

TIP No. 98-134-0322

OCONUS Disposal Guidance for Ellume OTC COVID-19 Home Test Kit Used for Screening Unvaccinated Personnel Returning to the Workplace

1. DESCRIPTION

The following addresses recommendations for disposal when the over-the-counter (OTC) Ellume Coronavirus Disease 2019 (COVID-19) Home Test self-test kit is used for conducting screening of unvaccinated personnel on outside the continental U.S. (OCONUS) Army installations when they return to the workplace, either at medical treatment facilities (MTF)/medical research facilities, or at other formal workplace locations (e.g., administrative buildings). All OCONUS facilities will need to consult with their host installation Directorate of Public Works (DPW) Environmental Division and/or local environmental health or infection control office for additional information and local guidance pertaining to their host countries.

The U.S. Food and Drug Administration authorized kits to be utilized for testing asymptomatic non-vaccinated personnel are non-prescription OTC self-test kits, not clinical diagnostic tests. If personnel being tested have any of the common COVID-19 symptoms, they should not be tested and not allowed access to the facility. When used by personnel at home, the kits should be disposed of per disposal guidance from their installation DPW Environmental Division (if they live on the installation), host nation, regional or local regulators, or their solid waste trash hauler. This guidance will be important due to the battery and electronic waste generated by the Ellume Home Test kit.

Note that the MTF is only responsible for this non-clinical screening of their own unvaccinated staff. It is the responsibility of each unit/activity, who conducts the screening tests of their unvaccinated personnel, to dispose of their own waste properly unless otherwise coordinated with another entity.

Disposal recommendations are summarized and grouped by country at the end of the document in Table 1 (for the countries of Germany and Italy) and Table 2 (for the countries of Japan and the Republic of Korea (ROK)).

2. ELLUME HOME TEST KIT DISPOSAL CONSIDERATIONS

a. Disposal Guidance: All equipment and waste should be discarded according to applicable Host Nation Final Governing Standards (FGS), Military Service Regulations, and local laws and policies. Where those policies differ from the guidance provided below, the more stringent requirements will be followed. Consult with your local environmental health or infection control office for additional information and local guidance.

b. Hazardous Waste (HW) Consideration: Prior to disposal of any waste, determine whether any of the components are considered an HW per the applicable Host Nation FGS. The Ellume Home Test kit has been evaluated against FGS regulations in Germany, Italy, Japan, and ROK.

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The mention of any non-federal entity and/or its products is not to be construed or interpreted, in any manner, as federal endorsement of that non-federal entity or its products.

c. Specific Ellume COVID-19 Home Test Kit HW Evaluations:

- Processing Fluid. Based on safety data sheet (SDS) information currently available for the processing fluid, only one of the components requires an SDS – ProClin®300. The processing fluid containing ProClin300 does not meet OCONUS HW criteria for any of the four countries evaluated (Germany, Italy, Japan, and ROK). The vial and its contents (unused/full, partially full, or empty) can be disposed as trash/solid waste.
- Analyzer Battery. The Analyzer used in the test kit contains a removable lithium “button” battery.
 - Germany and Italy: Both the Germany and Italy FGSs indicate lithium batteries will be managed as HW/hazardous batteries for turn-in for proper disposal and should not be disposed of in regular trash.
 - Japan and ROK: The Japan and ROK FGSs indicate that lithium batteries should be recycled when possible to recover the heavy metal (lithium) and address the reactivity characteristic prior to disposal; if not, they require HW management for reactivity.
- Analyzer (with the battery removed).
 - Germany and Italy: The sample Analyzer without the battery meets the definition in the Germany and Italy FGSs as “electronic waste” (i.e., waste that is considered bulky waste or household waste powered by electricity and/or batteries and contains electronic components (e.g., wires, circuit boards, switches, conductors)). This is due to its ability to detect fluorescence signals and transmit results via Bluetooth technology to a smartphone app. NOTE: per the European List of Wastes, the Analyzer (with the battery removed) does not meet requirements for hazardous electronic waste, but the user should confirm proper management with the HW manager or host installation’s DPW Environmental Division.
 - Japan and ROK: The Japan and ROK FGSs do not address waste management of these electronic devices. Contact the host DPW Environmental Division for guidance. Manage the Analyzer (with the battery removed) in the same manner as other small electronic devices.

