Distribution of Traceable Opioid Material* Kits (TOM Kits*) across U.S. and International Laboratories

(formerly known as "Distribution of Traceable Opioid Material* Kits [TOM Kits*] across U.S. Laboratories")

OMB Control No. 0920-1313
Expiration Date 12/31/2022

Revision

Supporting Statement Part A –

Justification

Project Officer: Rebekah Wharton, PhD
Title: Senior Service Fellow
Division of Laboratory Sciences (DLS), NCEH
Phone: 770-488-7630
Email: flo2@cdc.gov
Fax: 770-488-7518

Date: 12/02/2022

Table of Contents

Part A. Justification

Goal of the study: The purpose of this information collection request (ICR) is for the CDC to assure that the Traceable Opioid Material* Kits (TOM Kits*) are equitably distributed to domestic laboratory sectors (public, private, and non-profit) and to international partner laboratories.

Intended use of the resulting data: 1) To gather information on the types of laboratories requesting the kits, and 2) To determine the types of instrumentation and matrices for those requesting kits.

Methods to be used to collect: The CDC vendor will receive domestic requests for test kits using its online application form, including questions on laboratory characteristics to equitably distribute test kits to all laboratory sectors (academic, public, or private) in the US. On the domestic front, the shipment and distribution of test kits is federally sponsored.

On the international front, the shipment and distribution of test kits is not federally sponsored. Instead, the CDC vendor will ship test kits in partnership with the United Nations Office (UN) and under contract with the International Narcotics Control Board (INCB) (hereafter, collectively coined the "UN") for distribution. Under the INCB contract, the CDC vendor may also direct ship test kits upon UN request to select international laboratories. The CDC vendor will maintain identifiable international applicant information on its own servers, assign each lab a unique ID, and then direct the applicants to share their laboratory characteristics identified only by their unique lab ID with the CDC using the CDC vendor website. The collection of anonymized international laboratory information is federally sponsored.

Subpopulation to be studied: The domestic subpopulation for this information collection will be laboratories located in the U.S. They must have a verifiable business address, must have a current DEA registration, must comply with respective state and local regulations, and must submit requests for test kits directly to the vendor.

The international subpopulation for this information collection will apply for test kits through a separate vendor application webpage for international laboratories and will verify test kit eligibility for requesting laboratories through country-specific drug enforcement laboratory certifications.

How data will be analyzed: General purpose statistics such as aggregation of similar responses to compare quantities with different responses.

*TRACEABLE OPIOID MATERIAL, TOM KITS, and the TOM KITS logo are marks of the U.S. Department of Health and Human Services

A.1. Circumstances Making the Collection of Information Necessary

Opioid Crisis

The Acting Secretary of Health and Human Services (HHS) declared opioids a public health emergency on October 26, 2017. This was the first time that a drug class was declared a national public health emergency (Hargan, 2017; GAO, 2018). Since 2013, there have been significant increases in overdose deaths involving synthetic opioids – particularly those involving illicitly manufactured fentanyl. The U.S. Drug Enforcement Administration (DEA) estimates that 76% of all opioid identifications are illicit fentanyls (DEA, 2018 Emerging Threat Report). The drugs in the synthetic opioids other than methadone (SOOTM) category were involved in more than 31,335 overdose deaths in 2018 and accounted for 67 percent of opioid-involved deaths. The drugs in this category include illicit fentanyl and legal opioids available by prescription (DEA, 2020 National Drug Threat Assessment).

To this day, the crisis continues and a public health emergency declaration for opioids remains.[1] From 2019 to 2020, the rate of drug overdose deaths increased for all sex, age, and race and Hispanic-origin groups. The age-adjusted rate of drug overdose deaths increased 31 percent from 2019 (21.6 per 100,000 standard population) to 2020 (28.3). The age-adjusted rate of drug overdose deaths for males increased from 29.6 to 39.5 and the rate for females increased from 13.7 to 17.1. Rates of drug overdose deaths increased from 2019 to 2020 for all race and Hispanic-origin groups. The rates were highest for non-Hispanic American Indian and Alaska Natives (AIANs). The greatest percentage increase in rates occurred among non-Hispanic Black and non-Hispanic Native Hawaiian and Other Pacific Islanders (NHOPIs). (Hedegaard H et al., 2021).

