help maintain and update a national testing strategy.

However, HHS has not established either a national testing strategy or forum. Establishing these before the next emergency would strengthen HHS's ability to implement testing for pandemic threats and other related public health threats.