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
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Revision

Supporting Statement Part B –

Collections of Information Employing Statistical Methods

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Part B. Collections of Information Employing Statistical Methods

B.1. Respondent Universe and Sampling Methods

Respondent laboratories 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 DEA registration, must comply with respective state and local regulations, and must submit requests directly to the vendor (**Attachment 3**).

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.

Over the next three years, CDC will distribute an expanded array of TOM kits* through a single vendor (**Attachment 3**).[1] The kits are all manufactured by Cayman Chemical [2]

- 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

[1] Fentanyl Analog Screening Kit (FAS Kit) and Emergent Panels | CDC

[2] 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

- Stimulants and Hallucinogens
- Benzodiazepines
    - Includes 200 micrograms of each analytical reference material
    - 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

No statistical methods or sampling is necessary. The respondent laboratories will be a convenience sample of those interested in receiving the TOM Kits* at no cost from the CDC.

B.2. Procedures for the Collection of Information

Information collection will be performed on the TOM Kits* manufacturer's website (**Attachments 3, 5a, and 5b**). To receive TOM Kits*, the requestor must provide answers to the vendor survey (**Attachments 5a or 5b**). Questions on the survey involve the volume of samples processed by the requesting lab and other questions involving how many lab samples, including those provided by the TOM Kit*, will be prepared and analyzed. The attributes of the lab and the analysis method of the TOM Kits* may change; therefore, future requests will require filling the survey out again to ensure the most up-to-date information is used to prioritize kit distribution.

This information collection form is 100% electronic. There is no special software that will be used and the survey uses common internet interfaces to fill out, thereby minimizing any training time and cost to fill out the form. Upon completion, a submission button is used to submit electronically and instantaneously.

B.3. Methods to Maximize Response Rates and Deal with No Response

To receive any TOM Kit* or EDP Kit, the requestor must provide answers to the survey. Therefore, response rates will be 100 percent.

B.4. Test of Procedures or Methods to be Undertaken

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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**).

B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The individuals working on this information collection, including development, data collection, and data analysis are members of the CDC Emergency Response Branch (in the CDC National Center for Environmental Health – Division of Laboratory Sciences).

Table 1. Personnel Responsible for Collection and Analysis of Information

Name	Title	Affiliation	Phone	Email
Rebekah Wharton, PhD	Senior Service Fellow	CDC	*(770) 488-7630*	Flo2@cdc.gov

References

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*

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