Laboratories are routinely asked to confirm which fentanyl or other opioids are involved in an overdose or encountered by first responders, as it is critical to identify and classify the types of drugs involved in an overdose, how often they are involved, and how that involvement may change over time. By understanding which drugs are present, appropriate prevention and response activities can be implemented.

The illegal manufacture of a variety of fentanyl analogs presents one of the more difficult problems for laboratory analyses of forensic and post-mortem cases. In 2015, members of the scientific community called for more specificity in opioid analyses, and up until 2016, national epidemiological data was sparse on the specific illicit fentanyl analogs entering the market or causing death.

[1] Public Health Emergency Declarations: https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.

CDC TOM Kits Development*

Laboratory testing does exist for opioids that are available clinically or are widely recognized. However, there has been a rapid expansion in new types of illicit opioids, particularly fentanyl analogues. Health care providers, public health surveillance officials, and law enforcement officers need to know which opioids are in use to treat, monitor, and investigate fatal and non-fatal overdoses. For laboratories to test them, they need samples of the new illicitly manufactured fentanyls of concern. Laboratories will use small amounts of these deadly fentanyl types to develop and maintain the critical ability to identify them.

To fill this need, beginning in 2019, the Centers for Disease Control and Prevention (CDC) developed the Traceable Opioid Material* Kits (TOM Kits*), which provide over 200 opioid reference standards, including over 190 fentanyl analogs.[2] CDC maintains the contents of the TOM Kits* based on new needs identified, in part, through the DEA Emerging Threat Reports (DEA, 2016-2021) as well as the Center for Science Research and Education (CFSRE) Novel Psychoactive Substances (NPS) Trend and Scope Reports (2021-2022). These kits were designed to dramatically increase laboratory capability to confirm which opioids are on the streets and causing deaths. The kits are free to laboratories in the public, private, clinical, law enforcement, research, and public health domains (**Attachment 3**).

To equitably distribute the TOM Kits*, in 2019, the CDC conducted an emergency information collection, titled "Distribution of Traceable Opioid Material* Kits (TOM Kits*) across U.S. Laboratories," under the Health and Human Services (HHS) Secretary's Public Health Emergency Paperwork Reduction Act (PHE PRA) Waiver mechanism for the period from 03/20/2019 to 05/10/2019 (**Attachment 4a**). From 05/10/2019, CDC continued distributing kits using a generic information collection (GenIC) under "Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery" (OMB Control No. 0923-0047; expiration date 01/31/2022) (**Attachment 4b**). CDC next requested and received Paperwork Reduction Act (PRA) clearance in 2020 under "Distribution of Traceable Opioid Material* Kits (TOM Kits*) across U.S. Laboratories" (OMB Control No. 0920-1313, expiration date 12/31/2022) (**Attachment 4c**).

Emergent Drug Panel Kits

To continue this collection, the CDC is requesting a three-year Paperwork Reduction Act (PRA) clearance for a revision information collection request (ICR). As part of this revision, CDC will be expanding its TOM Kits* program to include its new Emergent Drug Panel (EDP) Kits. For the EDP Kits, the compounds will be identified by doing a search of recent lists put out by the DEA and the CFSRE. These lists provide data on all classes of drugs that are recently identified in the field and provide recommendations on which drugs should be included in testing. These lists are updated several times a year and keep up with the changing drug landscape in the United

[2] See CDC TOM Kits website at https://www.cdc.gov/nceh/dls/erb_opioid_kits.html.

*TRACEABLE OPIOID MATERIAL, TOM KITS, and the TOM KITS logo are marks of the U.S. Department of Health and Human Services

States. For the current round, EDP Kits will include synthetic cannabinoids, stimulants, hallucinogens, and benzodiazepines as well as opioids.

Distribution to Domestic and International Laboratories

CDC will continue to distribute TOM Kits*, including the new EDP Kits, through a single vendor instead of the previous two. The CDC vendor will distribute these kits to domestic laboratories, as previously approved. Additionally, the CDC vendor will now ship TOM Kits*, currently excluding the EDP kits, to international laboratories in partnership with the United Nations (UN) and under a separate non-CDC contract with the International Narcotics Control Board (INCB) (hereafter, collectively coined the "UN"). The CDC vendor may direct ship these kits to select international laboratories upon UN request.

CDC is updating **Attachment 5a** (formerly **Attachment 7**) to display the vendor's online application and questions for US laboratories. CDC is proposing several modifications to the questions to accommodate the next round of vendor requirements. See **Section A.15** for a detailed description of the form modifications.

