FOUNDATION MEDICINE

Urgent Field Safety Notice (FSN)

Date: 30 October 2019 FSCA Ref: Not Issued at this time

Cell-Free DNA Collection Tube 2 Pack
Mislabelled REF and IFU references

ATTENTION

Recipients of Cell-Free DNA Collection Kit Tube-2 Pack 16x100

Contact details of local representative:
: europe.foundationmedicine@roche.com : +49 (0)7624 / 14 - 2098

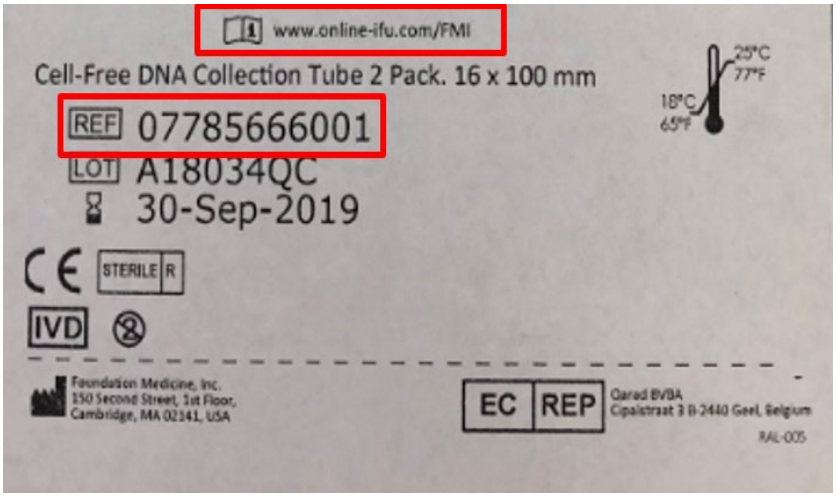

Figure 1 – Example of Cell-Free DNA Collection Tube 2 Pack 16x100mm outer label (RAL-005)

The primary label for the Cell-Free DNA Collection Tube 2 Pack 16x100 mm was distributed to customers and referenced an incorrect website for to access the Instructions for Use (IFU) and an incorrect REF number, which is to be used at the website to access the corresponding IFU. Figure 1 above highlights in **RED** the affected label (RAL-005) issues.

LABEL CORRECTION NOTES:

1. The correct REF number for the Cell-Free DNA Collection Tube 2 Pack 16 x 100 mm is: **P/N 00101**

2. The correct website to access the IFU is: **www.eifu.online/FMI**

Urgent Field Safety Notice (FSN)

	1. **Information on Affected Devices***
1.	1. Device Type(s)*
	Specimen receptacles
1.	2. Commercial name(s)
	Cell-Free DNA Collection Tube 2 Pack 16x100 mm
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)*
	Collection of patient samples to be sent to laboratory for testing
1.	5. Device Model/Catalogue/part number(s)*
	P/N 00101
1.	6. Software version
	N/A
1.	7. Affected lot numbers:
	A18034QC, A18073DD, A19033BA, 379696E18010, 379696E18016, 379696E19001, 379696E19002, 379696E19003, 379696E19005, 379696E19006, 379696E19008, 379696E19010, 379696E19011, 379696E19012
1.	8. Associated devices
	N/A

	2 **Reason for Field Safety Corrective Action (FSCA)***
2.	1. Description of the product problem*
	The REF and IFU website referenced on the label are incorrect
2.	2. Hazard giving rise to the FSCA*
	There is very low risk to the patient or end user.
2.	3. Probability of problem arising
	The occurrence level is categorized as “Possible”
2.	4. Predicted risk to patient/users
	The severity level is categorized as “Negligible”
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	Customer report of incorrect IFU website reference on a sample collection kit
2.	7. Other information relevant to FSCA
	The Cell-Free DNA Collection Tube 2 Pack 16x100 mm has the contact telephone number and website for customers to contact Foundation Medicine Roche. Customers may call for kit information or request to have a pdf copy of the IFU to be sent. Contact information by Phone: +49(0)7624/14-2098, email europe.foundationmedicine@roche.com

	3. Type of Action to mitigate the risk*	
3.	*1. By when should the action be completed?*	***November 10, 2019***
3.	*2. Particular considerations for:*	*IVD*
	Is follow-up of patients or review of patients’ previous results recommended? **None required**	

Urgent Field Safety Notice (FSN)

3.	*Is customer Reply Required? ** *(If yes, form attached specifying deadline for return)*	**No**
3.	***3. Action Being Taken by the Manufacturer*** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☒ **IFU/labelling correction** ☒ **Other** Roche Distribution Hubs that have inventory identified in this notice shall dispose/destroy that inventory. Customers that have inventory identified in this notice are being informed of the labelling error and are provided with instructions for how to access the Instructions for Use. Additionally, newly manufactured P/N 00101 Cell-Free DNA Collection Tube 2 Pack 16x100mm products will be shipped by FMI-Roche to identified distributor hubs in the EU. The new Cell-Free DNA Collection Tube 2 Pack 16x100mm products will have the correct IFU website and REF on the primary labelling.	
3	*4. By when should the action be completed?*	***DATE November 10, 2019***
3.	*5. Is the FSN required to be communicated to the patient /lay user?*	**No**
3	*6. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?*	

	4. General Information*	
4.	1. FSN Type*	**New**
4.	2. For updated FSN, reference number and date of previous FSN	**N/A**
4.	**3.** For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	**No**
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4	6. Anticipated timescale for follow-up FSN	**N/A No Follow up FSN is planned**
4.	7. Manufacturer information (For contact details of local representative refer to Page 3 of this FSN)	
	a. Company Name	Foundation Medicine Inc
	b. Address	150 Second Street, Cambridge MA 02142
	c. Website address	https://www.rochefoundationmedicine.com/
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * FAMHP- Federal Agency for Medicines and Health Products Place Victor Horta 40, box 40, B - 1060, Brussels	
4.	9. List of attachments/appendices:	**N/A**

Urgent Field Safety Notice (FSN)

4.	10. Name/Signature	Insert Name and Title here and signature below
	Transmission of this Field Safety Notice	
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*	

Contact Details
Name: Daniel Wauthier
Title: Europe Operational Excellence Manager
Roche Pharma AG
Business Operations
Roche Foundation Medicine
Address: Emil-Barell-Straße 1
D-79639 Grenzach-Wyhlen
Telephone: +49 (0)7624 / 14-3331
Email : daniel.wauthier@roche.com

Contact details of local representative:
: europe.foundationmedicine@roche.com : +49 (0)7624 / 14 - 2098