

TIP No. 98-133-1221

OCONUS Disposal Guidance for OTC COVID-19 Self-Test Kits Used for Screening Unvaccinated Personnel Returning to the Workplace

1. DESCRIPTION

The following addresses recommendations for disposal when over-the-counter (OTC) self-test kits are used for conducting screening of non-vaccinated 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 environmental office 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 Coronavirus Disease 2019 (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 in the regular trash per manufacturers' directions (assuming there are no prohibitions on disposal from their host nation, regional, local regulators, or their solid waste trash hauler). 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 Korea).

2. ALL SELF-TEST KITS

a. Disposal Guidance: All equipment and waste should be discarded according to applicable Host Nation, 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, determine if any of the components of the self-test kit are considered a HW per the applicable Host Nation (FGS) regulations. The three OTC self-test kits listed in Fragmentary Order (FRAGO) 10 to Headquarters, Department of the Army Executive Order (EXORD) 225-21, *COVID-19 Steady State Operation, ANNEX TTT General Instructions for all Screening Tests of Unvaccinated Personnel* (QuickVue® At-Home OTC COVID-19 Test, Orasure IntelliSwab™ COVID-19 Rapid Test, and Abbott BinaxNOW™ COVID-19 Antigen Self-Test), have been evaluated against regulations in the following nations: Germany, Italy, Japan, and Korea.

Approved for public release; distribution unlimited

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 Test Kit HW Evaluations:

- Two of the three OTC self-test kits (QuickVue and Orasure), listed in FRAGO 10 to HQDA EXORD 225-21, have been evaluated to not have HW components in Germany, Italy, Japan, and Korea (used and unused kit contents).
- The Abbott BinaxNOW COVID-19 Antigen Self-Test contains 0.0125% sodium azide (CAS 26628-22-8) as a preservative in the test reagent solution. Sodium azide is included on the Germany and Italy FGS lists for acute HW and no provision for percent content or sole active ingredient exemption exists. Therefore, the test reagent solution in the Abbott BinaxNOW dropper bottle must be managed as a HW in Germany and Italy (includes new/unused bottle or partially used bottle with reagent remaining inside). Note that the reagent bottle delivers drops of reagent to the test card but never contacts the patient specimen/sample.
- The FGS in Japan and Korea do include a requirement for the constituent of concern to be the sole active ingredient. The 0.0125% sodium azide is used as a preservative and is not the sole active ingredient in the Abbott BinaxNOW reagent solution. Therefore, the Abbott BinaxNOW COVID-19 Antigen Self-Test reagent is not a HW in Japan and Korea (used or unused).

d. Unspecified Test Kit HW Evaluations: If a self-test kit other than the three listed above is utilized, the facility conducting the testing will need to make a HW determination. Any wastes determined to be a HW will need to be managed and turned-in for disposal as such based on their HW management procedures. Consult with your facility's HW manager or host installation's environmental office for assistance with the HW determination.

e. Packaging, Wrapping, Empty Containers, and Package Inserts: Any empty packaging or wrapping (e.g., wrapping of self-test kit components, such as swabs, test cards, plastic vials, test strips), 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 containers of test reagent (dropper bottles/vials/cuvettes) can also be disposed of as solid waste.

3. SELF-TEST KITS ADMINISTERED IN AN MTF/MEDICAL RESEARCH FACILITY

Used testing materials that came in contact with the sample specimen (e.g., used swabs/test devices, used test cards, used test strips, used sample vials containing reagent) should be managed per the MTFs/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;

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- Labeling information on the used test material (e.g., the word “COVID” usually appears, as well as an indication of positive or negative test results);
- Healthcare professionals licensing requirements; and
- The manufacturer’s recommendations for when healthcare professionals conduct the test instead of personnel performing the testing at home.

If any Personally Identifiable Information (PII) is on the test kit material, it should be removed/blackened out prior to disposal.

Note: Only partially used and unused reagent solution bottles provided in the Abbott BinaxNOW Self-Test Kits that contain reagent must be managed as HW in Germany and Italy only, as described in Paragraph 2. The Abbott reagent does not come in contact with the patient sample specimen.

4. SELF-TEST KITS ADMINISTERED IN OTHER FORMAL WORKPLACES

a. Installation Medical Waste Scope: Medical waste management on military installations in Germany, Italy, Japan and Korea 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 Korea provide citations that allow disposal of commercial/office generated wastes as municipal solid waste (household waste) given that a 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 consideration must be conducted.

c. Managing Used Test Kit Materials: Used testing materials that came in contact with the sample specimen (e.g., used swabs/test devices, used test cards, used test strips, used sample vials containing reagent) 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., labeling information such as the appearance of the word “COVID” or an indication of positive or negative test results on the used test material); and
- The perceived safety of the housekeeping/janitorial staff when transporting the trash in the facility.

If any PII is on the test kit material, it should be removed/blackened out prior to disposal.

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Note: Only partially used and unused reagent solution bottles provided in the Abbott BinaxNOW Self-Test Kits that contain reagent must be managed as HW in Germany and Italy only, as described in Paragraph 2. The Abbott BinaxNOW reagent does not come in contact with the patient sample specimen.

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 COVID Self-Test Waste Disposal Summary

Location(s)	Kit Component/ Waste Stream	Test Kit(s)	Disposal Guidance	Background
<ul style="list-style-type: none"> • Medical Treatment Facility • Research Facility 	Packaging (foil wrapper, paper packaging, cardboard)	Abbott BinaxNOW™ QuickVue® At-Home OTC Orasure IntelliSwab™	Solid Waste/Recycling	These items do not come into contact with sample specimens or reagents. See Paragraph 2d for detailed discussion.
	<u>Used</u> testing materials that came <u>in contact with the sample specimen</u> (e.g., used swabs/test devices, used test cards, used test strips, used sample vials/bottles containing reagent) Note: Abbott reagent in dropper bottle does not contact the sample specimen – see unused reagent	Abbott BinaxNOW QuickVue Orasure	Regulated Medical Waste Manufacturer’s statement: “Treat all specimens as potentially infectious.”	See Paragraph 3 for detailed discussion.