As part of the revision ICR and in parallel to the domestic application information, the CDC vendor will also receive test kit applications from international laboratories which are directed to the CDC vendor website by the UN, assign each lab a unique ID, and then direct the applicants to complete questions on their laboratory characteristics using the CDC vendor website, and identified only by their unique lab ID. See the new **Attachment 5b**.

Proposed Changes to Estimated Burden Hours and Responses

The following changes to burden hours and to the number of responses per year are as follows. We estimate a total time burden of 80 hours, which is a decrease of 40 hours over the previously approved 120 hours. We estimate a total number of 900 annual responses which is a decrease of 300 over the previously approved 1,200 responses.

- We anticipate that 600 domestic laboratories will request test kits per year (a decrease of 600 applicants over the previously approved 1,200). The annual time burden for domestic laboratories will be 60 hours.
- We will add 20 additional annual burden hours with the expansion to international distribution of test kits, assuming that 300 international partner labs will request test kits through the UN and will complete their laboratory information for the CDC.

Details of the requested revisions can be found in **Section A.15**.

Authority

*TRACEABLE OPIOID MATERIAL, TOM KITS, and the TOM KITS logo are marks of the U.S. Department of Health and Human Services

CDC is authorized to carry out this program under the Public Health Service Act, Section 301, "Research and Investigation," (42 U.S.C. 241) (**Attachment 1**). The 60-day Federal Register Notice was published on 09/16/2022 (**Attachment 2**) and is further discussed in **Section A.8**.

A.2. Purpose and Use of the Information Collection

The purpose of this information collection is for an application for benefits and general-purpose statistics.

Since 2019, CDC began supplying TOM Kits* through two vendors including the: (1) Opioid Certified Reference Material Kit (Opioid CRM Kit); and (2) Fentanyl Analog Screening Kit (FAS Kit). CDC received a total of 230 requests for and distributed 519 Opioid CRM Kits. CDC also received a total of 1,242 requests for and distributed 2,488 FAS Kits. Therefore, the number of requests for TOM Kits* since 2019 is 1,472, or approximately 490 requests per year (1,472 divided by 3 = 491).

Over the next three years, CDC will distribute an expanded array of TOM kits* through a single vendor (**Attachment 3**).[3] The kits are all manufactured by Cayman Chemical [4]

- FAS Kits (original and four emergent panels: FAS Version 1, FAS Version 2 and 3, and FAS Version 4)
    - Opioids
        - See a list of compounds in each FAS Kit panel at https://www.cdc.gov/nceh/dls/erb_fas_kits.html.
        - Includes 200 micrograms each of 200+ fentanyl analog analytical reference materials
        - Provides largest collection of available fentanyl analog reference materials
        - Improves immunoassay and mass spectrometry screening methods
        - Includes structural variability for fentanyl analog
        - Distributed internationally and domestically by Cayman Chemical
- EDP Kits
    - Opioids
    - Synthetic Cannabinoids
    - Stimulants and Hallucinogens
    - Benzodiazepines
        - Includes 200 micrograms of each analytical reference material

[3] Fentanyl Analog Screening Kit (FAS Kit) and Emergent Panels | CDC
[4] Cayman Chemical - https://www.caymanchem.com/

*TRACEABLE OPIOID MATERIAL, TOM KITS, and the TOM KITS logo are marks of the U.S. Department of Health and Human Services

- Addresses the most prevalent drugs currently found in drug seizures and overdose deaths reported by the DEA and CRSRE
- Improves immunoassay and mass spectrometry screening methods
- Distributed domestically by Cayman Chemical

For domestic requests, respondent laboratories requesting the kits can be from any sector (academic, public, or private), must be located in the U.S., must have a verifiable business address, must have a current Drug Enforcement Administration (DEA) registration, must comply with respective state and local regulations, and must submit requests directly to the vendor. As the number of laboratories requesting test kits may exceed the supply, this information collection will be used to prioritize which laboratories will receive the limited quantities of kits. The brief six-minute web-based survey will allow the CDC to (1) determine what service the recipient laboratory performs and the volume of samples the laboratory processes and (2) equitably distribute TOM Kits* based on the analysis techniques and matrices used by the recipient laboratory (**Attachment 5a**).

