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 *

Marie-Michelle Ouellet
Roche Diagnostics Canada
201, Armand-Frappier Blvd, Laval, QC H7V 4A2
Telephone: (450) 686-3011 Fax: (450) 686-8187
marie-michelle.ouellet@roche.com

3. Reporter File No. *

20046

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

N/A

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:

2020-04-22 (YYYY-MM-DD)

6. Date Submitted *

2020-11-23 (YYYY-MM-DD)

	Manufacturer	Importer
7. Name and Address	Roche Diagnostics GmbH Sandhofer Strasse 116 Mannheim, Germany 68305 Telephone: 49(621)759-69438 Fax: 49(621)759-6593	Roche Diagnostics Canada 201, Armand-Frappier Blvd, Laval, QC H7V 4A2 Telephone: (450)686-7050 Fax: (450)686-8187
8. Health Canada assigned company identification number (if known):	114999	N/A
9. Establishment License Number (if applicable):	N/A	404

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

2020-02-25 (YYYY-MM-DD)

3. Reporter's Awareness Date

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

4. Patient Consequences

No adverse event resulted from this issue.

5. Details of Incident

(see detailed note on page 3/4)

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
Coaguchek XS PT Test PST

2. Control/Lot/Serial No.
43002021

3. Expiration Date
2021-04-30 (YYYY-MM-DD)

4. i. Device Classification
○ I ○ II ◉ III ○ IV

ii. Device License No.
2686

iii. Device Identification No
1000625

iv. Manufacturer's Medical Device Identifier (catalogue/model no.)
07671679190

5. Software Version
N/A

6. Age of Device
N/A

7. How long was the device in use?
N/A

8. Was the device labelled as sterile?
○ Yes ◉ No

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

The customer returned one vial of test strips lot number 449498-21 and 405014-22 for further investigation.

D. COMPLAINANT INFORMATION

1. Complainant is a:
◉ Consumer ○ Health professional ○ Other

2. Name of Complainant
Francine Brière

3. Name of Health Care Facility (if applicable)
N/A

4. Address
3638 Elsa Triolet
Laval, Quebec
H7P 0G4

5. Telephone No. and/or E-mail Address
450-934-3138

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

The manufacturer is presently conducting an investigation on this reported event and will evaluated the following:

- Establish the problematic
- Further investigate the implicated product history
- Analysis the data provide by the user and/or the affiliate
- Evaluate the potential risk of this incident to any user.

The manufacturer will provide a conclusion based on his findings in order to assess if the incident is an isolated case and/or if a corrective action is required as soon as possible after completion of the manufacturer's investigation (if possible within 6 months from this initial report). We will provide our final report to your section accordingly.

This section only applies for preliminary & final, and final reports

2. Root Cause of Problem
N/A (See below)

3. Corrective Actions taken as a result of the investigation
N/A (See below)

B. INCIDENT INFORMATION

5. Details of incident (Continuation):

A customer contacted our Roche Technical Support to report discrepant results obtained while using the Coaguchek XS PT Test PST (Cat: 07671679190) of lot number 43002021 and 40501422 in combination with their Coaguchek XS instrument of serial number UP0081287. Here are the results obtained by the customer:

Initial result obtained at 10am with strip lot 40501422: 4.2 INR
Second result obtained 2 minutes later with strip lot 43002021: 4.2 INR
Laboratory test done at 10am: 3.24 INR

The patient's therapeutic range is between 2.5 to 3.0 INR.

The manufacturer requested all pertinent information to be provided to them in order to investigate the issue further.

E. INVESTIGATION INFORMATION

(This section only applies for preliminary & final, and final reports)

2. Root Cause of Problem (Continuation):

Investigation:
The manufacturer requested the complained material to be returned for further investigation, but no product was sent back by the customer.

On a regular basis, CoaguChek strips are tested in comparison to the current master lot by the manufacturer. For this purpose, the test strips are measured with two human blood samples from Marcumar donors and two internal reference meters. All retention data are reviewed once testing is complete. If a failing result is observed during testing, appropriate actions are taken.

The customer stated they have APA Syndrome. As per the product labeling, this may cause false-high INR values and false-low Quick values. Where APA is known to be present, it is imperative that a result be obtained using an APA-insensitive laboratory method for comparison.

The corresponding retention material complied with the specification, based on the requirements of the regular retention testing process of the QC department and no error messages occurred.

The customer was referred to the applicable product labeling and operator's manual for details on instructions for use and system limitations, as this could be a potential cause for discrepant results. All package inserts of CoaguChek test strips used by patients (XS PT/ XS PT PST) contain the advice to contact their physician in case of unusual results of PT measured with the CoaguChek system.

CoaguChek uses human recombinant thromboplastin. Therefore, comparability to other human recombinant thromboplastins is best, whereas higher deviations can occur with other thromboplastins. However, those higher differences between thromboplastins of different (rabbit, bovine based) origin are not a CoaguChek specific issue. Similar differences can be observed when a human recombinant thromboplastin-based laboratory method is compared against several other (rabbit, bovine-based) laboratory methods.

To minimize these differences, in a monitoring situation, it is recommended that each site uses results from one type of thromboplastin method for each patient

3. Corrective Actions taken as a result of the investigation (Continuation):

Risk analysis:
No adverse event resulted from this issue.

Conclusion:
The manufacturer could not perform an investigation since the complained material was not returned by the customer.

The corresponding retention material complied with the specification, based on the requirements of the regular retention testing process of the QC department and no error messages occurred.

As per the product labeling, customer with APA Syndrome may cause false-high INR values and false-low Quick values. Where APA is known to be present, it is imperative that a result be obtained using an APA-insensitive laboratory method for comparison.

The customer was informed to refer to the applicable product labeling that provide more information on system limitation.

Updated final report:
The returned strips (lots 449498-21 and 405014-22) were tested on a reference meter with a high level control sample and the obtained results were in the allowed range.
No error messages occurred during investigation.

The relevant retention test strips were tested in comparison with the current CoaguChek PT / XS PT Masterlot using two human blood samples from Marcumar donors and one high level control sample on internal reference meters.
The retention samples were shown to be acceptable and no error messages occurred.

The two lots of the complained test strips as well as the retention strips were investigated and were shown to met the specifications.

Salazar, Glenda (HC/SC)

From: Ouellet, Marie-Michelle <marie-michelle.ouellet@roche.com>
Sent: 2020-11-23 10:16 AM
To: mdpr / dimm (HC/SC)
Subject: MDPR 20046 CN-512208 Updated Final
Attachments: 9a-MPR20046CN512208CN556618UpdatedFinalHC.pdf

Good day,

As required according to section 59 to 61 of the Medical Devices Regulations, please find attached a copy of the updated final report for the incident we want to report to your bureau.

Should you require additional information, please do not hesitate to contact us.

Regards,

Marie-Michelle Ouellet
Regulatory Compliance Advisor

Roche Diagnostics,

Division de/of Hoffmann-La Roche Limitée / Limited

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