d. Packaging, Wrapping, Empty Containers, and Package Inserts: For all four locations evaluated (Germany, Italy, Japan, and ROK), any empty packaging or wrapping (i.e., wrapping of the home test kit components (e.g., the nasal swab with child adaptor, processing fluid, and the dropper)), shipping/box container, and package inserts (i.e., containing information such as instructions for use or fact sheets), can be disposed of as regular trash or paper and cardboard may be recycled, if possible. Empty (or partial)

containers of the processing fluid can also be disposed of as solid waste, as they do not come in contact with the sample specimen and as noted above are not an HW.

3. ELLUME HOME TEST KIT ADMINISTERED IN AN MTF/MEDICAL RESEARCH FACILITY

Personally Identifiable Information (PII). If present, remove/blacken out any PII on the test kit materials prior to disposal.

Used Nasal Swab connected to the Dropper (Germany, Italy, Japan, and ROK). This used testing material will contain residual sample specimen and processing fluid; this material should be managed per the MTF's/Medical Research Facility's procedures and policies as though they could transmit disease and be disposed of as regulated medical waste (RMW). This guidance is recommended due to—

- The perception of where the waste is being generated (in an MTF/Medical Research Facility);
- The facility's ready access to RMW disposal;
- Healthcare professionals licensing requirements; and
- The manufacturer's product overview for healthcare professionals to "treat specimens and patient samples as well as used test kit components as potentially biohazardous materials."

Used Analyzer (with the battery removed). The 5 drops of specimen/processing fluid absorbed by the analyzer are not classified as infectious body fluids, will not drip or readily transmit disease, and will not be released during normal handling. Therefore, the waste may be collected for recycling or disposal. Note: allowing the used Analyzer to sit for 3 days in accumulation for recycling will allow all liquid components to dry, eliminating any exposure concerns related to disassembly of the devices.

- Germany and Italy: The Analyzer meets the definition of electronic waste. The Analyzer should be recycled with other electronic waste as identified in the European List of Wastes or as required by local Municipal authorities, which includes discarded electrical and electronic equipment. NOTE: per the European List of Wastes, the Analyzer (with the battery removed) does not meet requirements for hazardous electronic waste, but the user should confirm proper management with the HW manager or host installation's DPW Environmental Division.
- Japan and ROK: The Analyzer should be managed in the same manner as other small electronic waste following directions from the host installation's DPW Environmental Division.

Analyzer Battery (Germany, Italy, Japan, and ROK). Prior to disposal of the Analyzer, remove the battery following the manufacturer's instructions and dispose per the Installation DPW Environmental Division requirements for lithium battery waste.

Handling precautions may include enclosing each battery in a separate plastic bag or placing non-conductive tape (e.g., electrical tape) over each end of the battery prior to turn-in so the terminals will not come in contact with other batteries or metal during storage or transport, which could cause the batteries to short circuit, explode, and cause a fire.

4. ELLUME HOME TEST KIT ADMINISTERED IN OTHER FORMAL WORKPLACES

a. Installation Medical Waste Scope: Medical waste management on military installations in Germany, Italy, Japan, and ROK applies to wastes at medical, dental, research and development, and veterinary facilities generated in the diagnosis, treatment, or immunization of human beings or animals or in the production or testing of biologicals subject to certain exclusions. It does not apply to what would otherwise be household waste.

b. Municipal Solid Waste: Regulations for installations in Germany, Italy, Japan, and ROK provide citations that allow disposal of commercial/office generated wastes as municipal solid waste (household waste) given that an HW evaluation is conducted prior to disposal and the wastes are not hazardous per the applicable FGS HW regulations. If your location is in another host nation, a similar solid waste/HW evaluation must be conducted.

c. Managing Used Ellume Test Kit Materials:

Personally Identifiable Information (PII). If present, remove/blacken out any PII on the test kit materials prior to disposal.

