MARKETING LETTER

Date:	April 2022
From:	Roche Diagnostics
To:	SARS-CoV-2 Rapid Antigen Test NASAL users
Subject:	SARS-CoV-2 Rapid Antigen Test Nasal Shelf Life Extension

Dear Valued Customer,

Roche Diagnostics is pleased to inform you of our recent Health Canada amendment of interim order license #328889 extending the shelf life of our finished product SARS-CoV-2 Rapid Antigen Test NASAL to 24 months.

In consequence, the device identifier 9901-NCOV-03G (Roche product code 09365397023 and 09365397043) has been approved by Health Canada for an extended expiration date.

The table below provides information on some affected lots, their CURRENT short dated expiration date and their NEW expiration date following this amendment.

Material Description	SARS-CoV-2 Rapid Antigen Test NASAL 25T.						
Product Code	Lot	CURRENT Kit Expiry date	NEW Kit Expiry date	Product Code	Lot	CURRENT Kit Expiry date	NEW Kit Expiry date
09365397023	381068II-2	8/16/2022	2/13/2023	09365397023	381093II-1	8/22/2022	2/19/2023
09365397023	381069II-1	8/16/2022	2/13/2023	09365397023	381093II-2	8/22/2022	2/22/2023
09365397023	381071II-2	8/16/2022	2/13/2023	09365397023	381094II-1	8/23/2022	2/22/2023
09365397023	381071II-3	8/17/2022	2/13/2023	09365397023	381094II-2	8/23/2022	2/19/2023
09365397023	381072II-1	8/17/2022	2/13/2023	09365397023	381094II-3	8/22/2022	2/19/2023
09365397023	381072II-2	8/17/2022	2/13/2023	09365397023	381094II-4	8/22/2022	2/22/2023
09365397023	381073II-2	8/17/2022	2/18/2023	09365397023	381095II-2	8/23/2022	2/22/2023
09365397023	381074II-1	8/17/2022	2/18/2023	09365397023	381096II-1	8/23/2022	2/22/2023
09365397023	381074II-2	8/17/2022	2/18/2023	09365397023	381096II-2	8/23/2022	2/22/2023
09365397023	381075II-1	8/17/2022	2/18/2023	09365397023	381097II-1	8/23/2022	2/22/2023
09365397023	381078II-3	8/21/2022	2/18/2023	09365397023	381097II-2	8/23/2022	2/22/2023
09365397023	381079II-1	8/21/2022	2/19/2023	09365397023	381099II-1	8/23/2022	2/22/2023
09365397023	381079II-2	8/21/2022	2/19/2023	09365397023	381099II-2	8/23/2022	2/22/2023
09365397023	381081II-1	8/21/2022	2/18/2023	09365397023	381100II-1	8/23/2022	2/22/2023
09365397023	381081II-2	8/21/2022	2/19/2023	09365397023	381108II-3	9/1/2022	2/22/2023
09365397023	381083II-2	8/21/2022	2/19/2023	09365397023	381108II-4	9/1/2022	2/24/2023
09365397023	381084II-2	8/22/2022	2/19/2023	09365397023	381109II-1	8/24/2022	2/23/2023
09365397023	381089II-1	8/17/2022	2/19/2023	09365397023	381118II-2	9/2/2022	2/24/2023
09365397023	381089II-2	8/22/2022	2/19/2023	09365397023	381119II-1	8/25/2022	2/26/2023
09365397023	381090II-4	8/23/2022	2/22/2023	09365397023	381123II-1	9/1/2022	2/26/2023
09365397023	381235II-2	9/14/2022	3/15/2023				

Material Description		SARS-CoV-2 Rapid Antigen Test NASAL 25T.					
Product Code	Lot	CURRENT Kit Expiry date	NEW Kit Expiry date	Product Code	Lot	CURRENT Kit Expiry date	NEW Kit Expiry date
09365397023	381123II-2	9/1/2022	3/2/2023	09365397023	381175II-1	9/9/2022	3/11/2023
09365397023	381124II-1	9/1/2022	3/2/2023	09365397023	381177II-1	9/10/2022	3/10/2023
09365397023	381124II-2	9/1/2022	3/2/2023	09365397023	381180II-1	9/9/2022	3/11/2023
09365397023	381125II-1	9/1/2022	3/2/2023	09365397023	381197II-1	9/11/2022	3/15/2023
09365397023	381125II-2	9/1/2022	3/2/2023	09365397023	381198II-2	9/14/2022	3/18/2023
09365397023	381127II-1	9/1/2022	3/2/2023	09365397023	381198II-3	9/14/2022	3/15/2023
09365397023	381129II-2	9/1/2022	3/3/2023	09365397023	381204II-1	9/15/2022	3/16/2023
09365397023	381150II-1	9/4/2022	3/5/2023	09365397043	381052II-2	5/9/2022	2/9/2023
09365397023	381150II-2	9/4/2022	3/5/2023	09365397043	381133II-2	9/2/2022	3/3/2023
09365397023	381152II-1	9/4/2022	3/8/2023	09365397043	381134II-1	9/2/2022	3/3/2023
09365397023	381156II-1	9/7/2022	3/5/2023	09365397043	381135II-2	9/2/2022	3/4/2023
09365397023	381157II-1	9/7/2022	3/8/2023	09365397043	381136II-1	9/3/2022	3/4/2023
09365397023	381157II-2	9/7/2022	3/9/2023	09365397043	381136II-3	9/2/2022	3/4/2023
09365397023	381160II-2	9/7/2022	3/9/2023	09365397043	381137II-1	9/3/2022	3/4/2023
09365397023	381165II-1	9/7/2022	3/10/2023	09365397043	381138II-1	9/3/2022	3/4/2023
09365397023	381166II-1	9/7/2022	3/10/2023	09365397043	381139II-1	9/3/2022	3/4/2023
09365397023	381170II-1	9/9/2022	3/10/2023	09365397043	381142II-1	9/3/2022	3/5/2023