In addition, CDC will expand its distribution of FAS Kits to international labs in partnership with the UN and under a non-CDC contract with the INCB (**Attachment 3**).

- Cayman Chemical may direct ship test kits to international laboratories at UN request.
- The CDC vendor will receive test kit applications from international laboratories on its own servers, assign each lab a unique ID, and then direct the applicants to share their information with CDC by completing questions on their laboratory characteristics identified only by their unique lab ID using the CDC vendor website. See the new **Attachment 5b**.

The information collection will serve to gather information on the types of laboratories requesting the kits and to determine the types of instrumentation and matrices that those requesting kits will use them for. If the demand for the kits is greater than the supply of kits, questions about the laboratory function will aid in assuring that labs that serve a variety of different functions will have access to kits. Collecting information about the volume of samples that the lab typically processes assures that the labs with the biggest volume do not get all the kits, thereby allowing smaller labs access to the kits. Questions pertaining to the matrix and method of analysis is information that can be used to tailor future kits to the needs of the labs that are using the kits.

If no information about lab function is collected, there may be a disproportionate distribution of kits to labs that serve similar or identical functions, thereby leaving a paucity of kits for laboratories that perform other functions. Additionally, no information to assist in improving the program, or how to optimize the way the sample material is provided would be possible.

*TRACEABLE OPIOID MATERIAL, TOM KITS, and the TOM KITS logo are marks of the U.S. Department of Health and Human Services

A.3. Use of Improved Information Technology and Burden Reduction

Information from domestic laboratories will be collected through the TOM Kits* manufacturer's website (**Attachments 3, 5a**). The information collection is 100% electronic. There is no special software that will be used, and the survey uses common internet interfaces to complete, thereby minimizing any training time and cost to fill out the form. Upon completion, a submission button is used to submit electronically and instantaneously. By adopting a common internet interface, and one that can be accessed with any major web browser, errors are minimized, costs and burden time are reduced, and ease of submission is maximized.

Applicant information from international laboratories will be collected by the CDC vendor on its own secure servers. The CDC vendor website will direct applicants to complete the supplemental test kit questions for international laboratories located on the CDC vendor website (**Attachments 3, 5b**).

A.4. Efforts to Identify Duplication and Use of Similar Information

It is possible that a laboratory may submit more than one request for TOM Kits*. The CDC website [5], "Traceable Opioid Material* Kits to Improve Laboratory Detection of Synthetic Opioids in the U.S." states that although laboratories may request multiple kits, supplies are limited and requests will be filled based on product availability. If requesting multiple kits over time, the attributes of a laboratory and the analysis method of the TOM Kits* materials may change. Therefore, future requests will require filling the survey out again to ensure the most up-to-date information is being used to prioritize kit distribution.

There is no information elsewhere about the types of labs, quantity of samples analyzed by the labs, or matrix types used by labs performing opioid analysis, so it is critical that the program ask these questions for prioritizing kit distribution.

A.5. Impact on Small Businesses or Other Small Entities

Because this information collection involves laboratories as respondents, a large proportion will affect small businesses or other small entities. Nevertheless, the Test Kits survey (**Attachment 5a**) is designed to collect the absolute minimum amount of information needed (six-minute

[5] Available at https://www.cdc.gov/nceh/dls/erb_opioid_kits.html.

*TRACEABLE OPIOID MATERIAL, TOM KITS, and the TOM KITS logo are marks of the U.S. Department of Health and Human Services

survey) to distribute materials, and the recipient laboratories will benefit by receiving free TOM Kits*.

Based on our respondent estimates (**Section A.12**), we assume that 67 percent of the US respondents will be small businesses or other small entities (e.g., 200 state/local/tribal government laboratories + 200 private/not-for-profit institutions ÷ 600 = 67%). The remaining 33 percent (n=200) of the US respondents are estimated to come from the federal government.

A.6. Consequences of Collecting the Information Less Frequently

The US respondents will be able to follow the links from the CDC TOM Kits* Factsheet (**Attachment 3**) and CDC's website [2] to the vendor website [4] to fill out the domestic online "Test Kit Application and Questions for US Laboratories" (**Attachment 5a**). Cayman will provide the international applicants with a link to the international online "Test Kit Questions for International Laboratories" (**Attachment 5b**). This information collection is voluntary, but the respondents must complete their applications to be considered to receive the requested TOM Kits*.

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

This request fully complies with the regulation 5 CFR 1320.5.

