

URGENT: MEDICAL DEVICE RECALL NOTIFICATION
Gibco® Gurr Buffer Tablets
(Catalog #: 10582-013, Lot Numbers 2137716 and 2142056)

| Product Name | UDI | Catalog Number | Lot Number | Expiration Date |
|---------------------|----------------|----------------|------------|-----------------|
| Gurr Buffer Tablets | 10190302001540 | 10582-013 | 2137716 | 30APR2020 |
| Gurr Buffer Tablets | 10190302001540 | 10582-013 | 2142056 | 30APR2022 |

Institution: «Mailing Name»
Address: «Address Line 4»
«Address Line 1»
«Address Line 2»
«Address Line 3»
«City», «State» «Postal Code»

Date: «Date»

Dear Device Customer/Distributor,

We have become aware through customer complaints that two (2) lots of Gibco® Gurr Buffer Tablets (Catalog #: 10582-013, lot numbers 2137716 and 2142056) contain an incorrect/smaller tablet size. Upon investigation, it was determined that the tablets are one tenth the size of the tablets from previous lots (80g vs. 800g).

Please note that other than the tablet size, the chemical composition is identical, and the tablets can still be used by following the modified reconstitution instructions included on the next page.

How to recognize that the device may fail:

- The lot number on the product label matches either of the two lot numbers listed above
- The smaller tablets are 4 – 4.5mm in diameter and weigh approximately 80 grams. They are significantly smaller than tablets from past lots (11-11.5mm in diameter).
- If used, Giemsa staining with over-diluted Gurr buffer may cause inconclusive/unreadable test results

Actions Requested

Please examine your inventory immediately to determine if you have any of the smaller tablets on hand.

Notify all affected users in your facility. If you have shipped this lot outside of your facility, you must notify those customers or facilities of this correction.

Modified Reconstitution Instructions

Reconstitute the 80g smaller buffer tablets using 100 mL of distilled water instead of 1L as indicated on the product labeling. If your procedures require 1L of buffer, then you must use 10 of the smaller 80g buffer tablets to prepare the buffer solution.

Risk to Health

Life Technologies (Thermo Fisher Scientific) has no reason to believe that use of or exposure to product under recall will directly cause any serious adverse health consequences (e.g. Death, Life Threatening, Results in Permanent Impairment).

Thermo Fisher Scientific is committed to providing high quality products every day and we have initiated corrective and preventative actions to prevent such an event from occurring again. We will be updating the product labeling to 50 x 100mL instead of 50 x 1L to account for this change in tablet size.

Please complete the following Customer Response Sheet and outline your request of credit for the remaining material. Submit the sheet by emailing a scanned copy to techsupport@thermofisher.com.

We appreciate your assistance and apologize for any inconvenience. If you have any questions, please call Technical Support, at NA --800-955-6288 option 4, EMEA – 00 800 5345 5345 option 3, or eurotech@thermofisher.com

Sincerely,

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PLEASE FORWARD TO END USER

CUSTOMER RESPONSE
Acknowledgement and Receipt Form

Gurr Buffer Tablets (Catalog #: 10582-013)
(Customer response is required)

| Lot Number | Number of Bottles Corrected to 100mL dilution |
|------------|---|
| 2137716 | |
| 2142056 | |

Customer Name and Address:

Any adverse events associated with recalled product? YES NO

If yes, please explain:

I have read and understand the instructions provided in the letter dated «Date» YES NO

I request the following:

Credit my account

No request

I will use the tablets per the updated instructions

I have shipped affected lots to other facilities and notified them

YES

NO

If "YES," describe the method of notification & number of facilities notified:

Customer Signature of Receipt: _____ **Date:** _____

Please email a copy to ts.productinfo@thermofisher.com. For any questions or comments please contact Technical Support at 1-800-955-6288.

Ship-To Order Number: «Order Number» Thermo Fisher Scientific Reference Number: [PR423912](#)