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MEMORANDUM / NOTE DE SERVICE

TO
Rosslynn Miller-Lee
Executive Director,
Medical Device Evaluation Bureau
MDD

FROM / DE
Maria Carballo, Manager
IVD Device Evaluation Division
MDD

SUBJECT / OBJET
Recommendation for an **Amendment** to Authorization under Interim Order COVID-19

Manufacturer: **Roche Molecular Systems Inc..**

Device: **COBAS SARS-COV-2 kit** – **Application 312730**

Background

On March 18, 2020, Roche received an Interim Order Authorization for the following:

- cobas® SARS-CoV-2 : Catalogue Number: 09175431190
- cobas® SARS-CoV-2 Control Kit: Catalogue Number: 09175440190
- SW cobas SARS-CoV-2 ASAP Version 10.1.0: 09255478001
- SW cobas SARS-CoV-2 ASAP Version 11.1.0: 09255427001

This amendment is to add nasal swab (flocked or polyester-tipped) collection using the **cobas**® PCR Media Uni Swab Sample Kit (**HC license: 71115**), **cobas**® PCR Media Dual Swab Sample Kit (**HC license: 71115**), 0.9% physiological saline, Copan Universal Transport Medium (UTM-RT), and BD™ Universal Viral Transport (UVT) as another sample type to the intended use of the device. In addition, clear instructions regarding the nasal swab collection have been added to the Package insert.

The Media Swab collection kits are already licensed for use with other licensed cobas assays including the cobas® CT/NG v2.0 Test, cobas® CT/NG, cobas® TV/MG and cobas® Cdiff Test for use on a variety of the cobas instrument platforms.

New Amended Intended Use

cobas® SARS-CoV-2 for use on the **cobas**® 6800/8800 Systems is a real-time RT-PCR test intended for the qualitative detection of nucleic acids from SARS-CoV-2 in clinician-instructed self-collected nasal swab specimens (collected on site), and clinician-collected nasal, nasopharyngeal and oropharyngeal swab samples from patients with signs and

symptoms suggestive of COVID-19 (e.g., fever and/or symptoms of acute respiratory illness).

Results are for the detection of SARS-CoV-2 RNA that are detectable in nasal, nasopharyngeal and oropharyngeal swab samples during infection. Positive results are indicative of SARS-CoV-2 RNA detection, but may not represent the presence of transmissible virus.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.
cobas® SARS-CoV-2 is intended for use by trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures.
[9179909001-02EN Doc Rev. 2.0 2020]

Discussion: The information provided meets the minimum requirements for issue an amendment to the existing Interim Order Authorization.

Data from Matrix Equivalency studies between the UMT-RT and the cobas PCR media and the UMT-RT and 0.9% physiological saline demonstrate the samples collected in the cobas® PCR Media (CPM) provide comparable results to those collected in Copan UTM-RT System and those collected in saline.

The revised labelling is acceptable. The intended use includes the addition of clinician-instructed self-collected nasal swab specimens (collected on site), and clinician-collected nasal specimens which are acceptable specimens according to the CDC. On March 24, 2020, the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) made allowance for self- or healthcare worker-collected nasal swabs as an acceptable specimen type if Nasopharyngeal (NP) swab is not possible. The instructions included for collection of nasal swab specimens as well as storage instructions provided in the package insert for these samples concurs with CDC recommendations for COVID-19 samples.

In the context of the COVID-19 pandemic, the amendment to the issued Interim Order for the Roche cobas SARS Cov-2 kit to include nasal swab as a sample type with specific media collection kits is acceptable. The information submitted by the manufacturer provides reasonable assurance that the cobas SARS-CoV-2 kit will perform as claimed for its intended use under the current COVID-19 national health emergency.

RECOMMENDATION:

Amend the Interim Order Authorization of the cobas SARS-CoV-2 for the new Intended Use:
cobas® SARS-CoV-2 for use on the **cobas**® 6800/8800 Systems is a real-time RT-PCR test intended for the qualitative detection of nucleic acids from SARS-CoV-2 **in** clinician-instructed self-collected nasal swab specimens (collected on site), and clinician-collected nasal, nasopharyngeal and oropharyngeal swab samples from patients with signs and

symptoms suggestive of COVID-19 (e.g., fever and/or symptoms of acute respiratory illness).
Results are for the detection of SARS-CoV-2 RNA that are detectable in nasal, nasopharyngeal and oropharyngeal swab samples during infection. Positive results are indicative of SARS-CoV-2 RNA detection, but may not represent the presence of transmissible virus.
Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.
cobas® SARS-CoV-2 is intended for use by trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures.
[9179909001-02EN Doc Rev. 2.0 2020]

I concur / Je suis d'accord

2020-04-09			
Maria Carballo Manager, In Vitro Diagnostic Section / chef, Matériels diagnostiques in vitro Device Evaluation Division / Division de l'Évaluation des Matériels	Date	**Rosslyn Miller-Lee** Executive Director/ Directrice Executive Medical Devices Evaluation Bureau/ Bureau de l'évaluation des instruments médicaux	Date