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

A. A 60-day Federal Register Notice was published in the *Federal Register* on 09/16/2022, Vol. 87, No. 179, pp. 56957-8 (**Attachment 2**). CDC/ATSDR received one non-substantive comment requiring no agency response (see https://www.regulations.gov/comment/CDC-2022-0109-0002).

B. The data collection surveys were designed collaboratively by CDC personnel. Consultation will continue throughout the implementation process. There were no external consultations.

*TRACEABLE OPIOID MATERIAL, TOM KITS, and the TOM KITS logo are marks of the U.S. Department of Health and Human Services

Name	Title	Affiliation	Phone	Email
Rebekah Wharton, PhD	Senior Service Fellow	Emergency Response Branch	*(770) 488-7630*	flo2@cdc.gov
Rudolph, Johnson, PhD	Supervisory Research Chemist	Emergency Response Branch	*(770) 488-3543*	rmj6@cdc.gov
Mike Mojica, PhD	Associate Service Fellow	Emergency Response Branch	*(404) 498-1404*	lta4@CDC.gov
Samantha Isenberg, PhD	Associate Service Fellow	Emergency Response Branch	*(770) 488-3435*	yhx1@cdc.gov
Melissa Carter, PhD, MBA	(Former) Senior Service Fellow	n/a	*n/a*	n/a

A.9. Explanation of Any Payment or Gift to Respondents

Respondents will not receive payments for providing information. Selected recipient laboratories will receive the TOM Kits* at no cost as described in **Section A.2**.

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

On 12/02/2022, the CDC Chief Privacy Officer has reviewed this submission and determined that the Privacy Act does not apply (**Attachment 6**).

The following Information in Identifiable Form (IIF) Categories apply to the information collection from domestic laboratories (**Attachment 5a**): however, records will not be retrieved by these identifiers.

❑ Name (Business Contact)
❑ Email Address (Business Contact)
❑ Phone Numbers (Business Contact)

The records generated from this collection will be for research support and will be disposed of after their administrative usefulness has been met or no longer than 5 years after project completion, depending on the program need.

*TRACEABLE OPIOID MATERIAL, TOM KITS, and the TOM KITS logo are marks of the U.S. Department of Health and Human Services

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

The NCEH/ATSDR Human Subjects Advisor has determined that this information collection is not research involving human subjects and that IRB approval is not required (**Attachment 7**).

CDC collects information about laboratories and does not collect personally sensitive information. Laboratories may view information collections pertaining to Drug Enforcement Agency (DEA) Numbers, organizational policies, performance data, or other practices as sensitive; however, the information that CDC is requesting is not anticipated to result in liability or competitive disadvantage if a breach should occur.

A.12. Estimates of Annualized Burden Hours and Costs

The following domestic burden hours and number of annualized responses were estimated from CDC's experience since 2019. CDC is now distributing its domestic product line through a single vendor. We anticipate that the annual number of domestic respondents will be 600 applicants (or 200 per sector). With the average time per response at 6 minutes, this will yield an estimated annual burden of 20 hours per sector and a total of 60 hours for all domestic laboratories to apply for test kits.

The following international burden hours and number of annualized responses were estimated as follows. The international respondents will apply for test kits on UN servers and will be directed to respond to additional test kit questions on the CDC vendor website. Given that there are 300 international partner laboratories, we assume that it will take 4 minutes per response for a time burden of 20 hours per year.

The annualized time burden requested is 80 hours.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
US Federal Laboratories	Test Kit Application and Questions for US Laboratories (online)	200	1	6/60	20
State, Local, and Tribal Government Laboratories	Test Kit Application and Questions for US Laboratories (online)	200	1	6/60	20

*TRACEABLE OPIOID MATERIAL, TOM KITS, and the TOM KITS logo are marks of the U.S. Department of Health and Human Services

Private or Not-for-Profit US Institutions	Test Kit Application and Questions for US Laboratories (online)	200	1	6/60	20
International Laboratories	Test Kit Questions for International Laboratories	300	1	4/60	20
Total					80

Estimates of the annualized cost to domestic respondents were based on the Department of Labor "May 2021 National Occupational Employment and Wage Estimates, United States" mean hourly wages. (https://www.bls.gov/oes/current/oes_nat.htm#00-0000).

