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* **Labeling**		
Division: IVDD	Date Assigned: *Date assignée:* **2020-04-21**	Date Completed: *Date d'achèvement:* **2020-04-21**
Authored by: *Rédigé par:* Patrice Sarrazin		

1 Background/*Antécédents*

A request to revise the labeling of the RNA extraction kit was issued on 2020-04-18. The manufacturer submitted the revised reagent labels and the final version of the instructions for use on 2020-04-21.

2 Evaluation/*Évaluation*

Reagent Labels

The labels submitted meet all labeling requirements. All essential elements are present on the labels.

Package Insert

Instructions for Use **LuminUltra RNA Isolation Kit** *Version: 1.0 ; 2020-04-20*		
Sections	**Acceptable?**	**Comment**
Name of the device	Yes	
Name and address of the manufacturer	Yes	LuminUltra Technologies Ltd. 520 King Street Fredericton, NB, Canada E3B6G3 +1-506-459-8777

Identifier	Yes	Catalogue Number: RNAIK-480
Intended use	Yes	
Summary and explanation	Yes	
Directions for use	No	The instructions provided to prepare the reagents only provides an outline of the difference between the MagMax protocol and the protocol optimized for the LuminUltra kit. It is recommended that the instructions be provided as stand-alone instructions to avoid any potential confusion generated by the users going back and forth between both sets of instructions. This kit includes all reagents required to perform the protocol, therefore complete instructions, including steps specific to the LuminUltra kit, should be provided.
Performance characteristics	Yes	The graphs provided clearly demonstrate that extractions performed with the LuminUltra kit demonstrate a slight increase in Ct values. This accurately reflects the results obtained in the validation studies.
Storage instructions	N/A	Storage recommendations are provided on each reagent labels.
Limitations	N/A	There is no limitation section in the proposed package insert. The MagMax package insert was also reviewed and no limitations are listed in the package insert. Therefore, in comparison to another commercially available kit, absence of limitations for the LuminUltra isolation kit is deemed acceptable.

Reviewer's Discussion

The instructions for use provided in the proposed package insert defers the users to the MagMax's instructions for use and only outlines the difference in volume in specific steps. To avoid confusion and since this kit, intended to serve as an alternative to the MagMax extraction kit, includes all necessary reagents to perform the extraction and purification steps, it recommended to include detailed step-by-step instructions in the LuminUltra isolation kit.

The initial request asked to provide a package insert (instructions for use) meeting the labeling requirements of the Medical Device Regulations based on the instructions for use found in the Standard Operating Procedure "Automated Extraction Protocol for KingFisher using Luminultra Extraction Kit" (version 1) provided in "Health Canada Interim Order Request LuminUltra A1 SOP.doc". This version of the SOP provides more detailed instructions for use. However, the instructions included in the proposed package insert are equivalent to another SOP document (KingFisher SOP Final Apr 14.doc) providing only a summarized outline of the protocol with reference to the MagMax's protocol.

Additional Information Request

To mitigate the risks related to potential confusion, we believe that the package insert of the LuminUltra kit should include a stand-alone protocol. Revise the package insert to include step-by-step instructions to perform the protocol using LuminUltra reagents.

Note: If the SOP described in "Health Canada Interim Order Request LuminUltra A1 SOP.doc" is used, make sure to add the required volumes in steps 4.3 and 4.4 to create the Wash Buffers.

3 Conclusion

Further revisions to package insert are recommended.

4 Recommendation

Request for additional information