

**Requirement For Proof Of Negative Covid-19 Test Result For All Airline
Passengers Arriving Into The United States from The United Kingdom
(OMB Control No. 0920-XXXX)
Request for Emergency Clearance**

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**REQUIREMENT FOR PROOF OF NEGATIVE PRE-DEPARTURE COVID-19
TEST RESULT FOR ALL AIRLINE PASSENGERS ARRIVING INTO THE
UNITED STATES FROM THE UNITED KINGDOM (UK)
(OMB Control No. 0920-XXXX)**

- The goal of this information collection is to ensure that, consistent with the terms of the Order Under Section 361 of The Public Health Service Act (42 U.S.C. § 264) and 42 Code Of Federal Regulations §§ 71.20, 71.31(B), & 71.32(B) *Requirement For Proof Of Negative Covid-19 Test Result For All Airline Passengers Arriving Into The United States from The United Kingdom*, public health authorities in the United States can confirm that individuals have received a negative test result for COVID-19 prior to departing the United Kingdom and arriving in the United States.
 - The intended use of the information is to enable U.S. public health authorities to ensure that individuals who are coming into the United States via airlines have tested negative for SARS-CoV-2.
 - There are no statistical sampling or research design methods being used.
 - There is no subpopulation being studied. The universe of respondents is airline passengers over the age of two years coming to the United States from the UK, with the following exemptions:
 - Airline crew members, provided that they follow industry standard protocols for the prevention of COVID-19 as set forth in relevant Safety Alerts for Operators (SAFOs) issued by the Federal Aviation Administration (FAA).
 - Passengers who originate on flights outside the UK but connect through an airport in the UK on a transit flight with a connection time of no more than 24 hours.
- The requirements for testing include those itineraries that begin in the UK but have layovers in a second country before arriving in the United States.
- There is no predetermined methodology to analyze the provision of testing information. CDC will require that individuals retain proof of their negative test for potential inspection upon arrival and to assist local health authorities in evaluating individuals to determine if further public health measures are needed.

CDC is requesting an emergency clearance for this information collection for 90 days.

A. Justification

1. Circumstances Making the Collection of Information Necessary

This information collection accompanies the Notice and Order (Attachment A1) requiring that any airline arriving into the United States from the UK submit proof of a negative pre-departure test for COVID-19 for all onboard passengers over the age of 2 years as a condition of controlled free pratique to enter and disembark passengers in the United States. Passengers must provide a copy of the negative coronavirus disease 2019 (COVID-19) viral test result, which includes a matching identity, and attest to the truthfulness of the test results as instructed by the airline before being allowed to board a

flight to the United States as a public health prevention measure to mitigate the potential spread of COVID-19.

The COVID-19 pandemic has spread throughout the world. Individuals who travel may be at risk for exposure to SARS-CoV-2, the virus that causes COVID-19, before, during, or after travel. This could result in travelers' further spreading the virus to others during travel, upon arrival in the United States, or at their destinations.

Over the last few weeks, the United Kingdom (UK) has faced a rapid increase in COVID-19 cases in South East England, leading to enhanced epidemiological and virological investigations. On December 14, 2020, Public Health England announced that a new variant of SARS-CoV-2 had been identified across the southeast of England (i.e., Kent and the surrounding areas).¹

While it is known and expected that viruses constantly change through mutation leading to the emergence of new variants, preliminary analysis in the UK suggests that this variant may be more transmissible than previously circulating variants, with an estimated potential to increase the reproductive number (R) by 0.4 or greater with an estimated increased transmissibility of up to 70%.² This new variant has emerged at a time of the year when there has traditionally been increased family and social mixing and travel.

On December 19, 2020, in response to the emergence of this new variant, the countries comprising the UK announced stricter measures to be applied from December 20 and over the coming weeks, with affected areas going into a 'Tier 4' level with movement restrictions within and between more and less heavily affected areas. These measures include recommendations for residents of the most affected areas to restrict movements and travel, including international travel, outside of these areas. The government of Scotland announced a travel ban between Scotland and rest of UK. In addition, the Netherlands issued a travel ban from the UK effective through January 1, 2021, and Belgium halted flight and train travel to the UK. Other countries have taken similar measures to restrict travel from the UK.³

On March 14, 2020, the United States issued a "Proclamation on the Suspension of Entry as Immigrants and Nonimmigrants of Certain Additional Persons Who Pose a Risk of Transmitting Coronavirus" applicable to the UK.⁴ While this suspension remains in place and there is no current indication of increased infection severity associated with the new variant, timely efforts are needed to prevent the potential