NCEH used the following occupation codes and hourly wage estimates to represent each domestic respondent type in the burden table. Absent information on international wages, we assume the same hourly wage will apply to the international laboratory respondent staff.

Mean Hourly Wages for Domestic Respondent Types

Respondent Type	Occupation Code	Occupation Title	Mean Hourly Wage
Laboratorians and laboratory directors	19-0000	Life, Physical, and Social Science Occupations	$38.81

Estimated Annualized Burden Costs

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
US Federal Laboratories	Test Kit Application and Questions for US Laboratories (online)	200	1	6/60	20	$38.81	$776.20
State, Local, and Tribal Government Laboratories	Test Kit Application and Questions for US Laboratories (online)	200	1	6/60	20	$38.81	$776.20
Private or Not-for-Profit US	Test Kit Application and	200	1	6/60	20	$38.81	$776.20

*TRACEABLE OPIOID MATERIAL, TOM KITS, and the TOM KITS logo are marks of the U.S. Department of Health and Human Services

Institutions	Questions for US Laboratories (online)						
International Laboratories	Test Kit Questions for International Laboratories	300	1	4/60	20	$38.81	$776.20
Total							$3,104.80

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

The information system is designed to use existing hardware within vendor and applicant sites. No capital or maintenance costs are expected. Additionally, there are no start-up, hardware, or software costs.

A.14. Annualized Cost to the Federal Government

Average annualized cost is $5,000,000 or less. This estimate was based on the following table:

Staff	GS Level	Salary (2022)	% FTE	$ Cost
Project Officer, Senior Service Fellow	13	$106,234	10%	$10,623.40
Salary Sub-total				$10,623.40
Other Annualized Costs				$ Cost
Travel				$20,000.00
Contracts				
Procurement of Traceable Opioid Material* Kit Materials and Recipient Laboratory Support, 75D301-19-D-06777				$4,700,000.00
Total				$4,737,736.60

A.15. Explanation for Program Changes or Adjustments

As part of this revision, CDC is changing the title of this ICR from "Distribution of Traceable Opioid Material* Kits (TOM Kits*) across U.S. Laboratories" to "Distribution of Traceable Opioid Material* Kits (TOM Kits*) across U.S. *and International* Laboratories." The title change is necessary due to the expansion of test kit distribution to international customers. Additional revisions include the following:

*TRACEABLE OPIOID MATERIAL, TOM KITS, and the TOM KITS logo are marks of the U.S. Department of Health and Human Services

- CDC is adding their new line of TOM Kits*, Emergent Drug Panel (EDP) Kits, for distribution. The EDP compounds are identified by doing a search of recent lists put out by the DEA and the Center for Forensic Science Research and Education (CFSRE). These lists provide data on all classes of drugs that were recently identified in the field and provide recommendations on which drugs should be included in testing. These classes of drugs may be found mixed with opioids and contribute to the opioid epidemic. These lists are updated several times a year and keep up with the changing drug landscape in the United States.
- CDC will continue to distribute TOM Kits*, including the new EDP Kits, through a single vendor instead of two.

  To adjust for this program expansion, for domestic laboratories, CDC is modifying **Attachment 5a** (Test Kit Application and Questions for US Laboratories [screenshots/Word], formerly **Attachment 7**).

Attachment 5a. *Online application fields for US laboratories (Modifications shown in RED text.)*		
Approved 2020	Proposed 2022	Requested Change in 2022
First Name	First Name	No change to text
Last Name	Last Name	
Institution	Institution	
Lab Name (optional)	Lab Name (optional)	
Street Address Line 1	Street Address Line 1	
Street Address Line 2	Street Address Line 2	
City	City	
State	State	
Zip Code	Zip Code	
County	[DELETED]	Redundant with address
Email	Email	No change to text
Verify Email	Verify Email	
Telephone	Telephone	
Quantity Requested	[DELETED]	Move question after asking for test kit type(s) requested.
Does your laboratory have a current DEA registration to handle scheduled substances? ❑ Yes ❑ No	Does your laboratory have a current DEA registration to handle scheduled substances? ❑ Yes ❑ No	No change to text
	1. Which test kit(s) are you requesting/have you previously received? *(provide quantity requested)* Fentanyl Analog Screening (FAS) Quantity [___] FAS Version 1 Quantity [___]	Adjusting online application to expanded list of TOM Kits

*TRACEABLE OPIOID MATERIAL, TOM KITS, and the TOM KITS logo are marks of the U.S. Department of Health and Human Services

