



INTERNATIONAL, INC.

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June 23, 2022

Change Notification: CN-0007, Shelf life extension for SCoV-2 Ag *Detect*TM Rapid Self-Test (Over the Counter, OTC)

Impacted product(s): SCoV-2 Ag *Detect*TM Rapid Self-Test (CAGS-2)

Description of change(s):

Effective immediately, the shelf life of the SCoV-2 Ag *Detect*TM Rapid Self-Test has been extended to 13 months, when stored at 15 – 30°C. This change has been approved by the US Food and Drug Administration (FDA) as part of EUA210619/S005. A list of impacted kit lots is included below. Expiration dates for any kit lots not included below must be followed as provided on the relevant packaging.

Kit Lot Number	Labelled Expiration Date	Updated Kit Expiration Date
BA6335, BA6336, BA6349, BA6560, BB6177, BB6241, BB6242, BB6243, BB6294, BB6295, BB6323, BB6324, BB6515, BB6550, BC6184, BC6526, BC6528, BC6529	07/2022	02/2023
BB6463, BB6513, BC6527	08/2022	03/2023
BC6139, BC6141, BC6142	09/2022	04/2023
BB6468, BB6469, BB6470, BB6471, BB6512, BB6514	11/2022	03/2023
BC6424, BC6488, BC6579, BC6581, BD6435, BD6446	12/2022	04/2023
BC6312, BC6140, BC6309, BC6310, BC6311, BC6423, BC6425, BC6426, BC6427, BC6462, BC6463, BC6578, BC6580, BC6582, BC6583, BC6584, BC6585, BD6038, BD6436, BD6437, BD6438, BD6439, BD6440, BD6441, BD6445	01/2023	04/2023
BD6039, BD6040, BD6041, BD6042, BD6043, BD6044, BD6045, BD6392, BD6393, BD6394, BD6395, BD6431, BD6432, BD6434, BD6468, BD6471, BD6484, BD6551, BD6555, BD6556, BD6594, BD6605, BD6606, BD6636, BD6640, BD6641, BD6655, BD6684, BD6696, BD6757, BD6758, BD6759, BD6760, BD6847, BD6848, BD6863, BD6864, BE6034, BE6092, BE6137, BE7018, BD6690	02/2023	05/2023
BD6931, BE6024, BE6089, BE6091, BE6138, BE6178, BE6206, BE6235, BE6274, BE6289, BE6290, BE6291, BE6368, BE6418, BE6419, BE6445, BE6474, BE6491, BE6530, BE6538, BE6589, BE6599, BE6637, BE6638, BE6646, BE6687, BE6696, BE6697, BE6698, BE6737, BE6786, BE6787, BE6788, BE6788, BE6806, BE6844, BE6845, BE6856, BE6909, BE6978, BE6979, BE7015, BE7079, BF6041, BF6127	03/2023	06/2023
BF6181	04/2023	07/2023
BE6408, BE7058, BE7059, BE7060	05/2023	06/2023
BF6034, BF6035, BF6120, BF6121, BF6243, BF6253, BF6299, BF6361, BF6398, BF6449, BF6451, BF6564, BF6565, BF6566, BF6567	05/2023	07/2023



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Reason for change(s):

Shelf life extension has been approved by US FDA based on results provided from ongoing real-time stability monitoring.

Effective date: May 26, 2022

Written and approved by:

Shivani Dharmaraja
Sr. Quality Control Manager, Regulatory Special Projects

June 23, 2022

Date