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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 Authorization under Interim Order COVID-19

Manufacturer: **LUMINEX MOLECULAR DIAGNOSTICS, INC**

Device: **NxTAG CoV Extended Panel Assay – Application 312781**

Background

On March 27th, 2020, Health Canada issued an Authorization of the NxTAG® CoV Extended Panel Assay under Interim Order 32 with the following conditions:

Submit by April 20, 2020, the Instructions for Use (IFU) with a revised Intended Use statement that omit the US FDA specific EUA and US specific laboratory authorization requirements/CLIA language.

On April 11, 2020, the manufacturer responded to this condition by providing the revised labelling as requested.

Discussion: the manufacturer provided both a redlined version and a clean version of the Package Insert. The Intended Use statement was modified as requested, omitting the US FDA specific EUA and US specific laboratory authorization requirements/CLIA language. In addition, the manufacturer also made other FDA specific edits throughout the Package Insert, which are acceptable.

RECOMMENDATION:

Issue an Authorization with removal of the present condition for the NxTAG® CoV Extended Panel Assay.

Revised Intended Use:

NxTAG® CoV Extended Panel Assay for use on Luminex® MAGPIX® instrument is a RT-PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2

in nasopharyngeal swab specimens from individuals suspected of COVID-19 by their healthcare provider.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in nasopharyngeal swab specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

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.

The NxTAG CoV Extended Panel is intended for use by trained clinical laboratory personnel specifically instructed and trained in the techniques of reverse transcriptase-PCR and in vitro diagnostic procedures.

[Package Insert MLD-054- KPI-002 Rev A 03/2020]

I concur / Je suis d'accord

	2020-04-13		
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