ACTION REQUIRED

- Contact your Roche Account executive for additional details.
- Please forward this information to your Purchasing Department.
- Keep this document for future reference.

QUESTIONS

Should you have any questions or require additional information, you can contact Roche Care Center for technical questions at 1-877-273-3433, Customer Service Center at 1-800-227-2155 or your Account Executive.

We appreciate your continued use of Roche Diagnostics' products and services.

Sincerely,

Roche Diagnostics Canada

COVID-19 Medical Device Authorization for Importation or Sale

Autorisation d'importation ou de mise en vente d'un instrument médical relatif au COVID-19

Authorization Reference Number :	328889	**Numéro de référence de l'autorisation**
Issue Date:	2021-06-21	**Date de délivrance:**
Amendment Date:	2021-06-29, 2021-09-15, 2022-01-04, 2022-01-27, 2022-02-18, 2022-03-29, 2022-03-30,	**Date de modification:**
Reason for Amendment	Significant Difference	**Raison de la modification**
Amendment Reference Number	344971	**Numéro de référence de la modification**

Device Class/Classe de l'instrument : 4

Pursuant to section 5 of the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19, made by the Minister of Health on March 18, 2020, the medical device listed below is now authorized for sale or importation in Canada.

Each shipment of a COVID-19 medical device that is imported into Canada must be accompanied by a copy of this authorization document. Please ensure to highlight the **Authorization reference number** during the import declaration process to facilitate port entry without any delays.

This authorization is only valid for so long as the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19 is in effect.

Conformément à l'article 5 de *l'Arrêté d'urgence concernant l'importation et la vente d'instruments médicaux relatifs au Covid*-19, réalisé par la ministre de la Santé le 18 mars 2020, les instruments indiqués ci-dessous sont présentement autorisés pour la mise en vente ou l'importation au Canada.

Tout envoi d'un instrument médical relatif au COVID-19 doit être accompagné d'une copie de la présente autorisation. Veuillez vous assurez de souligner le **numéro de référence de l'autorisation** durant le processus de déclaration d'importation pour faciliter l'entrée sans délais aux points de contrôle frontalier.

Cette autorisation est uniquement valide tant que *l'Arrêté d'urgence concernant l'importation et la vente d'instruments médicaux relatifs au Covid*-19 est en vigueur, ou l'autorisation est annulée.

Device Name(s) Nom de l'instrument

SARS-COV-2 RAPID ANTIGEN TEST NASAL WITH CONTROL, SARS-COV-2 RAPID ANTIGEN TEST NASAL, STANDARD Q COVID-19 AG NASAL TEST, STANDARD Q COVID-19 AG NASAL TEST WITH CONTROL

Name & Address of Authorization Holder/Nom & adresse du titulaire de l'autorisation

SD BIOSENSOR, INC.
16, DEOGYEONG-DAERO, 1556BEON-GIL, YEONGTONG-GU, C-4 & 5 FLOOR,
SUWON-SI, GYEONGGI-DO
SOUTH KOREA
16690

David Boudreau, ing., Director General, Medical Devices Directorate
Directeur général, Direction des instruments médicaux

Components/Parts/Accessories/Devices for this Licence
Les composantes, parties, accessoires et instruments médicaux pour cette homologation

SARS-COV-2 RAPID ANTIGEN TEST NASAL WITH CONTROL

Device ID/No de l'instrument: 1031805
Device Identifier / Identificateur de l'instrument
(Model/Catalog Detail/No de modèle/Catalogue):
9901-NCOV-03G

SARS-COV-2 RAPID ANTIGEN TEST NASAL

Device ID/No de l'instrument: 1031806
Device Identifier / Identificateur de l'instrument
(Model/Catalog Detail/No de modèle/Catalogue):
9901-NCOV-04G

STANDARD Q COVID-19 AG NASAL TEST

Device ID/No de l'instrument: 1031807
Device Identifier / Identificateur de l'instrument
(Model/Catalog Detail/No de modèle/Catalogue):
09COV37H

STANDARD Q COVID-19 AG NASAL TEST WITH CONTROL

Device ID/No de l'instrument: 1031808
Device Identifier / Identificateur de l'instrument
(Model/Catalog Detail/No de modèle/Catalogue):
09COV36D