

May 13, 2015

URGENT PRODUCT NOTIFICATION
Revised Assay Sheets for VITROS® Performance Verifier I

Please distribute this information to the appropriate personnel at your facility

Dear Valued Customer,

This notification provides information regarding revisions to the Range of Means for VITROS® Performance Verifier I for unconjugated bilirubin (Bu) only. The following lots of Performance Verifiers have been revised:

Revised Lots of VITROS® Performance Verifier I (Product Code 8067324)	Performance Verifier I Expiry Date
A3823	2016-11-10
C4084	2017-03-02
Q2961	2015-09-30
T3161	2015-12-31
V3297	2016-03-31
X3569	2016-06-30
NOTE: All in date Generations (GENs) for Bu contain revised Range of Means. There are no changes to conjugated bilirubin (Bc) values.	

Revised Range of Means for VITROS® Performance Verifier I (Bu only)

The Range of Means (ROM) for the lots listed above has been revised for unconjugated bilirubin (Bu). Based upon customer feedback and our internal assessment, the ROMs have been revised using criteria that are in alignment with current Ortho Clinical Diagnostic processes.

We anticipate that the Assay Sheets containing the revised Range of Means for Bu will be available on May 23, 2015. In the interim, please use the revised ranges provided in the enclosed document.

Required Actions

- 1) Use the enclosed revised Range Means for unconjugated bilirubin (Bu).
- 2) Upon availability, use the VITROS® Performance Verifier I Assay Sheets dated 2015-05-18 that will contain the revised Range of Means for Bu only.
- 3) Complete and return the **Customer Acknowledgement Form** within 2 business days to acknowledge your reading and understanding of this notice.

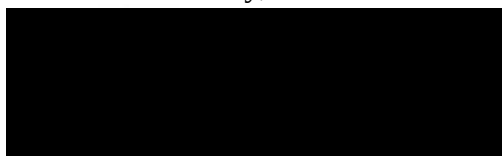
- 4) Forward this information if you have distributed this product outside of your facility.

Availability of Revised Assay Sheets for VITROS® Performance Verifier I (Bu only)

The revised ranges will be identified with a change box (■). The assay sheets dated 2015-05-18 contains the revised Range of Means and supersedes all previous versions. Assay Sheets are available on our website at www.orthoclinical.com in the IFU Library.

If you have any questions concerning this update, please call our Customer Technical Services at **1800 5646 766**.

Yours sincerely,



Lee Ching Hwee
Professional Affairs Executive

Attachment 1

Revised Range of Means for VITROS® Performance Verifier 1 for Unconjugated Bilirubin (Bu only)

Performance Verifier Lot A3823				
	Conventional Units (mg/dL)		SI Units (μmol/L)	
GEN	Current Range of Means	Revised Range of Means	Current Range of Means	Revised Range of Means
1	0.43 - 0.83	0.28 - 0.78	7.4 - 14.2	4.8 - 13.3
2	0.41 - 0.81	0.26 - 0.76	7.0 - 13.9	4.4 - 13.0
3	0.37 - 0.77	0.22 - 0.72	6.3 - 13.2	3.8 - 12.3
4	0.38 - 0.78	0.23 - 0.73	6.5 - 13.3	3.9 - 12.5
5	0.42 - 0.82	0.27 - 0.77	7.2 - 14.0	4.6 - 13.2
6	0.41 - 0.81	0.26 - 0.76	7.0 - 13.9	4.4 - 13.0
38	0.37 - 0.77	0.22 - 0.72	6.3 - 13.2	3.8 - 12.3
39	0.47 - 0.87	0.32 - 0.82	8.0 - 14.9	5.5 - 14.0
40	0.45 - 0.85	0.30 - 0.80	7.7 - 14.5	5.1 - 13.7
42	0.44 - 0.84	0.29 - 0.79	7.5 - 14.4	5.0 - 13.5
43	0.44 - 0.84	0.29 - 0.79	7.5 - 14.4	5.0 - 13.5
44	0.38 - 0.78	0.23 - 0.73	6.5 - 13.3	3.9 - 12.5
45	0.38 - 0.78	0.23 - 0.73	6.5 - 13.3	3.9 - 12.5
46	0.42 - 0.82	0.27 - 0.77	7.2 - 14.0	4.6 - 13.2
47	0.37 - 0.77	0.22 - 0.72	6.3 - 13.2	3.8 - 12.3
48	0.34 - 0.74	0.19 - 0.69	5.8 - 12.7	3.2 - 11.8
49	0.38 - 0.78	0.23 - 0.73	6.5 - 13.3	3.9 - 12.5
Note: GEN 26 is not supported				

