

**Urgent Field Safety Notice****Abbott Molecular Inc.****Product: m24sp****List Number: 03N06-01**

This issue is not serial number specific

September 12, 2014

Dear Abbott Molecular Customer,

This letter contains important information regarding the m24sp Instrument Plate Report. Please review this information carefully.

Background

The m24sp does not require the use of a unique sample ID for each sample within a run. If duplicate sample IDs are used within a run, issues occur on the m24sp Plate Report.

The m24sp Plate Report is a PDF file generated by the software for each instrument run. It provides a list of sample ID's and their processing information and error status.

Impact to Customers

When duplicate sample IDs are used for multiple replicates of a sample, calibrator or control in the same run:

- some samples may not be included in the Plate Report
- some duplicate sample IDs are reassigned a unique identifier by the software
- a warning message is displayed in the Plate Report

Refer to Appendix A for details regarding this issue.

Necessary Actions

To ensure proper function of the Plate Report, duplicate sample IDs should not be used on the m24sp. If two or more replicates of a sample, calibrator or control are being run, a unique sample ID should be used for each of the replicates.

Please review this information with laboratory personnel and retain this communication for future reference. If you have any questions regarding this communication, please contact your local Abbott Molecular representative.

We apologize for any inconvenience this issue may have created for your laboratory.

Sincerely,

A handwritten signature in black ink, appearing to read 'Julio Salwen'.

Julio Salwen
Quality Assurance
Abbott Molecular Inc.



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Appendix A

Scenario 1: When duplicate sample IDs are located in **one sample rack** the following would be observed:

1. All samples in the run will be shown in the Plate Report.
2. For samples with a duplicate ID, the last processed sample will retain the original ID. The other replicates are automatically assigned different unique identifiers (alphanumeric characters consisting of the testing date, rack serial number and sample position). The unique identifier is shown in the Plate Report.

See screenshot below where two Negative controls (positions A02 and A13) and two Cut Off Controls (positions A03 and A14) were included in the same sample rack in an m24sp run.

Plate Report Extended

2014040110242689062



Last action: 4/1/2014 10:44:43 AM

| Position | Sample Id | Volume | Concentration | Unit | Error List |
|----------|------------------------------|--------|---------------|------------|------------|
| A01 | Internal Control | -3200 | 1 | calculated | ok |
| A01 | Internal Control | -2250 | 1 | calculated | ok |
| A02 | 2014040110242689 062_A002 | -425 | 1 | calculated | ok |
| A03 | 2014040110242689 062_A003 | -425 | 1 | calculated | ok |
| A04 | PATIENT 1 | -425 | 1 | calculated | ok |
| A05 | PATIENT 2 | -425 | 1 | calculated | ok |
| A06 | PATIENT 3 | -425 | 1 | calculated | ok |
| A07 | PATIENT 4 | -425 | 1 | calculated | ok |
| A08 | PATIENT 5 | -425 | 1 | calculated | ok |
| A09 | PATIENT 6 | -425 | 1 | calculated | ok |
| A10 | PATIENT 7 | -425 | 1 | calculated | ok |
| A11 | PATIENT 8 | -425 | 1 | calculated | ok |
| A12 | PATIENT 9 | -425 | 1 | calculated | ok |
| A13 | CTNG_NEG | -425 | 1 | calculated | 3,i3,0 |
| A14 | CTNG_COC | -425 | 1 | calculated | 3,i3,0 |

3. A warning number is displayed in the Error List column of the Plate Report for last processed duplicate ID with message: "An identical barcode was scanned at an unexpected grid position."

See screenshot below.

Plate Report Extended

2014040110242689062



Last action: 4/1/2014 10:44:43 AM

| Errornumber (i = inherited) | Description | Errorlevel |
|-----------------------------|---|------------|
| 3 | An identical barcode was scanned at an unexpected grid position | Warning |



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Scenario 2: When duplicate IDs are located in both sample racks the following would be observed:

1. Only those samples located in the first sample rack (Internal Control Rack) will be shown in the Plate Report. ***ALL the samples in the second sample rack will not be included in the Plate Report***
2. For samples with a duplicate ID, the last processed sample in the first sample rack will retain the original ID. The other replicates are assigned the unique identifiers as described in observation 2 above. The unique identifier is shown in the Plate Report.
3. A warning number is displayed in the Error List column of the Plate Report for ALL samples with message: "Warning Macro aborted. Reason: ST Database returned an error for barcode: XXX."

See screenshot below.

Plate Report Extended

2014040113032703125



Last action: 4/1/2014 1:21:59 PM

| Errornumber (i = inherited) | Description | Errorlevel |
|-----------------------------|--|------------|
| 48 | Warning Macro aborted. Reason: ST Database returned an error for barcode: CTNG_NEG | Warning |