



INTERNATIONAL, INC.

307 Westlake Ave. N.

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March 22, 2022

Change Notification: Correction to CN-0005, Shelf life extension for SCoV-2 Ag *Detect*TM Rapid Test (Point-of-Care, POC)

Impacted product(s): SCoV-2 Ag *Detect*TM Rapid Test (Catalog Number COVAG-20, COVAG-RC)

Description of change(s):

CN-0005, Shelf life extension for SCoV-2 Ag *Detect*TM Rapid Test, was previously issued on March 10, 2022. This notification was in relation to product shelf life extension to 10 months. Upon further review, it was determined that incorrect information was provided for kit lot **BC6038**. Please see the table below for corrected information.

	Labelled Expiration Date	Updated Expiration Date
Previously listed (incorrect)	August 31, 2022	December 31, 2022
Update (correct)	September 30, 2022	January 31, 2023

A complete summary of lots impacted, with updated information for kit lot BC6038, is provided below.

Kit Lot Number	Labelled Expiration Date	Updated Expiration Date
AF6115, AF6233, AF6248, AF6307, AG6076, AG6110, AG6133, AH6061, AH6092, AH6095, AH6110, AH6211, AH6252, AH6253	December 31, 2021	April 30, 2022
AH6231, AH6232, AH6239, AH6284, AH6285, AH6330, AH6331	February 28, 2022	June 30, 2022
AJ6046, AJ6047, AJ6089, AJ6114, AJ6136, AJ6177, AJ6178, AJ6180, AJ6321, AJ6322, AJ6325, AJ6344, AJ6345, AJ6474, AJ6475, AK6016	March 31, 2022	July 31, 2022
AK6086, AK6087, AK6143, AK6144, AK6188, AK6189, AK6220, AK6226, AK6260, AK6268, AK6293, AK6294, AK6330, AK6369, AK6371, AK6373, AK6374, AK6403, AK6433, AK6461, AK6483, AL6028, AL6029, AL6059	April 30, 2022	August 31, 2022
AL6100, AL6101, AL6156, AL6187, AL6189, AL6209, AL6230, AL6231, AL6294, AL6296, AL6320, AL6336, AL6339, AL6357, AL6372, AL6414, AL6415, AL6416, AL6510, AL6511, AL6537, AM5042, AM6037, AM6039, AM6041, AM6042, AM6043	May 31, 2022	September 30, 2022
AM6168, AM6169, AM6210, AM6237, AM6268, AM6292, AM6331, AM6356, AM6418, AM6435, AM6443, AM6456, BA6037, BA6038, BA6039, BA6126, BA6214, BA6247, BA6248, AM6485	June 30, 2022	October 31, 2022



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BA6154, BA6112, BA6121, BA6123, BA6135, BA6136, BA6201, BA6202, BA6219, BA6291, BA6315, BA6327, BA6328, BA6338, BA6362, BA6363, BA6388, BA6559, BB6032, BB6244, BB6245, BB6246, BB6247, BB6296, BB6318, BB6319, BB6320, BB6321, BB6322, BC6040	July 31, 2022	November 30, 2022
BB6462, BC6033, BC6034, BC6035, BC6036, BC6037, BC6039, BC6138	August 31, 2022	December 31, 2022
BC6038	September 30, 2022	January 31, 2023

We sincerely apologize for this confusion. Please do not hesitate to reach out if you have any further questions regarding this notification.

Written and approved by:

Shivani Dharmaraja

Sr. Quality Control Manager, Regulatory Special Projects

March 22, 2022

Date