



## Media Lines

### Unusable COVID-19 Testing Kit Swabs – Update

**Issue statement:** On June 25, the recall for test kit swabs from ESBE Scientific, a Canadian distributor, was expanded to include additional lots. The media tubes and swabs may not have been adequately sterilized in accordance with published sterilization standards and may be contaminated. The swabs are intended for use in testing to diagnose the presence of the COVID-19 virus. The following key messages have been developed in anticipation of media inquiries.

Public Services and Procurement Canada has confirmed contracts with a variety of suppliers for 23 million swabs. A total of 628,000 swab kits have been recalled by ESBE Scientific.

#### Key messages:

- ESBE Scientific shipped swabs between March 28 and June 25, 2020, which were sent to various locations in Canada.
- On April 11, 2020, and again on June 25, 2020, the company issued an urgent recall notice because of a problem with swab kit contamination. In both instances, the company voluntarily recalled the product and committed to taking corrective action and replacing the product.
- The provincial and territorial public health laboratories were immediately informed of the recalls. All public health laboratories that received the affected swabs were advised of the issue on June 25. Recipients were asked to return the unused swabs to the distributor.
- Health Canada worked with the company to ensure that the recalls ran smoothly and posted all health product recalls in its [Recalls and Safety Alerts database](#).
- Health Canada will continue to work with the manufacturer to ensure that required corrective action is taken and follows the appropriate protocols.
- The Government of Canada has awarded contracts for over 23 million swabs from a variety of suppliers and is providing or producing other items required for laboratory tests to support the provinces and territories. It is currently looking into ways of ensuring a steady, safe supply of sterile swabs, including options for producing and sterilizing swabs in Canada.
- The Public Health Agency of Canada is continuing to work with the provinces and territories to determine their medical supply needs to place bulk orders.
- Public Services and Procurement Canada is continuing to identify suppliers capable of meeting Canada's needs.
- Health Canada is working to ensure that swabs with a novel design or swabs manufactured through retooling meet standards of safety and effectiveness.



- ESBE Scientific holds a valid medical device establishment licence (company number 103659).

### **If pressed**

- The swabs are sterile and do not pose a risk to patients as the concern is with the transfer medium gel used to store the sample and not with the swab itself.
- As of July 9, 2020, Health Canada has received only one mandatory incident report for the recalled devices. This report was related to a swab breaking because of an error made by the user.

### **Questions and Answers**

#### **Q1. How many more swabs have been ordered from ESBE Scientific?**

The Government of Canada has two contracts with ESBE Scientific. The first contract was for approximately 800,000 swabs – the recalled swabs are from this contract. The second contract is for approximately 6 million swabs – this contract is still pending.