



3<sup>rd</sup> September 2020

To [Wholesalers/Hospital/Healthcare Professional/Pharmacy]

## **URGENT MEDICAL DEVICE RECALL**

**SBM Pregnancy cassette test 25mIU/ml**

**Medsafe reference No.: 26499**

**Supplier code: PREGC40 / 2544873**

**WAND number: 161211-WAND-6N816U**

### **Affected Batch and Expiry**

- Batch HCG19110040 exp 2022-11
- Batch HCG19120028 exp 2022-12

Supplied in kits of 40 tests, 20 kits per carton

### **Issue**

It has come to our attention that due to issues with the affected batches of the SBM pregnancy cassette test, it is appropriate to recall this batch. We have made this decision after consultation with Medsafe.

Please be advised that this recall only applies to the above batch numbers, other batches of these pregnancy cassette test are not affected by this recall action.

Issues include:

- False positives
- Ink remains blurry within the reading panel to an extent that no lines are discernable (Note: the ink will run initially for anything up to 3 minutes as normal but then clear)

### **Action**

Please:

- Immediately check / inspect stock, cease using and quarantine affected stock to prevent further use.
- Notify other relevant staff and/or locations that you may have supplied stock, of this recall.
- Please complete the attached document that outlines the batch (even if no affected stock is held) and quantity you may have and scan back to the e-mail provided.
- Please continue to display this letter in a prominent place for at least one month.

On receipt of the documentation, Smith Biomed will be in contact to:

- Replace the affected stock with a different batch and
- Arrange pickup of the affected tests to return to SBM for quarantine and destruction.
- Pregnancy test kits are only intended to provide indicative results. If the result obtained is inconclusive or different to that expected then the instructions for use recommend retesting. Any doubt can be confirmed by doing a blood test.

This recall action is being undertaken by Smith Biomed (NZ) Ltd, after consultation with Medsafe, Ministry of Health New Zealand. We apologise for the inconvenience caused by the recall.

**Company Contact Number:** Phone: 0508 246 633 email : [info@smithbiomed.com](mailto:info@smithbiomed.com)

John Spurway,  
Executive Director  
Smith Biomed Ltd



## URGENT MEDICAL DEVICE RECALL

### Acknowledgment and Inventory Form

**SBM Pregnancy cassette test 25mIU/ml**  
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#### Affected Batch and Expiry

- Batch HCG19110040 exp 2022-11
- Batch HCG19120028 exp 2022-12

Smith Biomed (NZ) Ltd  
Federated Farmers Building  
15 Young Street  
New Plymouth 4342

Scan and email reply to [info@smithbiomed.com](mailto:info@smithbiomed.com)

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From:

Contact Person:

Telephone Number:

Address (for replacement stock) :  
\_\_\_\_\_

We are holding the following quantity of SBM Tests Kits as follows:

Batch HCG19110040 number of full boxes \_\_\_\_\_ number of single tests \_\_\_\_\_

Batch HCG19120028 number of full boxes \_\_\_\_\_ number of single tests \_\_\_\_\_

We confirm we have no other quantities on hand of the above batches

Signature \_\_\_\_\_

Position \_\_\_\_\_

Date \_\_\_\_\_