¹ <https://www.gov.uk/government/news/phe-investigating-a-novel-variant-of-covid-19>

² <https://www.ecdc.europa.eu/en/publications-data/threat-assessment-brief-rapid-increase-sars-cov-2-variant-united-kingdom>

³ On December 20, 2020, Austria, Belgium, Italy, Ireland, Germany, France, and the Netherlands announced travel bans from the United Kingdom. The measures vary in scope and generally are short-term. The Republic of Ireland, Portugal, Latvia, Estonia, and Czech Republic also announcing new travel restrictions, testing requirements, and quarantine rules. Bulgaria suspended flights to and from the UK until January 31, 2021, one of the longer bans announced. Greece issued new rules requiring a seven-day quarantine for travelers from the UK, rather than the current three-day period, starting December 21, 2020. Turkey temporarily has banned all flights from the UK, as has Switzerland. Eurostar train service will be cut beginning on December 21, between London, Brussels, and Amsterdam.

⁴ <https://www.whitehouse.gov/presidential-actions/proclamation-suspension-entry-immigrants-nonimmigrants-certain-additional-persons-pose-risk-transmitting-coronavirus-2/>

spread of this new virus variant into the United States.

Predeparture testing may detect travelers infected with SARS-CoV-2 before they initiate their travel. CDC's Order aligns with published guidance for travelers and involves viral testing and receipt of results 1-3 days (to include day of testing)⁵. This guidance is based on evidence suggesting testing prior to departure for international travelers, particularly those traveling long-distances or passing through transportation hubs such as airports where social distancing may be challenging, may be useful as a means to reduce the risk of SARS-CoV-2 transmission during travel. Testing does not eliminate all risk, but when predeparture testing is combined with other measures such as self-monitoring for symptoms of COVID-19, wearing masks, social distancing, and hand hygiene, it can make travel safer by reducing spread on conveyances and in transportation hubs.

The Order is enforceable through the provisions of 18 U.S.C. §§ 3559, 3571 (Attachment A2); 42 U.S.C. §§ 243, 268, 271 (Attachment A3); and 42 C.F.R. § 71 (Attachment A4).

2. Purpose and Use of Information Collection

Pursuant to 42 C.F.R. § 71.20, the Order prohibits the introduction into the United States of any airline passenger departing from the UK unless the passenger has a negative pre-departure test result for COVID-19. The test must be a viral test that was conducted on a specimen collected during the 3 calendar days preceding the flight's departure (Qualifying Test). Passengers must retain written or electronic documentation reflecting the negative Qualifying Test result presented to the airline and produce such results upon request to any U.S. government official or a cooperating state or local public health authority.

Pursuant to 42 C.F.R. § 71.31(b), the Order constitutes a controlled free pratique to any airline with an aircraft arriving into the United States from the UK. Pursuant to the controlled free pratique, the airline must comply with the following conditions in order to receive permission for the aircraft to enter and disembark passengers in the United States:

- Airline must verify that every passenger—2 years of age or older—onboard the flight has attested to having received a negative Qualifying Test result.
- Airline must confirm that every passenger onboard the aircraft has documentation reflecting a negative Qualifying Test result.

CDC modeling indicates that predeparture testing is most effective when combined with self-monitoring.⁶ Travel should be delayed (i.e., individuals should self-isolate) if symptoms develop or a pre-departure test result is positive. Testing before departure results in the greatest reduction of transmission risk during travel when the specimen is collected close to the time of departure. Earlier testing, i.e., more than 3 days before travel, provides little benefit beyond what self-monitoring alone can provide.

⁵ <https://www.cdc.gov/coronavirus/2019-ncov/travelers/testing-air-travel.html>

⁶ Johansson MA, Wolford H, Paul P, et al. Reducing travel-related SARS-CoV-2 transmission with layered mitigation measures: Symptom monitoring, quarantine, and testing. Available at: <https://www.medrxiv.org/content/10.1101/2020.11.23.20237412v1external icon>

Predeparture testing must be completed and results available to the traveler at maximum 3 days before the traveler attempts to board an aircraft. Travelers who test positive should remain in isolation and delay travel until they meet criteria for discontinuing isolation. Travelers whose test results are not available before departure should delay their travel until results are available, and will be denied boarding.

