freenome



| Supersedes: | V4 | Withdrawn date: | N/A | Effective date: | 13.09.2023 |
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Date: 03 October 2024

# Field Safety Notice RR003

## EarlyCDT Lung Test kit

For Attention of*: All Freenome Ltd customers in receipt of Batch Number ECDTL2-KIT-006 and ECDTL2-KIT-007 with software version 3.0.2

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**Field Safety Notice (FSN)**

Device Commercial Name: **EarlyCDT Lung Test kit**

Risk addressed by FSN: **Software error for 1 plate format tests**

| Information on Affected Devices* |
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| 1. Device Type(s)* |
| In Vitro Diagnostic Medical Device |
| 2. Commercial name(s) |
| EarlyCDT Lung |
| 3. Unique Device Identifier(s) (UDI-DI) |
| 506088522ECDTL26B |
| 4. Primary clinical purpose of device(s)* |
| The EarlyCDT Lung test kit is intended to be used as an immunoassay for the in vitro detection of a panel of seven lung cancer autoantibodies. |
| 5. Device Model/Catalogue/part number(s)* |
| ECDTL2-UK<br>ECDTL2-007<br>ECDTL2-ES<br>ECDTL2-SG |
| 6. Software version |
| 3.0.2 |
| 7. Affected serial or lot number range |
| ECDTL2-KIT-006 and ECDTL2-KIT-007 |
| 8. Associated devices |
| None |

## Reason for Field Safety Action (FSA)*

### 1. Description of the product problem*

A software issue that affects a single patient's result when software version 3.0.2 is run on the 1-Plate format. The error results in an incorrect Test result being displayed within Patient Report 1. The Patient Test reports affected are within the following tabs of the software:

- Step3b. Patient Report - Patient 1 report affected
- Step3b. Patient Report (nb) - Patient 1 report affected
- Step3b1. Patient Report 1

All other Test Results in Patient Reports 2-5 are unaffected.

The cause of the issue is due to an underlying calculation incorrectly populating the Test Result box for Patient Report 1.

### 2. Hazard giving rise to the FSA*

Incorrect result

### 3. Probability of problem arising

Likely, depending on whether the 1-Plate format of the software is used.

### 4. Predicted risk to patient/users

Incorrect patient treatment pathway

### 5. Further information to help characterise the problem

For patient 1 samples there is a likelihood of a false positive or false negative in the test result displayed on the laboratory report as the result of patient 2 is being presented in patient 1 result despite the individual antibody results.

### 6. Background on Issue

Freenome received communication on the 26th September 2024 reporting a discrepancy between the Patient 1's result shown in tab "Step 3a. Results" and the "Test Result" displayed in Patient Report 1, when the 1-Plate format of the software was used.

The test result in the "Step 3a. Results" sheet showed the correct result of "No significant level" , however the test result in the "Step 3b1 patient report 1" sheet showed a 'Moderate level"; the individual Autoantibody result shown within the same patient report did show the correct result of 'No significant level' on all 7 biomarkers.

On investigation, the error was introduced during a design change improving the test kit with a single chimeric control to replace two separate controls. The change led to the addition of a further patient test in the one plate format of the kit software, requiring reformatting of Step 3b1 sheets to generate a report for the additional sample.

An incorrect cell reference was introduced which resulted in the Step 3b2 patient 2 Test Result being pulled through into Step 3b1 patient 1 Test Result section and also is pulled through into the patient 1 reports contained within sheet 3b and sheet 3b (nb). The secondary validation of the amended software for this design change did not identify this error before release.

**Test results for patients 2-5 were not affected by this error, and individual autoantibody assessments for patient 1 summarised in the table below the Test Result remain correct.**

A Corrective action already initiated for a benign identified issue with the 1 plate format in an earlier software version will ensure that internal processes are updated to prevent recurrence.

**It is important to note that the Kit software – 2Plate format test software application is unaffected.**

Type of Action to mitigate the risk*

1. Action To Be Taken by the User*

X Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device

☐ On-site device modification/inspection

☐ Follow patient management recommendations

X Take note of amendment/reinforcement of Instructions For Use (IFU)

X Other ☐ None

**Important:**
Please **DO NOT** use the 1 plate format of software v3.0.2.
The 2 plate format of software v3.0.1 has no issues and can be used normally. It is **highly recommended** that only the 2 plate format is used even when 1 plate format is desired, to do this please refer to the instructions below.

