

March 2016

To: Our dear clients

Sysmex Corporation  
Quality Assurance and Regulatory Affairs division, Quality Assurance

**Announcement for voluntary recall and stop supply of Lynoamp® BC**

Thank you very much for your patronage on our products and services.

Today, we regret to inform you that the possibility has been revealed that a positive rate is high compared with past product "LYNOAMP BC" for OSNA® marketed and manufactured by our company. Regarding the issue, we would like to voluntarily recall the product of the corresponding lots shown below.

We deeply apologize for causing so much trouble to you.

Though we do try to identify root cause, we don't promise the supply of Lynoamp® BC at present. So please respond by alternative procedure such as tissue diagnosis by restart supply of this product.

1. Relevant product

Product code	Product name	Lot No.	JAN code	Expiry date
06428017	LYNOAMP BC	ZS5008	4987562412723	October 31,2016

We don't recognize this issue against another Lot No. except above Lot No.

2. Defects and their cause

There is the possibility of difference of reactivity between actual sample and calibrator for objective Lot No. and influence of primer which is one of this kit components and main material, but we don't identify root cause at present.

3. Risk to health when objective lot No. is used

There is the possibility of false positive for partial actual sample which was measured "Negative" on past, and there is the possibility of and implementing unnecessary medical procedure.

4. Actions to be taken by the Customer

- 1) If you have the products on hand, please stop using. Also, please inform to your customer support person and send back them to us.
- 2) Though we do try to identify root cause, we don't promise the supply of Lynoamp® BC at present. So please respond by alternative procedure such as tissue diagnosis by restart supply of this product.
- 3) We guess that the degree of false positive is different by each hospital. If you would like to know it, please offer to your customer support person since the person will go and explain it to you by bringing exchange formula as your reference.

## 5. Contact

If you have any questions, please contact following division.

Sysmex corporation

Life Science Product Engineering, Marketing

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