Used Nasal Swab connected to the Dropper (Germany, Italy, Japan, and ROK). This used testing material will contain residual sample specimen and processing fluid; this material should be managed per the manufacturer's instructions for home use and disposed of in the facility's regular trash, unless prohibited by the host installation or their solid waste trash hauler. The wastes should be enclosed in a non-transparent bag or container prior to disposal in the facility trash. This additional "bagging" guidance is recommended due to—

- Potential negative perception issues of the waste when picked up by housekeeping/janitorial personnel (e.g., appearance of swab connected to the dropper as an indication that a test was conducted), and
- The perceived safety of the housekeeping/janitorial staff when transporting the trash in the facility.

Used Analyzer (with the battery removed). The Analyzer will also have been in contact with the sample specimen (i.e., will contain 5 drops of the sample specimen/processing fluid mixture). However, generation of waste in an office setting is approved as commercial municipal solid waste and does not fall under the scope of RMW generation on an installation at an MTF. The 5 drops of specimen/processing fluid absorbed by the analyzer

are not classified as infectious body fluids, will not drip or readily transmit disease, and will not be released during normal handling. Note: allowing the used Analyzer to sit for 3 days in accumulation for recycling will allow all liquid components to dry, eliminating any exposure concerns related to disassembly of the devices.

- Germany and Italy. The Analyzer should be recycled with other electronic waste as identified in the European List of Wastes or as required by local Municipal authorities, which includes discarded electrical and electronic equipment. NOTE: per the European List of Wastes, the Analyzer (with the battery removed) does not meet requirements for hazardous electronic waste, but the user should confirm proper management with the HW manager or host installation's DPW Environmental Division.
- Japan and ROK. The Analyzer should be managed in the same manner as other small electronic waste following directions from the host installation's DPW Environmental Division.

Analyzer Battery (Germany, Italy, Japan, and ROK). Prior to disposal of the Analyzer, remove the battery following the manufacturer's instructions and dispose per the Installation DPW Environmental Division requirements for lithium battery waste. Handling precautions may include enclosing each battery in a separate plastic bag or placing non-conductive tape (e.g., electrical tape) over each end of the battery prior to turn-in so the terminals will not come in contact with other batteries or metal during storage or transport, which could cause the batteries to short circuit, explode, and cause a fire.

5. QUESTIONS

Please contact the Environmental Health Sciences Division, Waste Management Branch, at 410-436-3651 or DSN 584-3651 for additional guidance.

Table 1. Germany and Italy Only - OCONUS Ellume COVID-19 Home Test Kit Waste Disposal Summary

Location(s)	Kit Component/ Waste Stream	Disposal Guidance	Background
<ul style="list-style-type: none"> • Medical Treatment Facility • Research Facility 	Packaging (wrappers, paper packaging, cardboard)	Solid Waste/Recycling	<p>These items do not come into contact with sample specimens or processing fluid.</p> <p>See Paragraph 2d for detailed discussion.</p>
	<u>Used Nasal Swab connected to the Dropper</u> (i.e., <u>used testing materials that came in contact with the sample specimen</u>)	Regulated Medical Waste Manufacturer’s statement: “Treat specimens and patient samples as well as used test kit components as potentially biohazardous materials.”	See Paragraph 3 for detailed discussion.
	Analyzer Battery (Lithium “button” battery removed from Analyzer)	Hazardous Waste/Hazardous Battery Waste	See Paragraphs 2c and 3 for detailed discussion.
	<u>Used Analyzer</u> (battery removed)	Recycled with other electronic waste.	See Paragraphs 2c and 3 for detailed discussion.
	<u>Unused Processing Fluid</u> in vial (expired, defective, or cracked prior to use; or partial if any remains after use)	Solid Waste	<p>None of the chemicals meets FGS HW requirements in countries of Germany and Italy.</p> <p>See Paragraph 2c for detailed discussion.</p>

