

Field Safety Notice (FSN 02.2016)**Quantum Blue® Calprotectin Assay**
Quantum Blue® Calprotectin High Range

Date: 2016-08-11

Incorrect Expiration Date

Dear Customer,

Our records indicate that your facility received one of the following products:

| Product | Catalog order code | Lot Number | Expiry date |
|---------------------------------------|--------------------|------------|-------------|
| Quantum Blue® Calprotectin Assay | LF-CAL25 | 2930N | 2017-07-31 |
| Quantum Blue® Calprotectin Assay | LF-CAL25-U | 2930N.U | 2017-07-31 |
| Quantum Blue® Calprotectin High Range | LF-CHR25 | 2930N.HR | 2017-04-30 |
| Quantum Blue® Calprotectin High Range | LF-CHR25-HR.U | 2930N.HR.U | 2017-04-30 |

We are notifying you that BÜHLMANN has identified a typographical error in the Quantum Blue® Calprotectin Assay kits mentioned above. **The printed expiration date on the labelling of the kits is incorrect.** The correct expiration date for Quantum Blue® Calprotectin Assay is

| Product | Catalog order code | Lot Number | Expiry date |
|---------------------------------------|--------------------|------------|-------------------|
| Quantum Blue® Calprotectin Assay | LF-CAL25 | 2930N | 2016-12-31 |
| Quantum Blue® Calprotectin Assay | LF-CAL25-U | 2930N.U | 2016-12-31 |
| Quantum Blue® Calprotectin High Range | LF-CHR25 | 2930N.HR | 2016-12-31 |
| Quantum Blue® Calprotectin High Range | LF-CHR25-HR.U | 2930N.HR.U | 2016-12-31 |

Risk to Health: There is no risk to health if products are consumed within the shelf life of December 31st, 2016.

To prevent customers to use afore mentioned kits beyond the true shelf life of December 31st, 2016, we kindly ask you to comply with the following:

- Identify and notify your customers having received afore mentioned kits. You may include a copy of this letter in your notification to your customers.
- Be advised that this notification does not impact any consumed kit or patient results generated with these kit.
- Check your stocks for Quantum Blue® Calprotectin Assay Kits about the above mentioned lots and add a copy of this letter inside each kit and close the Kit again.
- Customers receiving such kits shall be informed additionally about the correct expiration date of the kit. You may use this letter for such notification to customers.
- Complete and return the Field Correction Effectiveness Check attached to this letter within 30 days.

We sincerely apologize for any inconvenience caused as a result of this Field Safety Notice. BÜHLMANN is committed to offering quality products and superior customer service. If you have any questions or comments arising from this Field Safety Notice, please contact our **Product Support** at: