Health Canada Santé Canada

Mandatory Medical Device Problem Reporting Form for Industry

CANADA VIGILANCE - MEDICAL DEVICE PROBLEM REPORTING PROGRAM

If more space is required, please attach additional sheets
Fields required to be completed for updates/final reports are indicated by an *

A. REPORTER INFORMATION

1. i. Reporter Type

○ Manufacturer ◉ Importer

In the case where the reporter is the importer:

ii. Did the importer report the incident to the manufacturer?

◉ Yes ○ No

iii. Is the importer also submitting the report on behalf of the manufacturer?

◉ Yes ○ No

2. Reporter Contact Information *

ecc122dda5dadea3e49c4c3ad5d76bda

3. Reporter File No. *

1233279

4. Health Canada File No. (if applicable) *

not assigned yet

5. Type of Report *

○ Preliminary ○ Update ◉ Final ○ Preliminary & Final

If "preliminary" only, anticipated date for the final report:

(YYYY-MM-DD)

If "update/final", date the previous report was submitted to Health Canada:

2019-11-14 (YYYY-MM-DD)

6. Date Submitted *

2020-02-27 (YYYY-MM-DD)

	Manufacturer	Importer
7. Name and Address	BECTON DICKINSON AND COMPANY 1 Becton Drive Franklin Lakes, NJ, US, 07417	Becton Dickinson Canada Inc. 2100 Derry Road, Suite 100, Mississauga, ON L5N 0B3
8. Health Canada assigned company identification number (if known):	101288	101291
9. Establishment License Number (if applicable):		204

B. INCIDENT INFORMATION

1. Classification of Incident *

i. ○ 10-Day ◉ 30-Day

ii. ◉ Canadian ○ Foreign

iii. ○ Investigational testing ○ Special Access Program
○ Radiation emitting device (if applicable)

2. Date of Incident

(YYYY-MM-DD)

3. Reporter's Awareness Date

2019-10-17 (YYYY-MM-DD)

4. Patient Consequences

f992c434152bb402cebc4ed827b71db7

5. Details of Incident

fa0cc099eedbc9445c90f45dd736f73b

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
13x100 mm 6.0 mLBD Vacutainer® SPC Plus plastic tube

2. Control/Lot/Serial No.
Unknown

3. Expiration Date
(YYYY-MM-DD)

4. i. Device Classification
(•) I ( ) II ( ) III ( ) IV

ii. Device License No.
n/a

iii. Device Identification No
n/a

iv. Manufacturer's Medical Device Identifier (catalogue/model no.)
368380

5. Software Version
not applicable

6. Age of Device
unknown

7. How long was the device in use?
unknown

8. Was the device labelled as sterile?
(•) Yes ( ) No

9. Availability of device for evaluation
( ) Destroyed ( ) Returned to Manufacturer/Importer
(•) Neither (with explanation)

BD has not received samples or photos from the customer facility for evaluation.

D. COMPLAINANT INFORMATION

1. Complainant is a:
( ) Consumer (•) Health professional ( ) Other

2. Name of Complainant
b33716b603812f08ba38330eaf46f08e

3. Name of Health Care Facility (if applicable)
f46fb06e9313dde978b6cd80d76f212d

4. Address
6f17970e92b48c54d8186641160186f6

5. Telephone No. and/or E-mail Address
840097f15c168e673e466d0bd45e4680

Privacy Notice Statement: For the purposes of the Canada Vigilance - Medical Device Problem Reporting Program, information related to the identity of the complainant and/or reporter will be protected as personal information under the *Privacy Act*, and under the *Access to Information Act* in the case of an access to information request. For details with regard to personal information collected under this program, visit the Personal Information Bank; Health Canada; Health Products and Food Branch; Branch Incident Reporting System; HC PPU 088 at: http://infosource.gc.ca/inst/1476/1476-fedemp00-eng.asp

E. INVESTIGATION INFORMATION

1. Investigative Actions and Timeline
f392d25238de0dc08a259cced8c5dd36

2. Root Cause of Problem
e0d97afe4c8b4b119c2f7389c6ea7f63

3. Corrective Actions taken as a result of the investigation
eeb6716fca9ac1af114b432a1b42f2d5