Application Information *Information de soumission*			
Application ***Soumission*** 313982	**Licence Name** ***Nom de l'homologation*** RNA ISOLATION KIT	**Licence Number** ***No. de l'homologation***	**Risk Class** ***Classe de l'instrument*** 3
Application Type ***Type de soumission*** COVID-19 IO	**Licence Type** ***Type d'homologation*** Test Kit	**Manufacturer** ***Fabricant*** LUMINULTRA TECHNOLOGIES LTD.	**Company ID** ***No. d'entreprise*** 153483

Note to File Purpose *Objet de Note au dossier*		
Subject/*Objectif* **Final version of the Instructions for Use**		
Division: IVDD	Date Assigned: *Date assignée:* **2020-04-22**	Date Completed: *Date d'achèvement:* **2020-04-22**
Authored by: *Rédigé par:* Patrice Sarrazin		

1 Background/*Antécédents*

In order to mitigate the risks related to potential confusion related to the protocol, the addition of a stand-alone step-by-step protocol (not referring to the MagMax instructions for use) to the package insert of the LuminUltra kit was requested. A request for additional information (AI Request #2) was issued on 2020-04-19. On 2020-04-22, the manufacturer submitted a revised version (*Version 1; file LuminUltra RNA Isolation Kit Use Instructions FINAL.docx)*. This note to file is the AI#2 review report and should be interpreted in conjunction with the initial review report and the AI#1 review report.

NOTE: The manufacturer submitted an unsolicited revision of the instructions for use to further streamline the protocol. This document was received by email on 2020-04-22. During the review of this IFU, it was noted that the volume of the patient sample to be added was changed from 265 µL to 50 µL. A request for additional information was sent on 2020-04-22 to confirm this change and to inform the manufacturer that a change in the volume of input material represents a significant change that would require additional validation. On 2020-04-22, the manufacturer responded that this change was an error, the protocol was revised and is now consistent with the protocol used for the validation studies. The approved version of the IFU is saved in Docubridge. The following review applies to the final approved version of the IFU.

2 Evaluation/*Évaluation*

The package insert (version 1.0; 2020-04-22) now includes step-by-step instructions to perform the extraction and purification steps using the LuminUltra isolation kit.

Reviewer's Discussion
The instructions provide clear instructions to adequately use the LuminUltra isolation kit as per its intended use. The instructions are consistent with the protocol used in the validation studies and are also consistent with the protocol of the commercial MagMax isolation used as the comparator. The package insert (version 1.0) meets all labelling requirements.

3 Conclusion

Based on all information provided by the manufacturer to support the quality, efficacy and safety of this product that have been assessed under the current application (Initial review, AI#1 Review, AI#2 Review), the LuminUltra isolation kit is deemed to be equivalent to the MagMax isolation kit.

In the context of the COVID-19 pandemic and shortage of reagents used for RNA extraction potentially impeding testing capacity in Canada, the risks associated with the use of the LuminUltra isolation kit is outweighed by the benefits of having an alternative solution to the isolation kit currently in shortage in Canada.

4 Recommendation

Authorization under the COVID-19 Interim Order is recommended.