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Location(s)	Kit Component/ Waste Stream	Test Kit(s)	Disposal Guidance	Background
	<p><u>Unused reagent</u> in dropper bottle (partially used bottle, or unused bottle due to expiration, defective or cracked prior to use). (Reagent never touches sample specimen- it delivers drops to the test card.)</p>	Abbott BinaxNOW	Hazardous Waste	<p>Test reagent contains 0.0125% sodium azide (CAS 26628-22-8) as a preservative. Sodium azide is included on the Germany and Italy FGS lists for acute HW.</p> <p>See Paragraph 2 for detailed discussion.</p>
<ul style="list-style-type: none"> • Medical Treatment Facility • Research Facility 	<p><u>Unused reagents</u> in vials, bottles, or cartridges (expired, defective or cracked prior to use)</p>	QuickVue Orasure	Solid Waste	<p>None of the chemicals meets FGS HW requirements in countries of Germany and Italy.</p> <p>See Paragraph 2b for detailed discussion.</p>
<ul style="list-style-type: none"> • Office Setting • Mission/Troop Locations – non-medical 	<p>Packaging (foil wrapper, paper packaging, cardboard)</p>	Abbott BinaxNOW QuickVue Orasure	Solid Waste/Recycling	<p>These items do not come into contact with sample specimens or reagents.</p> <p>See Paragraph 2d for detailed discussion.</p>
	<p><u>Used testing materials that came in contact with the sample specimen</u> (e.g., used swabs/test devices, used test cards, used test strips, used sample vials/bottles containing reagent) Note: Abbott reagent in dropper bottle does not contact the sample specimen – see unused reagent</p>	Abbott BinaxNOW QuickVue Orasure	<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 waste generation on an installation.</p> <p>See Paragraphs 2 & 4 for detailed discussion.</p>

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	<p>Unused reagent in dropper bottle (partially used bottle, or unused bottle due to expiration, defective or cracked prior to use). (Reagent never touches sample specimen- it delivers drops to the test card.)</p>	<p>Abbott BinaxNOW</p>	<p>Hazardous Waste</p>	<p>Test reagent contains 0.0125% sodium azide (CAS 26628-22-8) as a preservative. Sodium azide is included on the Germany and Italy FGS lists for acute HW.</p> <p>See Paragraph 2 for detailed discussion.</p>
<ul style="list-style-type: none"> • Office Setting • Mission/Troop Locations – non-medical 	<p><u>Unused reagents</u> in vials, bottles, or cartridges (expired, defective or cracked prior to use)</p>	<p>QuickVue Orasure</p>	<p>Solid Waste</p>	<p>None of the chemicals meets FGS HW requirements in countries of Germany and Italy.</p> <p>See Paragraph 2b for detailed discussion.</p>

Table 2. Japan and Korea Only - OCONUS COVID Self-Test Waste Disposal Summary

Location(s)	Kit Component/ Waste Stream	Test Kit(s)	Disposal Guidance	Background
<ul style="list-style-type: none"> • Medical Treatment Facility • Research Facility 	Packaging (foil wrapper, paper packaging, cardboard)	Abbott BinaxNOW™ QuickVue®At-Home OTC Orasure IntelliSwab™	Solid Waste/Recycling	These items do not come into contact with sample specimens or reagents. See Paragraph 2d for detailed discussion.
	<u>Used testing materials that came in contact with the sample specimen</u> (e.g., used swabs/test devices, used test cards, used test strips, used sample vials/bottles containing reagent)	Abbott BinaxNOW QuickVue Orasure	Regulated Medical Waste Manufacturer's statement: "Treat all specimens as potentially infectious."	See Paragraph 3 for detailed discussion.
	<u>Unused reagents</u> in vials, bottles, or cartridges (expired, defective or cracked prior to use) (includes all new/unused bottles or partially used Abbott dropper bottles)	Abbott BinaxNOW QuickVue Orasure	Solid Waste	None of the chemicals meets FGS HW requirements in countries of Japan and Korea. See Paragraph 2b for detailed discussion.

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<ul style="list-style-type: none"> • Office Setting • Mission/Troop Locations – non-medical 	Packaging (foil wrapper, paper packaging, cardboard)	Abbott BinaxNOW QuickVue Orasure	Solid Waste/Recycling	These items do not come into contact with sample specimens or reagents. See Paragraph 2d for detailed discussion.
	<u>Used testing materials that came in contact with the sample specimen</u> (e.g., used swabs/test devices, used test cards, used test strips, used sample vials/bottles containing reagent)	Abbott BinaxNOW QuickVue Orasure	Solid waste Enclose wastes in a non-transparent bag or container prior to disposal to avoid perception issues.	Generation of waste in an office setting is approved as commercial municipal solid waste and does not fall under the scope of RMW waste generation on an installation. See Paragraphs 2 and 4 for detailed discussion.
	<u>Unused reagents</u> in vials, bottles, or cartridges (expired, defective or cracked prior to use) (includes all new/unused bottles or partially used Abbott dropper bottles)	Abbott BinaxNOW QuickVue Orasure	Solid Waste	None of the chemicals meets FGS HW requirements in countries of Japan and Korea. See Paragraph 2b for detailed discussion.