For Use in Low and Middle-Income Countries

Disposal of Xpert® Test Cartridges

Biological material and chemical reagent content of virology Xpert cartridges necessitate, as with all medical waste, appropriate disposal. As is the case with commercial nucleic acid amplification preparation products from several major manufacturers, Xpert tests for HIV, HCV, CT/NG, and Ebola, use Guanidinium Thiocyanate (GTC) to facilitate extraction and preservation of DNA and RNA from patient samples (see Table 1 below).

The GTC content of used cartridges is low and as such the cartridge waste poses a minimal risk ranging from acute toxicity when ingested, to skin and eye irritation[1]. There is minimal risk to users and the environment if GTC is properly disposed of as stated below.

Table 1. Virology Xpert Tests and GTC content

Test	GTC Present	Total GTC Volume in a Cartridge (ml)*	% GTC in reagent product[1]
Xpert® HIV-1 Qual XC**	No	None	None
Xpert® HIV-1 Qual	Yes	1.4 ml per cartridge	10-20%
Xpert® HIV-1 Viral Load XC	Yes	2.0 ml per cartridge	10-20%
Xpert® HIV-1 Viral Load	Yes	2.0 ml per cartridge	10-20%
Xpert® HCV Viral Load	Yes	2.0 ml per cartridge	10-20%
Xpert® HCV VL Fingerstick	Yes	1.0 ml per cartridge	10-20%
Xpert® HBV Viral Load	Yes	1.7 ml per cartridge	10-20%
Xpert® CT/NG	Yes	2.5 ml per cartridge	10-20%
Xpert® Ebola	Yes	2.5 ml per bottle	10-15%
Xpert® BCR-ABL	Yes	2.9 ml per ampoule	10-15%
Xpert® C. difficile (Xpert® C. difficile/Epi, Xpert® C. difficile BT)	Yes	2.0 ml per pouch	20-30%
Xpert® EV (Enterovirus)	Yes	300 µl per cartridge	1 - 3%
Xpert® Flu, Xpert® Flu/RSV XC (Influenza/ RSV)	Yes	1.5 ml per cartridge	10-20%
Xpert® MRSA,	Yes	1.5 ml per vial	20-30%
Xpert® MRSA/SA SSTI		2.0 ml per pouch	20-30%
Xpert® SA Nasal Complete	Yes	2.0 ml per vial	20-30%
Xpert® Norovirus	Yes	2.7 ml per cartridge	20-30%
Xpert® TV (Trichomonas vaginalis)	Yes	1.6 ml per cartridge	5-10%

*Safety Data Sheets (SDS) are available at www.cepheid.com or www.cepheidinternational.com under the SUPPORT tab[1]

**XC: Extended Coverage

Routine disposal of sample reagent vials*** and cartridges containing GTC (either before or after use)

1. **Handling, storage, and transportation of hazardous healthcare waste**

   As with all medical waste, used GTC-containing vials and cartridges should be packaged in a leak-proof container and should be separated from other forms of waste to ensure that they go through the appropriate treatment and disposal processes. Typically, this would be as follows:

   i. Primary containment: The vial or cartridge itself is the primary containment – be sure that the caps of vials and lids of cartridges are closed tightly before discarding.

   ii. Secondary containment: Discarded items should be placed into a plastic, leak-proof, hazardous waste disposal bag.

   iii. Tertiary containment: A hard-sided container should be used as the final level of containment. The cardboard box in which the shipment arrived or another cardboard box can be used for this purpose.

   Seal and label the external package as “Biowaste” or “Chemical waste” in accordance with the guidelines of your country before removal to the final disposal facility. Refer to the World Health Organization (WHO) guidelines[2] where the country guidelines are not available at:
   https://aslm.org/wpcontent/uploads/2019/12/The-WHO-BlueBook-5Apr2019-final.pdf

   *** Several GeneXpert Tests do **NOT** require reagent vials

2. **Biohazardous waste disposal**

   i. Cepheid does not recommend placing vials or cartridges containing GTC into a diluted bleach solution bath or tub. Contact between GTC and bleach may release hazardous gas, which should be avoided with ample ventilation. For complete destruction, we recommend that cartridges and reagent vials containing GTC be disposed of using high-temperature incineration preferably above 1000°C[3].

   ii. Preferably, disposal of all laboratory testing plastics and containers is accomplished by incineration. This recommendation applies to all such products and not just those of Cepheid. Incineration of all Xpert cartridges should follow World Health Organization (WHO) recommendations. Specifically, for GTC-containing waste, WHO recommends double combustion incineration[3], preferably at temperatures above 1000°C as detailed by WHO available for download at:
   https://apps.who.int/iris/bitstream/handle/10665/43123/9241592745.pdf

   iii. In addition, the WHO proposes additional practical solutions for the safe disposal of GTC-containing waste through high-temperature co-incineration of GTC waste in cement factory kilns. This method has been explored and identified as an effective, inexpensive, and high-capacity disposal option for GTC-containing

waste in low-resource settings. Cement factories offer ideal conditions for high-temperature incineration > 1400 °C at the burner side and > 1050 °C at the entrance side[3,4]

iv. In countries where there are no incinerators outsourcing waste management to private companies is an alternative that has been used in some settings.[5]

v. Cepheid understands the inconvenience of disposing of the plastics and reagents generated using Xpert tests and most other molecular tests, but we are committed to working with programs to develop solutions to minimize this impact while continuing to provide the great benefits of accurate and fast near-patient diagnosis.

3. Response to spills or physical contact with GTC from reagent vials or cartridges

i. GTC is irritating to skin and mucous membranes and should be washed with soap and water after exposure. Flush the area with running water as quickly as possible, and then wash with soap and water (if appropriate). For eye exposure, flush your eyes with copious amounts of water.

ii. A spill from a single cartridge or a reagent vial onto a laboratory surface would contain a maximum of 1.5 mL of 10-20% GTC. We recommend that the worker wear gloves and protective eyewear and use paper towels to wet the area of the spill thoroughly with water and detergent, which will remove the chemical components, then dry the area with paper towels, being certain to remove all residual liquid before final disinfection with 10% (0.5% final active concentration) household bleach (or 1% v/v sodium hypochlorite) in water.

iii. Alternatives to bleach, such as OxiClean (Church & Dwight Co., Ewing, New Jersey), a stabilized acidified version of hydrogen peroxide disinfectant, is even safer than bleach, but it is not available everywhere. A hydrogen peroxide/acetic acid combination (7.35% H2O2 and 0.23% peracetic acid), such as SporGon (Decon, King of Prussia, Pennsylvania) is also effective for disinfecting spills containing GTC without producing any hazardous byproducts. However, although most bacteria and viruses are killed in 5 minutes, Mycobacteria require 15 minutes of contact for killing, whereas spores require 3 hours of contact.

iv. If a liquid spill from a used cartridge containing GTC is sprayed with 10% bleach or is cleaned up using bleach-wetted paper towels, the risk of harm from any gaseous products, such as hydrogen cyanide, is very low since the cartridges contain concentrated sodium hydroxide that is mixed with the GTC during operation of the cartridges.

References

1. www.cepheid.com
2. https://aslm.org/wp-content/uploads/2019/12/The-WHO-BlueBook-5Apr2019-final.pdf
3. https://apps.who.int/iris/bitstream/handle/10665/43123/9241592745.pdf
4. https://aslm.org/wp-content/uploads/2023/05/LabCoPCookbookWasteMgt-Recipe-EN.pdf?x89467
5. https://www.sciencedirect.com/science/article/pii/S2666911021000186?via%3Dihub