



**FDA** U.S. FOOD & DRUG  
ADMINISTRATION

July 19, 2022

Jon Nakamoto  
Amazon.com Services LLC  
c/o Amazon Legal Dept  
410 Terry Ave. N.  
Seattle, WA 98109  
**Re: Revocation of EUA210481**

Dear Jon Nakamoto:

This letter is in response to a request from STS Lab Holdco (a subsidiary of Amazon.com Services LLC), received July 11, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR Test issued on August 11, 2021, and amended on December 17, 2021, and January 26, 2022. FDA understands there is no viable (non-expired) Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR Test remaining in distribution in the United States.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety. Because STS Lab Holdco (a subsidiary of Amazon.com Services LLC) has notified FDA that there is no viable (non-expired) Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR Test remaining in distribution in the United States and requested FDA revoke the authorization of the Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210481 for the Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR Test is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Jacqueline A. O'Shaughnessy, Ph.D.  
Acting Chief Scientist  
Food and Drug Administration

cc: Kenneth Bedsted, Director, Amazon Labs

Dated: August 22, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022-18529 Filed 8-25-22; 8:45 am]

**BILLING CODE 4164-01-C**

**DEPARTMENT OF HEALTH AND  
HUMAN SERVICES**

**[Document Identifier: OS-0990-0407-30D]**

**Agency Information Collection  
Request. 30-Day Public Comment  
Request**

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the

Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

**DATES:** Comments on the ICR must be received on or before September 26, 2022.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular

information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

**FOR FURTHER INFORMATION CONTACT:**

Submit requests to Sherrette Funn, [Sherrette.Funn@hhs.gov](mailto:Sherrette.Funn@hhs.gov) or (202) 264–0041. When submitting comments or requesting information, please include the document identifier OS–0990–0407–30D and project title for reference.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Title of the Collection:* Think Cultural Health (TCH) website Quality Improvement Effort.

*Type of Collection:* Reinstatement with Change.

*OMB No.:* 0990–0407.

*Abstract:* The Office of Minority Health (OMH), Office of the Secretary (OS), Department of Health and Human Services (HHS) is requesting approval by OMB on a reinstatement with change to a previously approved data collection. The Think Cultural Health (TCH) website is an initiative of the HHS OMH’s Center for Linguistic and Cultural Competence in Health Care (CLCCHC) and is a repository of resources and tools to promote cultural and linguistic competency in health and health care. The TCH website offers a suite of e-learning programs that afford health and health care professionals the ability to earn continuing education credits through training in cultural and linguistic competency. The revision to this information collection request includes revisions to the online website registration form to streamline and change response options for some elements.

*Need and Proposed Use of the Information:*

The data will be used to ensure that the offerings on the TCH website are relevant, useful, and appropriate to their target audiences. The findings from the data collection will be of interest to HHS OMH in supporting maintenance and revisions of the offerings on the TCH website.

*Likely Respondents:*

Likely respondents are users of the TCH e-learning program(s) and/or e-resource(s). There are no requirements for annual, quarterly or monthly responses. A single respondent completes the registration process to access an e-learning program or e-resource on the website only one time and completes a course-specific evaluation form for each e-learning program course/unit or e-resource per completion. A respondent may be invited to participate in the follow-up survey, a focus group, or a key informant interview and will not be asked to participate in more than one follow-up activity (*i.e.*, survey, focus group, or key informant interview).

**TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS**

Forms	Respondents	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Registration Form .....	Health and Health Care Professionals.	9,460	1	3/60	473
Course/unit Evaluation Form .....	Health and Health Care Professionals.	9,460	1	5/60	788
Follow-Up Survey .....	Health and Health Care Professionals.	4,208	1	10/60	701
Focus Groups .....	Health and Health Care Professionals.	15	1	120/60	29
Key Informant Interviews .....	Health and Health Care Professionals.	13	1	60.60	13
Total .....	.....	23,156	.....	.....	2,004

**Sherrette A. Funn,**

*Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.*

[FR Doc. 2022–18415 Filed 8–25–22; 8:45 am]

**BILLING CODE 4150–29–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute on Aging; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting 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 Institute on Aging Initial Review Group; Career Development for Clinicians/Health Professionals Study Section Clinical career development.

*Date:* October 3–4, 2022.

*Time:* 9:30 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Maurizio Grimaldi, Ph.D., MD, Scientific Review Officer, Scientific Review Branch, NIA (National Institute on Aging), Gateway Building, Rm 2W200, 7201 Wisconsin Ave., Bethesda, MD 20892, 301–496–9374, [maurizio.grimaldi@nih.gov](mailto:maurizio.grimaldi@nih.gov).

Information is also available on the Institute’s/Center’s home page: [www.nia.nih.gov/](http://www.nia.nih.gov/), where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)