**Patient consideration**
Please identify whether the plate 1 format has been used for any devices from the batches indicated above. If it has for these cases, review the patient 1 result to identify if there has been an incorrect result reported by performing the following simple check:

1. Compare cell K20 on sheet 'Step 3a. Results' to 'Cell B22 of sheet Step3b1. Patient Report 1.'. If the two do not match, then an incorrect test result may have been reported.

If patient reports have been affected, confirm the number of affected patients to the local representative / manufacturer. Please do this by sending details by email to EarlyCDT@freenome.com as well as your local representative if outside the UK, as soon as possible.

**For all incorrect test results identified , please re-run the patient 1 data obtained from the original test using the 2 plate format of the software by following the procedure below.** Once run, this result can be forwarded as necessary to the originator of the test request:

1.The raw data and sample IDs for all 5 patients, including control data, contained within the "Step 1. Data Input" worksheet of impacted 1Plate software should be copied into the PLATE 1 region of the "Step 1. Data Input" worksheet of the "EarlyCDT-Lung Test Kit Software - 2Plate V3.0.1" software for the corresponding Kit Lot. The PLATE 2 region can be left blank.

2. The 2Plate version of the software already provided within the kit USB should be used. Patient 1 reports generated by the 2Plate software may then **replace** affected reports generated by the 1Plate software.

**Unused product consideration**
Please identify quantities of any unused kits from batches ECDTL2-KIT-006 & ECDTL2-KIT-007 with 1Plate Format software v3.0.2 and confirm numbers to EarlyCDT@freenome.com.

The manufacturer will send the appropriate numbers of USBs with uprevised software to local representatives within 2 weeks of notification of requirements, for onward distribution as identified. All USBs containing the 1Plate format software v3.0.2 should be discarded.

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| 2. By when should the action be completed? | **As soon as possible or immediately prior to running 1 plate format testing. Responses should be provided by 10th October 2024.** |
| 3. Particular considerations for: Is follow-up of patients or review of patients' previous results recommended? | **Yes** |
| 4. Is customer Reply Required? * (If yes, form attached specifying deadline for return) | **Yes** |

5. Action Being Taken by the Manufacturer

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| ☐ Product Removal | ☐ On-site device modification/inspection |
| X Software upgrade | ☐ IFU or labelling change |
| ☐ Other | ☐ None |

6. Provide further details of the action(s) identified:

**Any new orders will be supplied with the revised software automatically.**

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| 7. By when should the action be completed? | **Immediately upon receipt of this notice** |
| 8. Is the FSN required to be communicated to the patient /lay user? | **Yes, if incorrect test results are identified.** |
| 9. If yes, has the manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet? | **Available upon request** |

## General Information*

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| 1. FSN Type* | **Field Safety Corrective Action (FSCA)** |
| 2. For updated FSN, reference number and date of previous FSN | **N/A** |
| 3. For Updated FSN, key new information as follows: | **N/A** |
| 4. Further advice or information already expected in follow-up FSN? * | **N/A** |

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| 5. | If follow-up FSN expected, what is the further advice expected to relate to: | **N/A** |
| 6. | Anticipated timescale for follow-up FSN | **N/A** |
| 7. | **Importers/distributors:** The Competent (Regulatory) Authority of your country is required to be informed about this communication to customers. Please inform the respective authorities as required, through your systems. | |
| 8. | List of attachments/appendices: | **None provided** |
| 9. | Name/Signature | [redacted] QA/RA Manager [redacted] |

## Transmission of this Field Safety Notice

This notice needs to be passed on to all those who need to be aware within your organisation or to any other organisation where the potentially affected devices have been transferred (as appropriate).

Please transfer this notice to other organisations cn which this action has an impact (as appropriate).

Please keep hold of this for 3 weeks post notification on this notice. There may be a requirement for further reference to this notice. If you have not been communicated to after this time period, the corrective action is effective.

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. *

**Revision history:**

| Date | Initials | Explanation of and Reason for revision |
|---|---|---|
| 03/30/09 | LECB | Change form number to standardize with US format |
| 03.18.10 | SC | Version numbering format changed |
| 05.19.16 | JK | Change of logo. Change of form title in header box. |
| 23.07.19 | JK | Form updated to be in line with MEDDEV template |
| 14.07.20 | HB | Rebranded. |
| 13.09.23 | HB | Rebranded. |
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