3. Use of Improved Information Technology and Burden Reduction

At this time, CDC is not specifying the format of the proof of negative test or attestation. Either format is acceptable, as long as the electronic or hard copy contain the information as specified in the Order. Federal or state and local officials may request the documentation of proof of negative COVID-19 test results, and those this must be retained by the individual.

4. Efforts to Identify Duplication and Use of Similar Information

Currently, certain classes of individuals traveling from the UK are not permitted entry to the United States under the March 14, 2020 212(f) Presidential Proclamation, available here: <https://www.whitehouse.gov/presidential-actions/proclamation-suspension-entry-immigrants-nonimmigrants-certain-additional-persons-pose-risk-transmitting-coronavirus-2/>

This Presidential Proclamation does not apply to U.S. citizens, legal permanent residents of the United States, and other limited classes of individuals. This Order applies to all travelers coming to the United States, with the limited noted exceptions, and so the collection is different in nature and population. To our knowledge, there is no duplication to CDC's ongoing information collections.

5. Impact on Small Businesses or Other Small Entities

While some aviation, maritime, and other travel companies may be considered small businesses, CDC anticipates that the majority of the burden rests with larger passenger airlines given their volume of travelers. CDC has been judicious in determining the required information collection to those minimally necessary to achieve public health objectives.

6. Consequences of Collecting the Information Less Frequently

Given the scope of the outbreak of COVID-19 identified in international airline travelers, CDC needs this data on a routine basis. Further reduction of required reporting would prevent CDC from meeting its statutory and public health mission, thereby endangering the public's health.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. Because this is a request for an emergency clearance, OIRA has waived the 60-day comment period. However, in the event that this collection exceeds 60 days, CDC is posting a 60 day notice in the Federal Register seeking additional notice and comment (Attachment B 60-day FRN).

B. CDC communicates frequently with airlines and state and local health departments concerning the latest efforts to address the COVID-19 pandemic. In this case, CDC is aware of several states that have requested federal public health actions to mitigate the risk of entry of this variant of SARS-CoV-2. To attempt to streamline the process and work with airlines' policies and procedures, CDC routinely obliges airlines' requests concerning these kinds of collections. Additionally, CDC is aware that some airlines are already including testing in the business processes, and so this may not represent a significant additional burden in those cases. CDC also anticipates that many travelers will retain copies of their COVID-19 test results regardless of this information collection, and does not anticipate significant additional burden as a result of this Order.

9. Explanation of Any Payment or Gift to Respondents

No payment is made to any respondent.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

This information collection request has been reviewed by the CDC National Center for Emerging and Zoonotic Diseases (NCEZID). NCEZID has determined that the Privacy Act applies to this information collection request. The applicable System of Records Notice is 09-20-0171. Individual's identifiable information will only be shared according to the Routine Uses described in the SORN, which are generally focused on providing public health authorities and cooperating medical provides with this information to assist in dealing with public health threats or for medical follow-up for a traveler.

While in the vast majority of events CDC will not be in receipt of this information, as these information collection requirements are 3rd party disclosures or involve records retention, CDC may need to inspect a test result in the event some public health action is needed at the time of arrival. Those documents may enter into CDC possession and would be treated according to the requirements of the SORN above.

Further information concerning the protection of privacy can be found in the attached Privacy Impact Assessment (Attachment 4).

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

IRB Determination

The protocols and tools used to conduct this information collection request have been reviewed and approved by NCEZID’s Human Subjects Advisor, who determined that this data collection does not meet the definition of research under 45 CFR 46.102(d). IRB review is not required.

Justification for Sensitive Questions

This information collection request includes records of clinical testing and identifying information to ensure the test results match the bearer. Specifically, the requirement documentation of a negative test means that:

- 1) the personal identifiers (e.g., name and date of birth) on the Qualifying Test result match the personal identifiers on the passenger’s passport or other travel documents;
- 2) the specimen was collected within 3 calendar days of the flight’s departure;
- 3) the type of test performed was a viral test (as defined below); and
- 4) the test result states “NEGATIVE,” “SARS-CoV-2 RNA NOT DETECTED,” or “SARS-CoV-2 ANTIGEN NOT DETECTED.”

12. Estimates of Annualized Burden Hours and Costs

A.

The current Order is scheduled for 90 days. CDC estimates of the burden for these 90 days to be approximately 514,583 hours (rounded to nearest hour.)

Based on data provided to CDC by U.S. Customs and Border Protection, arrivals to the United States from the United Kingdom have been between 10 to 20 thousand per week. CDC is using the upper end of this range to estimate an approximate 90-day volume of arrivals of 247,000 travelers. CDC understands that this number is depressed due to the COVID-19 pandemic, but does not anticipate a significant change in the volume through the period of this collection.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Traveler (3 rd Party Disclosure)	Proof of a negative COVID-19 test	247,000	1	2	494,000

Airline Desk Agent	Review of proof of negative COVID-19 test	247,000	1	5/60	20,583
Total					514,583

B. The cost to respondents was calculated using the May 2018 National Occupational Employment and Wage Estimates United States data from the Bureau of Labor Statistics (http://www.bls.gov/oes/current/oes_nat.htm). The total estimated respondent cost is \$16,914,548.

- 53-2031 Flight Attendants (<https://www.bls.gov/oes/current/oes532031.htm>) was used to account for airline staff time soliciting traveler information. The BLS does not offer an hourly wage for this occupation so mean annual salary was adjusted to provide an hourly wage of \$27.23. CDC further adjusted the salary to account for non-wage benefits to obtain a figure of \$36.48
- 00-0000 All Occupations (https://www.bls.gov/oes/current/oes_nat.htm#00-0000) was used to account for international passenger time. The mean hourly wage for this category is \$24.98, and was adjusted to account for non-wage benefits to obtain a figure of \$32.72.

Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Traveler (3 rd Party Disclosure)	Proof of a negative COVID-19 test	494,000	\$32.72	\$16,163,680
Airline Desk Agent	Review of proof of negative COVID-19 test	20,583	\$36.48	\$750,868
Total				\$16,914,548

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

For the 90 days under the current Order, CDC anticipates certain additional cost burdens to respondents and record keepers due to the requirements.

CDC is requiring that individuals retain copies of their negative tests. CDC anticipates this will result in no significant costs or burden in either hard copy or electronic form as most people may want to retain this information for other purposes.

CDC does anticipate estimated costs to individuals who must obtain testing in order to travel at approximately \$57,481,840. CDC is assuming that costs for testing will be paid by the traveler, as the UK is advising travelers not to use the National Health Services for

this purpose.⁷ CDC anticipates these tests will cost between \$100 and \$200⁸ to obtain and 1 hour of their time to make an appointment, travel to the appointment and have the test taken. CDC is taking the top end of this range for estimated burden. The calculations for estimated burden are as follows:

	Test Cost	Time cost	# of Travelers	Total
Traveler	\$200	\$32.72	247,000	\$57,481,840

There may also be a cost to the travelers for deferred travel in the event they test positive or miss the 3-calendar day window for the validity of the proof of negative test. CDC anticipates that airlines will be flexible in waiving rescheduling fees, but some travelers may endure costs associated with finding accommodations to stay for a limited period of time. CDC cannot predict what percentage of travelers may experience these inconveniences. For the purposes of this collection, CDC is estimating that 1% of travelers will experience deferred travel and a cost of ⁹ \$150 dollars for an overnight hotel stay. With 1% of 247,000 travelers experiencing this deferred travel, CDC estimates the additional burden at \$370,000.

CDC is also requiring that the airlines retain the attestation of negative test provided by the passenger. As long as the attestation conforms to Attachment A of the Order, either electronic or hard copy retention is acceptable. CDC anticipates that any hard copy attestation would be digitized and result in negligible storage costs.

14. Annualized Cost to the Government

This collection generally does not involve any direct collection of information by the CDC. In the event that an inspection of a test result or attestation is required, this will generally be performed as part of a routine activity from quarantine station staff in concert with U.S. Customs and Border Protection for arriving flights.

15. Explanation of Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Data are not collected for statistical purposes, but only to meet the regulatory and public health mandate as outlined in 42 CFR part 71.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

No exemption is requested. The OMB Control Number and expiration date will be displayed on the attestation form.

⁷ <https://www.gov.uk/guidance/travel-advice-novel-coronavirus?priority-taxon=774cee22-d896-44c1-a611-e3109c8e8eae>

⁸ <https://www.bbc.com/news/uk-55052381>

⁹ <https://www.statista.com/statistics/614026/overnight-accommodation-costs-london-city/>

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachments

Attachment A1: CDC UK Airline Testing Order

Attachment A2 18 U.S.C. §§ 3559, 3571

Attachment A4: Section 361 of the Public Health Service Act (42 USC 264)

Attachment A4: 42 CFR Part 71

Attachment B: Attachment 2: 60-day Federal Register Notice

Attachment C: Attachment A - Attestation

Attachment D: QARS Privacy Impact Assessment