	FAS Version 2 and 3 Quantity [___] FAS Version 4 Quantity [___] Emergent Drug Panel (EDP) Quantity [___]	
Modifications to TOM Kit Questions due to expanding to several types of Opioid Kits and addition of new Emergent Drug Panel (EDP) types*		
TOM Kit Questions (formerly Attachment 7)* Approved 2020	*Test Kit Questions (renamed; now Attachment 5a)* Proposed 2022	Requested Change in 2022
1. Which of the following best describes your laboratory? *(Select only one)* ❑ Academic Research Laboratory ❑ Environmental Laboratory ❑ Government Crime Laboratory ❑ Government Toxicology Laboratory ❑ Private of Public Clinical Laboratory ❑ Other *(please specify)* - _____	2. Which of the following best describes your laboratory? *(Select only one)* ❑ Academic Research Laboratory ❑ Environmental Laboratory ❑ Government Crime Laboratory ❑ Government Toxicology Laboratory ❑ Private or Public Clinical Laboratory ❑ Other *(please specify)* - _____	Renumber as 2. Correct typo from "of" to "or"
2. Which of the following tests or services are performed by your laboratory? *(Select all that apply)* ❑ Seized drug sample testing ❑ Post-mortem toxicology sample testing ❑ Workplace drug screening ❑ Newborn drug screening ❑ Drug pharmacology and pharmacokinetics research ❑ Clinical testing for disease diagnosis and treatment or surveillance ❑ Other	3. Which of the following tests or services are performed by your laboratory? *(Select all that apply)* ❑ Seized drug sample testing ❑ Post-mortem toxicology sample testing ❑ Workplace drug screening ❑ Newborn drug screening ❑ Drug pharmacology and pharmacokinetics research ❑ Clinical testing for disease diagnosis and treatment or surveillance ❑ Other	Renumber as 3
	4. Which of the following drug categories does your laboratory test for? (*Select all that apply*) q Opioids q Synthetic Cannabinoids q Stimulants and Hallucinogens q Benzodiazepines	Add new question 4; TOM Kits* includes a variety of opioids, of which FAS Kits are a subtype. The other three categories are part of the EDP Kits.

3. On average, how many opioid-related samples does your laboratory analyze on a weekly basis? ❑ <100 ❑ 101-500 ❑ 501-1000 ❑ >1000	5. On average, how many opioid, synthetic cannabinoid, stimulant, hallucinogen, or benzodiazepine-related samples does your laboratory analyze on a weekly basis? q <100 q 100-500 q 501-1000 q >1000	Renumber as 5; specify new Emergent Drug Panel (EDP) types; correct typo from "101" to "100"
4. Which of the following analytical techniques do you perform in your laboratory? *(Select all that apply)* ❑ Immunoassay ❑ Infrared Spectroscopy ❑ Mass Spectrometry ❑ Nuclear Magnetic Resonance Spectroscopy ❑ Raman Spectroscopy ❑ X-ray Diffraction Chromatographic Separation ❑ UV/Vis ❑ Other *(please specify)* - _____	6. Which of the following analytical techniques do you perform in your laboratory? *(Select all that apply)* ❑ Immunoassay ❑ Infrared Spectroscopy ❑ Mass Spectrometry Nuclear Magnetic Resonance Spectroscopy ❑ Raman Spectroscopy ❑ X-ray Diffraction Chromatographic Separation ❑ UV/Vis ❑ Other *(please specify)* - _____	Renumber as 6; no change to text
5. Which matrix type does your laboratory analyze? *(Select all that apply)* ❑ Blood ❑ Urine ❑ Other (please specify) - _____	7. Which sample matrices does your laboratory analyze? *(Select all that apply)* ❑ Blood ❑ Urine ❑ Drug Powders ❑ Waste Water ❑ Other (*please specify*) - _____	Renumber as 7; modify "matrix type" to "sample matrices;" add two additional types of sample matrices
6. What sample sizes are being tested? *(Select all that apply)* ❑ <0.1 mL ❑ 0.1- 0.5 mL ❑ >0.5 mL ❑ Other (please specify) - _____	[DELETED]	Eliminate question
*TRACEABLE OPIOID MATERIAL, TOM KITS, and the TOM KITS logo are marks of the U.S. Department of Health and Human Services.		