Performance Verifier Lot C4084				
	Conventional Units (mg/dL)		SI Units (μmol/L)	
GEN	Current Range of Means	Revised Range of Means	Current Range of Means	Revised Range of Means
1	0.43 - 0.83	0.28 - 0.78	7.4 - 14.2	4.8 - 13.3
2	0.41 - 0.81	0.26 - 0.76	7.0 - 13.9	4.4 - 13.0
3	0.37 - 0.77	0.22 - 0.72	6.3 - 13.2	3.8 - 12.3
4	0.40 - 0.80	0.25 - 0.75	6.8 - 13.7	4.3 - 12.8
5	0.41 - 0.81	0.26 - 0.76	7.0 - 13.9	4.4 - 13.0
6	0.40 - 0.80	0.25 - 0.75	6.8 - 13.7	4.3 - 12.8
39	0.46 - 0.86	0.31 - 0.81	7.9 - 14.7	5.3 - 13.9
40	0.45 - 0.85	0.30 - 0.80	7.7 - 14.5	5.1 - 13.7
42	0.40 - 0.80	0.25 - 0.75	6.8 - 13.7	4.3 - 12.8
43	0.43 - 0.83	0.28 - 0.78	7.4 - 14.2	4.8 - 13.3
44	0.40 - 0.80	0.25 - 0.75	6.8 - 13.7	4.3 - 12.8
45	0.39 - 0.79	0.24 - 0.74	6.7 - 13.5	4.1 - 12.7
46	0.44 - 0.84	0.29 - 0.79	7.5 - 14.4	5.0 - 13.5
47	0.36 - 0.76	0.21 - 0.71	6.2 - 13.0	3.6 - 12.1
48	0.36 - 0.76	0.21 - 0.71	6.2 - 13.0	3.6 - 12.1
49	0.36 - 0.76	0.21 - 0.71	6.2 - 13.0	3.6 - 12.1
Note: GENs 26 and 38 are not supported				

Performance Verifier Lot Q2961				
	Conventional Units (mg/dL)		SI Units (μmol/L)	
GEN	Current Range of Means	Revised Range of Means	Current Range of Means	Revised Range of Means
1	0.39 - 0.79	0.24 - 0.74	6.7 - 13.5	4.1 - 12.7
2	0.35 - 0.75	0.20 - 0.70	6.0 - 12.8	3.4 - 12.0
3	0.45 - 0.85	0.30 - 0.80	7.7 - 14.5	5.1 - 13.7
4	0.42 - 0.82	0.27 - 0.77	7.2 - 14.0	4.6 - 13.2
5	0.44 - 0.84	0.29 - 0.79	7.5 - 14.4	5.0 - 13.5
6	0.41 - 0.81	0.26 - 0.76	7.0 - 13.9	4.4 - 13.0
26	0.35 - 0.75	0.20 - 0.70	6.0 - 12.8	3.4 - 12.0
38	0.42 - 0.82	0.27 - 0.77	7.2 - 14.0	4.6 - 13.2
39	0.43 - 0.83	0.28 - 0.78	7.4 - 14.2	4.8 - 13.3
40	0.42 - 0.82	0.27 - 0.77	7.2 - 14.0	4.6 - 13.2
42	0.43 - 0.83	0.28 - 0.78	7.4 - 14.2	4.8 - 13.3
43	0.44 - 0.84	0.29 - 0.79	7.5 - 14.4	5.0 - 13.5
44	0.45 - 0.85	0.30 - 0.80	7.7 - 14.5	5.1 - 13.7
45	0.44 - 0.84	0.29 - 0.79	7.5 - 14.4	5.0 - 13.5
46	0.40 - 0.80	0.25 - 0.75	6.8 - 13.7	4.3 - 12.8
47	0.42 - 0.82	0.27 - 0.77	7.2 - 14.0	4.6 - 13.2
48	0.40 - 0.80	0.25 - 0.75	6.8 - 13.7	4.3 - 12.8
49	0.45 - 0.85	0.30 - 0.80	7.7 - 14.5	5.1 - 13.7

Performance Verifier Lot T3161				
	Conventional Units (mg/dL)		SI Units (μmol/L)	
GEN	Current Range of Means	Revised Range of Means	Current Range of Means	Revised Range of Means
1	0.45 - 0.85	0.30 - 0.80	7.7 - 14.5	5.1 - 13.7
2	0.42 - 0.82	0.27 - 0.77	7.2 - 14.0	4.6 - 13.2
3	0.50 - 0.90	0.35 - 0.85	8.5 - 15.4	6.0 - 14.5
4	0.47 - 0.87	0.32 - 0.82	8.0 - 14.9	5.5 - 14.0
5	0.50 - 0.90	0.35 - 0.85	8.5 - 15.4	6.0 - 14.5
6	0.47 - 0.87	0.32 - 0.82	8.0 - 14.9	5.5 - 14.0
26	0.41 - 0.81	0.26 - 0.76	7.0 - 13.9	4.4 - 13.0
38	0.46 - 0.86	0.31 - 0.81	7.9 - 14.7	5.3 - 13.9
39	0.48 - 0.88	0.33 - 0.83	8.2 - 15.0	5.6 - 14.2
40	0.46 - 0.86	0.31 - 0.81	7.9 - 14.7	5.3 - 13.9
42	0.49 - 0.89	0.34 - 0.84	8.4 - 15.2	5.8 - 14.4
43	0.50 - 0.90	0.35 - 0.85	8.5 - 15.4	6.0 - 14.5
44	0.51 - 0.91	0.36 - 0.86	8.7 - 15.6	6.2 - 14.7
45	0.51 - 0.91	0.36 - 0.86	8.7 - 15.6	6.2 - 14.7
46	0.47 - 0.87	0.32 - 0.82	8.0 - 14.9	5.5 - 14.0
47	0.48 - 0.88	0.33 - 0.83	8.2 - 15.0	5.6 - 14.2
48	0.46 - 0.86	0.31 - 0.81	7.9 - 14.7	5.3 - 13.9
49	0.51 - 0.91	0.36 - 0.86	8.7 - 15.6	6.2 - 14.7
Performance Verifier Lot V3297				