Location(s)	Kit Component/ Waste Stream	Disposal Guidance	Background
<ul style="list-style-type: none"> • Office Setting • Mission/Troop Locations – non-medical 	Packaging (wrapper, paper packaging, cardboard)	Solid Waste/Recycling	<p>These items do not come into contact with sample specimens or processing fluid.</p> <p>See Paragraph 2d for detailed discussion.</p>
	<u>Used Nasal Swab connected to the Dropper (i.e., used testing materials that came in contact with the sample specimen)</u>	<p>Solid Waste</p> <p>Enclose wastes in a non-transparent bag or container prior to disposal to avoid perception issues.</p>	<p>Generation of waste in an office setting is approved as commercial municipal solid waste and does not fall under the scope of RMW generation on an installation.</p> <p>See Paragraph 4c for detailed discussion.</p>
	Analyzer Battery (Lithium “button” battery removed from Analyzer)	Hazardous Waste/Hazardous Battery Waste	See Paragraphs 2c and 4c for detailed discussion.
	<u>Used Analyzer</u> (battery removed)	Recycled with other electronic waste.	See Paragraphs 2c and 4c for detailed discussion.
	<u>Unused Processing Fluid</u> in vial (expired, defective or cracked prior to use; or partial if any remains after use)	Solid Waste	<p>None of the chemicals meets FGS HW requirements in countries of Germany and Italy.</p> <p>See Paragraph 2c for detailed discussion.</p>

Table 2. Japan and Republic of Korea Only - OCONUS Ellume COVID-19 Home Test Kit Waste Disposal Summary

Location(s)	Kit Component/ Waste Stream	Disposal Guidance	Background
<ul style="list-style-type: none"> • Medical Treatment Facility • Research Facility 	Packaging (wrappers, paper packaging, cardboard)	Solid Waste/Recycling	<p>These items do not come into contact with sample specimens or processing fluid.</p> <p>See Paragraph 2d for detailed discussion.</p>
	<u>Used Nasal Swab connected to the Dropper</u> (i.e., <u>used testing materials that came in contact with the sample specimen</u>)	Regulated Medical Waste Manufacturer’s statement: “Treat specimens and patient samples as well as used test kit components as potentially biohazardous materials.”	See Paragraph 3 for detailed discussion.
	Analyzer Battery (Lithium “button” battery removed from Analyzer)	Turn-in for recycling or treatment.	See Paragraphs 2c and 3 for detailed discussion.
	<u>Used Analyzer</u> (battery removed)	Manage same as other small electronic waste per host installation DPW Environmental Division guidance.	See Paragraphs 2c and 3 for detailed discussion.
	<u>Unused Processing Fluid</u> in vial (expired, defective or cracked prior to use; or partial if any remains after use)	Solid Waste	<p>None of the chemicals meets FGS HW requirements in countries of Germany and Italy.</p> <p>See Paragraph 2c for detailed discussion.</p>

Location(s)	Kit Component/ Waste Stream	Disposal Guidance	Background
<ul style="list-style-type: none"> • Office Setting • Mission/Troop Locations – non-medical 	Packaging (wrapper, paper packaging, cardboard)	Solid Waste/Recycling	<p>These items do not come into contact with sample specimens or processing fluid.</p> <p>See Paragraph 2d for detailed discussion.</p>
	<u>Used Nasal Swab connected to the Dropper (i.e., used testing materials that came in contact with the sample specimen)</u>	<p>Solid Waste</p> <p>Enclose wastes in a non-transparent bag or container prior to disposal to avoid perception issues.</p>	<p>Generation of waste in an office setting is approved as commercial municipal solid waste and does not fall under the scope of RMW generation on an installation.</p> <p>See Paragraph 4c for detailed discussion.</p>
	Analyzer Battery (Lithium “button” battery removed from Analyzer)	Turn-in for recycling or treatment.	See Paragraphs 2c and 4c for detailed discussion.
	<u>Used Analyzer</u> (battery removed)	Manage same as other small electronic waste per host installation DPW Environmental Division guidance.	See Paragraphs 2c and 4c for detailed discussion.
	<u>Unused Processing Fluid</u> in vial, (expired, defective or cracked prior to use; or partial if any remains after use)	Solid Waste	<p>None of the chemicals meets FGS HW requirements in countries of Germany and Italy.</p> <p>See Paragraph 2c for detailed discussion.</p>