

December 2016

## **Field Safety Notice Decreased Calibrator Slope For Toxo IgM**

Dear Bio-Rad Customer,

This notification is regarding the BioPlex 2200 ToRC IgM Calibrator Set (Catalog No. 663-1700 and Lot No. 49659) and BioPlex 2200 ToRC IgM Control Set (Catalog No. 663-1730 and Lot No. 49526). During routine stability testing at the Norwest Manufacturing facility, a decreased calibrator slope was observed for Toxo IgM in the effected lots of BioPlex 2200 ToRC IgM Calibrator and Control Sets. The observed issue only affects the Toxo IgM results, and does not affect the Rubella IgM and CMV IgM results.

The observed decrease in calibrator slope for Toxo IgM in the effected lots of BioPlex ToRC IgM Calibrator and Control Sets presents the potential for a small increase in valid false negative results. Therefore, Bio-Rad is requesting to immediately discontinue use of the affected lots of BioPlex ToRC IgM Calibrator and Control Sets.

Please check your inventory for the product listed below. If you have received this product, complete the attached customer response form and return it to your local Bio-Rad Technical Support.

- BioPlex 2200 ToRC IgM Calibrator Set (Catalog No. 663-1700 and Lot No. 49659)
- BioPlex 2200 ToRC IgM Control Set (Catalog No. 663-1730 and Lot No. 49526).

Please contact your local Technical Support for replacement product and dispose of the effected lots according to local waste management procedures.

Thank you in advance for your cooperation. We apologize for any inconvenience this may cause.

Sincerely,

CID Product Support

## Customer Response Form

Reference Number: 2950880-FCA16-007/2016-004

### Instructions:

1. Complete the information and sign where requested.
2. Please fax completed response form to your local Bio-Rad Technical Support number listed below.

Product	Catalog No.	Lot No.	Number of Sets
BioPlex 2200 ToRC IgM Calibrator Set	663-1700	49659	
BioPlex 2200 ToRC IgM Control Set	663-1730	49526	

Account Name:	
Customer Account Number:	
Contact Name / Title:	
Address:	
Telephone Number / Fax:	

### STATEMENT:

- ☐ I am aware of information about the field safety corrective action concerning the above referenced product and have proceeded according to the instructions issued by Bio-Rad.

Please fax complete response form to your local Bio-Rad Technical Support.

Bio-Rad Technical Support Fax Number:



**Bio-Rad  
Laboratories**

## Clinical Diagnostics Group

4000 Alfred Nobel Drive  
Hercules, California 94547  
Telephone (510) 724-7000  
FAX (510) 741-6373  
[www.bio-rad.com/diagnostics](http://www.bio-rad.com/diagnostics)

**Australia**, Bio-Rad Laboratories Pty. Ltd., Level 5, 446 Victoria Road, Gladesville NSW 2111 • Phone 61-2-9914-2800 • Telefax 61-2-9914-2888  
**Austria**, Bio-Rad Laboratories Ges.m.b.H., Hummelgasse 88/3-6, A-1130 Vienna • Phone 43-1-877-8901 • Telefax 43-1-876-5629  
**Belgium**, Bio-Rad S.A.-N.V. Winninglaan 3, BE-9140 Temse • Phone +32 (3)710-53-00 • Telefax +32 (3)710-53-01  
**Brazil**, Bio-Rad Laboratórios Brasil Ltda, Rua Alfredo Albano da Costa, 100, Lagoa Santa - MG, CEP: 33400-000 • Phone +55 (31)3689-6600 • Telefax +55 (31)3689-6611  
**Canada**, Bio-Rad Laboratories, Ltd., 2403 Guénette Street, Montréal, Québec H4R 2E9 • Phone 1-514-334-4372 • Telefax 1-514-334-4415  
**China**, Bio-Rad Laboratories Shanghai Ltd., 3rd Floor, #18 Dong Fang Road, Bldg E, Poly Plaza, Pudong, Shanghai, PRC 200120 • Phone 86-21-61698500 • Telefax 86-21-61698599  
**Czech Republic**, Bio-Rad spol. s r.o., Nad ostrovem 1119/7, 147 00 Prague 4 • Phone 420-241-430-532 • Telefax 420-241-431-642  
**Denmark**, Bio-Rad Laboratories, Symbion Science Park, Fruebjergvej 3, DK-2100 Copenhagen East • Phone +45-4452-1000 • Telefax +45-4452-1001  
**Finland**, Bio-Rad, 3 boulevard Raymond Poincaré, 92430 Marnes-la-Coquette • Phone 33-1-47-95-60-00 • Telefax 33-1-47-41-91-33  
**France**, Bio-Rad, 3 boulevard Raymond Poincaré, 92430 Marnes-la-Coquette • Phone 33-1-47-95-60-00 • Telefax 33-1-47-41-91-33  
**Germany**, Bio-Rad Laboratories GmbH, Heidemannstrasse 164, D-80939 Munich • Phone +49 (0)89-318-840 • Telefax +49 (0)89-318-84100  
**Greece**, Bio-Rad Laboratories M.E.P.E., 2-4 Mesogeion Street, Fourth Floor 115 27 Athens • Phone 30-210-7774396 • Telefax 30-210-7774376  
**Hong Kong**, Bio-Rad Pacific Ltd., Unit 1101, 11/F DCH Commercial Centre, 25 Westlands Road, Quarry Bay • Phone 852-2789-3300 • Telefax 852-2789-1290  
**Hungary**, Bio-Rad Hungary Ltd., H-1082 Budapest, Futo Street 47-53, Hungary • Phone +36-1-459-6100 • Telefax +36-1-459-6101  
**India**, Bio-Rad Laboratories (India) Pvt. Ltd., Bio-Rad House, 86-87, Udyog Vihar Phase IV, Gurgaon, Haryana 122 015 • Phone 1800-180-1224 • Telefax 91-124-2398115  
**Israel**, Bio-Rad Laboratories Ltd., 14 Homa Street, New Industrial Area, Rishon Le Zion 75655 • Phone 972-9-9636050 • Telefax 972-3-9514129  
**Italy**, Bio-Rad Laboratories S.r.l., Via Cellini 18/A, 20090 Segrate, Milan • Phone +39-02-216091 • Telefax +39-02-21609553  
**Japan**, Bio-Rad Laboratories K.K., Tennoz Central Tower 20F, 2-2-24 Higashi-Shinagawa, Shinagawa-ku, Tokyo 140-0002 • Phone 81-3-6361-7070 • Telefax 81-3-5463-8481  
**Korea**, Bio-Rad Korea Ltd., 10th Floor, Hyunjuk Building, 832-41, Gangnam-gu, Seoul 135-080 • Phone 82-2-3473-4460 • Telefax 82-2-3472-7003  
**Mexico**, Bio-Rad, S.A., Avenida Eugenia 197, Piso 10-A, Col. Narvarte, C.P. 03020 Mexico, D.F. • Phone +52 (55)5488-7670 • Telefax +52 (55)1107-7246  
**The Netherlands**, Bio-Rad Laboratories B.V., Fokkerstraat 2-8, 3905 KV Veenendaal • Phone +31-318-540666 • Telefax +31-318-542216  
**New Zealand**, Bio-Rad New Zealand, 189 Bush Road Unit B, Albany, Auckland • Phone 64-9-415-2280 • Telefax 64-9-415-2284  
**Spain**, Bio-Rad Laboratories, Nydalsveien 33, 0484 Oslo • Phone +47-23-38-41-30 • Telefax +46(0)8-5551-2780  
**Poland**, Bio-Rad Polska Sp. z o.o., Nakielska Str. 3, 01-106 Warsaw • Phone 48-22-3319999 • Telefax 48-22-3319998  
**Portugal**, Bio-Rad Laboratories, Lda., Edificio Prime, Ave. Quinta Grande, 53 - Fração 3B Alfragide 26114-521 Amadora • Phone 351-21-472-7700 • Telefax 351-21-472-7777  
**Russia**, Bio-Rad Laboratorii, 117105, Russian Federation, Moscow, Varshavskoe sh., 9, Bldg., 1B • Phone +7-495-721-1404 • Telefax +7-495-721-1412  
**Singapore**, Bio-Rad Laboratories (Singapore) Pte. Ltd., 27 International Business Park, #01-02 iQuest @IBP, Singapore 609924 • Phone 65-6415-3170 • Telefax 65-6415-3189  
**South Africa**, Bio-Rad Laboratories (Pty) Ltd., 34 Bolton Road, Parkwood, Johannesburg 2193 • Phone 27-11-442-85-08 • Telefax 27-11-442-85-25  
**Switzerland**, Bio-Rad Laboratories, S.A., C/ Caléndula, 95, Edificio M. Miniparc II, El Soto de la Moraleja, 28109 Madrid • Phone 34-91-590-5200 • Telefax 34-91-590-5211  
**Sweden**, Bio-Rad Laboratories A.B., Box 1097, Solna Strandväg 3, SE-171 54, Solna • Phone +46-8-555-127-00 • Telefax +46-8-555-127-80  
**Switzerland**, Bio-Rad Laboratories AG, Pra Rond 23, CH-1785 Cressier • Phone +41 (0)26-674-55-05/06 • Telefax +41 (0)26-674-52-19  
**Taiwan**, Bio-Rad Laboratories Taiwan Ltd., 14F-B, No. 126 Nan-King East Road, Sec. 4, Taipei, Taiwan 10546 R.O.C. • Phone 886-2-2578-7189 • Telefax 886-2-2578-6890  
**Thailand**, Bio-Rad Laboratories Ltd., 1st & 2nd Floor, Lumpini I Bldg., 239/2 Rajdamri Road, Lumpini, Pathumwan, Bangkok 10330 • Phone 662-651-8311 • Telefax 662-651-8312  
**United Kingdom**, Bio-Rad Laboratories Ltd., Bio-Rad House, Maxted Road, Hemel Hempstead, Herts HP2 7DX • Phone +44 (0)20-8328-2000 • Telefax +44 (0)20-8328-2550

**Effective Date: December 2016**