Ortho Clinical Diagnostics

PART OF THE *Johnson & Johnson* FAMILY OF COMPANIES

	Conventional Units (mg/dL)		SI Units (μmol/L)	
GEN	Current Range of Means	Revised Range of Means	Current Range of Means	Revised Range of Means
1	0.58 - 0.98	0.43 - 0.93	9.9 - 16.8	7.4 - 15.9
2	0.54 - 0.94	0.39 - 0.89	9.2 - 16.1	6.7 - 15.2
3	0.62 - 1.02	0.47 - 0.97	10.6 - 17.4	8.0 - 16.6
4	0.59 - 0.99	0.44 - 0.94	10.1 - 16.9	7.5 - 16.1
5	0.60 - 1.00	0.45 - 0.95	10.3 - 17.1	7.7 - 16.2
6	0.60 - 1.00	0.45 - 0.95	10.3 - 17.1	7.7 - 16.2
26	0.58 - 0.98	0.43 - 0.93	9.9 - 16.8	7.4 - 15.9
38	0.62 - 1.02	0.47 - 0.97	10.6 - 17.4	8.0 - 16.6
39	0.66 - 1.06	0.51 - 1.01	11.3 - 18.1	8.7 - 17.3
40	0.62 - 1.02	0.47 - 0.97	10.6 - 17.4	8.0 - 16.6
42	0.61 - 1.01	0.46 - 0.96	10.4 - 17.3	7.9 - 16.4
43	0.60 - 1.00	0.45 - 0.95	10.3 - 17.1	7.7 - 16.2
44	0.62 - 1.02	0.47 - 0.97	10.6 - 17.4	8.0 - 16.6
45	0.60 - 1.00	0.45 - 0.95	10.3 - 17.1	7.7 - 16.2
46	0.59 - 0.99	0.44 - 0.94	10.1 - 16.9	7.5 - 16.1
47	0.61 - 1.01	0.46 - 0.96	10.4 - 17.3	7.9 - 16.4
48	0.58 - 0.98	0.43 - 0.93	9.9 - 16.8	7.4 - 15.9
49	0.63 - 1.03	0.48 - 0.98	10.8 - 17.6	8.2 - 16.8

Performance Verifier Lot X3569				
	Conventional Units (mg/dL)		SI Units (μmol/L)	
GEN	Current Range of Means	Revised Range of Means	Current Range of Means	Revised Range of Means
1	0.44 - 0.84	0.29 - 0.79	7.5 - 14.4	5.0 - 13.5
2	0.40 - 0.80	0.25 - 0.75	6.8 - 13.7	4.3 - 12.8
3	0.49 - 0.89	0.34 - 0.84	8.4 - 15.2	5.8 - 14.4
4	0.45 - 0.85	0.30 - 0.80	7.7 - 14.5	5.1 - 13.7
5	0.49 - 0.89	0.34 - 0.84	8.4 - 15.2	5.8 - 14.4
6	0.47 - 0.87	0.32 - 0.82	8.0 - 14.9	5.5 - 14.0
26	0.48 - 0.88	0.33 - 0.83	8.2 - 15.0	5.6 - 14.2
38	0.44 - 0.84	0.29 - 0.79	7.5 - 14.4	5.0 - 13.5
39	0.52 - 0.92	0.37 - 0.87	8.9 - 15.7	6.3 - 14.9
40	0.51 - 0.91	0.36 - 0.86	8.7 - 15.6	6.2 - 14.7
42	0.52 - 0.92	0.37 - 0.87	8.9 - 15.7	6.3 - 14.9
43	0.52 - 0.92	0.37 - 0.87	8.9 - 15.7	6.3 - 14.9
44	0.48 - 0.88	0.33 - 0.83	8.2 - 15.0	5.6 - 14.2
45	0.48 - 0.88	0.33 - 0.83	8.2 - 15.0	5.6 - 14.2
46	0.49 - 0.89	0.34 - 0.84	8.4 - 15.2	5.8 - 14.4
47	0.51 - 0.91	0.36 - 0.86	8.7 - 15.6	6.2 - 14.7
48	0.43 - 0.83	0.28 - 0.78	7.4 - 14.2	4.8 - 13.3
49	0.48 - 0.88	0.33 - 0.83	8.2 - 15.0	5.6 - 14.2