threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that (A) the product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; (4) in the case of a determination described in section 564(b)(1)(B)(ii), that the request for emergency use is made by the Secretary of Defense; and (5) that such other criteria as may be prescribed by regulation are satisfied. No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act.

II. Electronic Access

An electronic version of this document and the full text of the Authorizations are available on the internet and can be accessed from *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

III. The Authorizations

FDA concluded that the criteria for the issuance of the following Authorizations under section 564(c) of the FD&C Act are met, and therefore authorized the emergency use of the following products for diagnosing, treating, or preventing COVID–19 subject to the terms of each Authorization. The Authorizations in their entirety, including any authorized fact sheets and other written materials, can be accessed from FDA's web page titled ''Emergency Use Authorization,'' available at *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.* The list that follows includes Authorizations issued from July 24, 2024, through December 11, 2025, and we have included explanations of the reasons for their issuance, as required by section 564(h)(1) of the FD&C Act. Additionally, FDA has incorporated an EUA issued on June 10, 2024, that was omitted from the previous compilation (89 FR 60432, July 25, 2024). The EUAs can be accessed from FDA's web page: *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

FDA is hereby announcing the following Authorization for antigen test for COVID–19, excluding multianalyte tests:

- LumiraDx UK Ltd.'s (an indirect wholly owned subsidiary of Roche) [3] LumiraDx SARS–CoV–2 Ag Test, re-issued on June 10, 2025.[4]

FDA is hereby announcing the following Authorizations for multianalyte tests:

- Aptitude Medical Systems Inc.'s Metrix COVID/Flu Test, issued on February 21, 2025; [5] and
- Healgen Scientific, LLC's Healgen COVID–19/Flu A&B Ag Combo Rapid Test Cassette (Swab), issued on June 10, 2024.[6]

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–01069 Filed 1–20–26; 8:45 am]

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[3] On July 26, 2024, LumiraDx UK Ltd. and their US entity LumiraDx Inc. became indirect, wholly owned subsidiaries of Roche Holding AG and Roche Holdings, Inc., respectively (collectively referred to as ''Roche'' for ease of reference). Roche Diagnostics Operations, Inc., a wholly owned subsidiary of Roche Holdings, Inc., will act on behalf of LumiraDx UK Ltd. (an indirect, wholly owned subsidiary of Roche).

[4] As set forth in the EUAs for this product, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID–19, and that the known and potential benefits of the product, when used for diagnosing COVID–19, outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[5] As set forth in the EUA for this product, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID–19 through the simultaneous detection and differentiation of SARS–CoV–2, influenza A virus and/or influenza B virus RNA, and that the known and potential benefits of the product when used for diagnosing COVID–19, outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[6] As set forth in the EUA for this product, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID–19 through the simultaneous detection and differentiation of SARS–CoV–2, influenza A virus and/or influenza B virus protein antigens, and that the known and potential benefits of the product when used for diagnosing COVID–19, outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Information Technology Advisory Committee Schedule of Meetings

AGENCY: Assistant Secretary for Technology Policy (ASTP), HHS.

ACTION: Notice of meetings.

SUMMARY: The Health Information Technology Advisory Committee (HITAC) was established in accordance with the 21st Century Cures Act and the Federal Advisory Committee Act. The HITAC, among other things, identifies priorities for standards adoption and makes recommendations to the Assistant Secretary for Technology Policy/National Coordinator for Health Information Technology. The HITAC will hold public meetings throughout 2026. See list of public meetings below.

FOR FURTHER INFORMATION CONTACT: Seth Pazinski, Designated Federal Officer, at *Seth.Pazinski@hhs.gov,* (202) 384–2246.

SUPPLEMENTARY INFORMATION: Section 4003(e) of the 21st Century Cures Act (Pub. L. 114–255) establishes the Health Information Technology Advisory Committee (referred to as the ''HITAC''). The HITAC will be governed by the provisions of the Federal Advisory Committee Act (FACA) (Pub. L. 92–463), as amended, (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees.

Composition: The HITAC is comprised of at least 25 members, of which:

- No fewer than 2 members are advocates for patients or consumers of health information technology;

- 3 members are appointed by the HHS Secretary:
  - 1 of whom shall be appointed to represent the Department of Health and Human Services, and
  - 1 of whom shall be a public health official;
- 2 members are appointed by the majority leader of the Senate;
- 2 members are appointed by the minority leader of the Senate;
- 2 members are appointed by the Speaker of the House of Representatives;
- 2 members are appointed by the minority leader of the House of Representatives;
- Other members are appointed by the Comptroller General of the United States.

Members serve for one-, two-, or three-year terms. All members may be reappointed for a subsequent three-year term. Each member is limited to two three-year terms, not to exceed six years of service. Members serve without pay but will be provided per-diem and travel costs for committee services, if warranted.

Recommendations: The HITAC recommendations to the Assistant Secretary for Technology Policy/National Coordinator for Health Information Technology are publicly available at *https://www.healthit.gov/topic/federal-advisory-committees/recommendations-national-coordinator-health-it.*

Public Meetings: All HITAC meetings will be virtual. Please note that some HITAC meetings may also have an in-person meeting option. For web conference instructions and the most up-to-date information, including in-person meeting location (if applicable), please visit the HITAC calendar on the ASTP website, *www.healthit.gov/topic/federal-advisory-committees/hitac-calendar.*

The schedule of meetings to be held in 2026 is as follows:

- February 19, 2026, from approximately 10:00 a.m. to 3:00 p.m./Eastern Time.
- May 7, 2026, from approximately 10:00 a.m. to 3:00 p.m./Eastern Time.
- September 24, 2026, from approximately 10:00 a.m. to 3:00 p.m./Eastern Time.
- November 5, 2026, from approximately 10:00 a.m. to 3:00 p.m./Eastern Time.

All meetings are open to the public. Additional meetings may be scheduled as needed.

Contact Person for Meetings: Seth Pazinski, *Seth.Pazinski@hhs.gov.* A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Please email Seth Pazinski for the most current information about meetings.

Agenda: As outlined in the 21st Century Cures Act, the HITAC will develop and submit recommendations to the Assistant Secretary for Technology Policy/National Coordinator on Health Information Technology on the topics of interoperability, privacy and security, and patient access to information. In addition, the committee will also address any administrative matters and hear periodic reports from ASTP. ASTP intends to make background material available to the public no later than 24 hours prior to the meeting start time. If ASTP is unable to post the background material on its website prior to the meeting, the material will be made publicly available on ASTP's website after the meeting, at *www.healthit.gov/hitac.*

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person prior to the meeting date. An oral public comment period will be scheduled at each meeting. Time allotted for each commenter will be limited to three minutes. If the number of speakers requesting to comment is greater than can be reasonably accommodated during the scheduled public comment period, ASTP will take written comments after the meeting.

ASTP welcomes the attendance of the public at its HITAC meetings. If you require special accommodations due to a disability, please contact Seth Pazinski at least seven (7) days in advance of the meeting.

Notice of these meetings are given under the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App. 2).

Dated: January 12, 2026.

Stanley S. Pazinski,

Designated Federal Officer, Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology.

[FR Doc. 2026–01046 Filed 1–20–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of meetings of the National Advisory Allergy and Infectious Diseases Council.

The meeting will be open to the public. The open sessions will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov*). Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Allergy and Infectious Diseases Council.

Date: April 6, 2026.

Closed: 8:30 a.m. to 10:00 a.m.

Agenda: To review and evaluate grant applications.

Address: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Grand Hall, Rockville, MD 20892.

Meeting Format: Virtual Meeting.

Open: 10:30 a.m. to 11:45 a.m.

Agenda: Report of Institute Director.

Address: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Grand Hall, Rockville, MD 20892.

Meeting Format: Virtual Meeting.

Closed: 11:45 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Grand Hall, Rockville, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Kelly Y. Poe, Ph.D., Director, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, MSC 9834, Rockville, MD 20892, (240) 669–5036, *poeky@mail.nih.gov.*

Name of Committee: National Advisory Allergy and Infectious Diseases Council Meeting of Division of AIDS Subcommittee.