import XML | fix + save

fill with test data #1

new case, keep base data

Report Form
Field Safety Corrective Action
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

Version 2.7en
2012-12-03

1 Administrative information

To which NCA(s) is this report being sent?

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre, Earlsfort Terrace
Dublin 2
Ireland D02 XP77

Type of report

- (•) Initial report
- ( ) Follow-up report
- ( ) Final report

Date of this report

2025-03-11

Reference number assigned by the manufacturer

ACHC 24-07

FSCA reference number assigned by NCA

CRN00G4KT

Incidence reference number assigned by NCA

N/A

Name of the co-ordinating NCACompetent Authority (if applicable)

HPRA

2 Information on submitter of the report

Status of submitter

- ( ) Manufacturer
- (•) Authorised Representative within EEA and Switzerland
- ( ) Others: (identify the role)

3 Manufacturer information | new

Name	
Siemens Healthcare Diagnostics Inc	
Contact Name	
Syreeta Wynn	
Address	
511 Benedict Avenue	
Postcode	**City**
Tarrytown, NY	10591
Phone	**Fax**
001 914-413-5428	
E-mail	**Country**
syreeta.wynn@siemens-healthineers.com	US - USA

4 Authorised Representative Information

new

Name Siemens Healthcare Diagnostics Manufacturing Ltd	
Contact Name Emma Jayne Flaherty	
Address Chapel Lane	
Postcode N/A	**City** Swords, Co. Dublin
Phone +353 1 6990 531	**Fax**
E-mail dx-euar.team@siemens-healthineers.com	**Country** IE - Ireland

5 National contact point information

new

National contact point name	
Name of the contact person	
Address	
Postcode	**City**
Phone	**Fax**
E-mail	**Country** N/A

6 Medical device information

new

Class

- ◯ AIMD Active implants
- ◯ MDD Class III
- ◯ MDD Class IIb
- ◯ MDD Class IIa
- ◯ MDD Class I
- ◯ IVD Annex II List A
- ◯ IVD Annex II List B
- ◯ IVD Devices for self-testing
- ◉ IVD General

Nomenclature system (preferable GMDN)	**Nomenclature code**
GMDN	53705

Nomenclature text

See section 8

Commercial name/ brand name / make

Atellica CH Revised C-Reactive Protein (RCRP)

Model number	**Catalogue number**
N/A	11537223
Serial number(s)	**Lot/batch number(s)**
N/A	N/A
Device Mfr Date	**Expiry date**

Notified Body (NB) ID-number

N/A

Accessories / associated devices (if applicable)

N/A

Software version number (if applicable)

N/A

7 Description of the FSCA

Background information and reason for the FSCA

Siemens Healthineers has confirmed that incorrect software flagging may occur for the Atellica CH RCRP assay that may potentially lead to an erroneous result. The probability of occurrence for an erroneous result in the absence of a flag is less than 0.1%. The probability of occurrence for an erroneous result with an error flag is 1% or less. This incorrect flagging is mitigated through the customer actions listed in the letter. This issue can present with serum or plasma and with all Atellica CH RCRP reagent lots. Below are the observed scenarios:

Scenarios #1 and #2 are applicable to only the Atellica CH analyzer.

Scenario 1:
No Calculation flags can be inappropriately posted for samples with true C-reactive protein (CRP) concentrations that are less than or above the measuring interval of 0.05 – 25.00 mg/dL (0.5 - 250.0 mg/L).

Scenario 2:
A sample with true CRP concentration of approximately 35.00 to 200.00 mg/dL (350.0 to 2,000.0 mg/L), can sometimes display falsely depressed initial results 0.30 to 24.00 mg/dL (3.0 to 240.0 mg/L), accompanied by a > Measuring Interval flag on the analyzer.

Scenarios #3 and #4 are applicable to the Atellica CH and Atellica CI analyzers.

Scenario 3:
In rare situations, samples with true CRP concentrations above the measuring interval can report as within the measuring interval (results between 12.00 to 18.00 mg/dL (120.0 to 180.0 mg/L)) and without the > Measuring Interval flag.

Scenario 4:
In rare instances, samples with true CRP concentrations of approximately 10.00 to 14.00 mg/dL (100.0 to 140.0 mg/L) can be initially reported as > Measuring Interval with no numerical RCRP value displayed. The subsequent auto-diluted result is not displayed, and instead Error is displayed accompanied, by Conc Error and Repeat flags.

Description and justification of the action (corrective / preventive)

An Urgent Field Safety Notice (UFSN) is being issued by the manufacturer.

Siemens country organizations will issue this Urgent Field Safety Notice to all customers who received the Atellica CH RCRP reagent informing them of the potential for incorrect software flagging that may lead to erroneous results when using the Atellica CH RCRP assay.

Atellica CI customers will be instructed to reduce the upper end of the measuring interval. Atellica CH customers will be instructed to remove any previously entered rules for the “No Calculation” flag, install Atellica Solution Software version 1.29.0 or higher, and reduce the upper end measuring interval.

The UMDC and UFSN indicate that the incorrect flagging is mitigated through the customer actions listed in the letter. A follow-up communication will be provided when “Customer Actions” are no longer required.

The Root Cause Investigation is in progress and is currently scheduled to be completed at the end of April 2025.

Advice on actions to be taken by the distributor and the user

An Urgent Field Safety Notice (UFSN) is being issued by the manufacturer.

Siemens country organizations will issue this Urgent Field Safety Notice to all customers who received the Atellica CH RCRP reagent, informing them of the potential for incorrect software flagging that may lead to erroneous results when using the Atellica CH RCRP assay.

Atellica CI customers will be instructed to reduce the upper end of the measuring interval. Atellica CH customers will be instructed to remove any previously entered rules for the “No Calculation” flag, install Atellica Solution Software version 1.29.0 or higher, and reduce the upper end measuring interval.

Progress of FSCA , together with reconciliation data (Mandatory for a Final FSCA)

Time schedule for the implementation of the different actions

Manufacturer confirms that the scheduled date for the next report is end of March 2025.

Attached please find	FSN Status
☒ Field Safety Notice (FSN) in English	○ Draft FSN
☐ FSN in national language	◉ Final FSN
☐ Others (please specify)	

The medical device has been distributed to the following countries:

within the EEA and Switzerland

☒ AT	☒ BE	☐ BG	☒ CH	☐ CY	☒ CZ	☒ DE	☒ DK
☒ EE	☒ ES	☒ FI	☒ FR	☒ GB	☒ GR	☒ HU	☒ IE
☐ IS	☒ IT	☐ LI	☒ LT	☐ LU	☒ LV	☐ MT	☒ NL
☒ NO	☒ PL	☒ PT	☒ RO	☒ SE	☒ SI	☒ SK	☒ TR

Candidate Countries

☒ HR

☐ All EEA, candidate countries and Switzerland

Others:

See Section 8 below

8 Comments

Other Countries (outside of the EU):
Australia, Bahrain, Brazil, Canada, Chile, China, Columbia, Curacao, French Polynesia, Hong Kong, India, Israel, Kuwait, Malaysia, Maldives, New Zealand, Oman, Pakistan, Qatar, Saudi Arabia, Serbia, Singapore, South Africa, South Korea, Taiwan, Uganda, United Arab Emirates, Uzbekistan, Vatican City.

Nomenclature text:
C-reactive protein (CRP) IVD, kit, nephelometry/turbidimetry

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature

Flaherty
Emma Jayne

I affirm that the information given above is correct to the best of my knowledge

print | check | send XML-data by E-Mail