- CDC is expanding the distribution of these test kits to international laboratories through a partnership with the UN. The CDC vendor will bulk ship test kits to UN for international

*TRACEABLE OPIOID MATERIAL, TOM KITS, and the TOM KITS logo are marks of the U.S. Department of Health and Human Services

distribution, or the vendor may direct ship these kits to select international laboratories upon UN request.

Based on this change, we are adding **Attachment 5b** (Test Kit Questions for International Laboratories [screenshots/Word]) and a new row in the burden table (Section A12). These reports will contain similar laboratory information as on the domestic application (**Attachment 5a**). On behalf of the UN, the vendor, but not CDC, will collect application PII on international laboratories. International laboratories may receive the same test kits as domestic laboratories, except for the EDP kits.

Burden Estimations

The following changes to burden hours and the number of annualized responses are as follows.

- We estimate a total time burden of 80 hours, which is a decrease of 40 hours over the previously approved 120 hours. We estimate a total number of 900 annual responses which is a decrease of 300 over the previously approved 1,200 responses.
    - Changes to the burden for domestic laboratories are as follows, based on CDC's experience since 2019:
        - The annual number of responses are 600, with 200 responses from each of the three sectors (academic, public, or private). This is a decrease of 600 applicants over the previously approved 1,200.
        - The annual time burden will be 60 hours, which is a decrease of 60 hours over the previously approved 120 hours.
    - With the expansion to international distribution of test kits, the following changes have been made.
        - A new row in the time and cost burden tables have been added (**Section A12**).
        - We assume that 300 international partner laboratories will request test kits.
        - Each international laboratory will take 4 minutes to complete this information on the CDC vendor website (20 hours for 300 laboratories per year).

A.16. Plans for Tabulation and Publication and Project Time Schedule

Information collected will be used to prioritize requests received by the CDC. If this prioritization is discussed within a manuscript describing kit distribution, then it may be published with other data.

Table A.16.1

Project Time Schedule	
Activity	Time Schedule
Collection continues with PRA clearance	Beginning January 2023
Analyses	As needed
Publication	TBD if applicable

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

The display of the OMB expiration date is appropriate.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

References

U.S. Drug Enforcement Agency (DEA). 2016-2021. DEA Emerging Threat Reports. (CESAR) Center for Substance Abuse Research. University of Maryland. (Accessed 07/14/2022 at https://cesar.umd.edu/publications/dea-emerging-threat-reports#:~:text=DEA%20Emerging%20Threat%20Reports%20The%20Drug%20Enforcement%20Administration%27s,analyzed%20by%20the%20Drug%20Enforcement%20Administration%E2%80%99s%20laboratory%20system.)

U.S. Drug Enforcement Agency (DEA). 2021. 2020 National Drug Threat Assessment (NDTA). (Accessed 07/14/2022 at https://www.dea.gov/sites/default/files/2021-02/DIR-008-21%202020%20National%20Drug%20Threat%20Assessment_WEB.pdf)

U.S. Government Accountability Office (GAO). 2018. Opioid Crisis: Status of Public Health Emergency Authorities (GAO-18-685R). 2018. (Accessed 07/14/2022 at https://www.gao.gov/assets/gao-18-685r.pdf)

Hargan ED. 2017. HHS Acting Secretary Declares Public Health Emergency to Address National Opioid Crisis. (Accessed 07/14/2022 at https://public3.pagefreezer.com/browse/HHS.gov/31-12-2020T08:51/https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html and at https://public3.pagefreezer.com/browse/HHS.gov/31-12-2020T08:51/https://www.hhs.gov/sites/default/files/opioid%20PHE%20Declaration-no-sig.pdf).

Hedegaard H, Miniño AM, Spencer MR, Warner M. Drug overdose deaths in the United States, 1999–2020. NCHS Data Brief, no 428. Hyattsville, MD: National Center for Health Statistics. 2021. DOI: https://dx.doi.org/10.15620/cdc:112340. (Accessed 07/14/2022 at https://www.cdc.gov/nchs/products/databriefs/db428.htm)

Traceable Opioid Material® Kits to Improve Laboratory Detection of Synthetic Opioids in the U.S. https://www.cdc.gov/nceh/dls/erb_opioid_kits.html

https://www.cdc.gov/nceh/dls/pdf/Opiod_Factsheet-508.pdf

https://www.caymanchem.com/forensics/faskit/?q=*%3A*