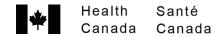


Application Information / Information de soumission						
*Licence Name/Nom de l'homologation:		olication Number/Numéro de soumission				
TOTAL RNA PURIFICATION KIT DX	_	314587				
Licence # / # de l'homologation:		Application Type/Type de soumission: Interim Order				
Manufacturer/Fabricant:		Company ID/Identificateur d'entreprise:				
NORGEN BIOTEK CORP.		2105				
Risk Class:		ionale:				
2		DD Rule 2(b)(i)				
*Licence Type/Type d'homologation:	Rat	ionale:				
Single Device						
☐ Contains Controlled Substance(s) ☐ Contains Drug(s) ☐ Contains Biological Material(s)						
*Intended Use and/or Indications for Use/ Utilisation Prévue et/ou Indications						
Norgen's Total RNA Purification Kit Dx provides a rapid method for the isolation and purification of total RNA from tissue samples, blood, plasma, serum, bacteria, yeast, fungi and viruses for subsequent <i>in vitro</i> diagnostic use. The kit purifies all sizes of RNA, from large mRNA and ribosomal RNA down to microRNA (miRNA) and small interfering RNA (siRNA). The RNA is preferentially purified from other cellular components such as proteins, without the use of phenol or chloroform. This kit is designed to be used with any downstream application employing enzymatic amplification or other enzymatic modifications of RNA followed by signal detection or amplification. Any diagnostic results generated using the RNA isolated with Norgen's Total RNA Purification Kit Dx in conjunction with an <i>in vitro</i> diagnostic assay should be interpreted with regard to other clinical or laboratory findings. To minimize irregularities in diagnostic results, suitable controls for downstream applications should be used. Norgen's Total RNA Purification Kit Dx is intended for use by professional users such as technicians, physicians and biologists experienced and trained in molecular biological techniques. Norgen's Total RNA Purificaiton Kit Dx does not provide a diagnostic result. It is the sole responsibility of the user to use and validate the kit in conjunction with a downstream <i>in vitro</i> diagnostic assay.						
		formation				
OEM Licence Name :	0	DEM Manufacturer :				
OEM Intended Use and/or Indications for Use						
Reason for Change		Comment(s)				
Change to classification of a device		Comment(s)				
Manufacturer name change						
License name change						
Device name change						
Change to the purpose/indication of license						
Addition of device(s)						
Deletion of device(s)						
Reason for Change		Comment(s)				
Change in name and/or address of the						
Private Label Manufacturer						
Private Label License name change						
Private Label Device name change						



Addition of device(s)								
Deletion of device(s)								
Certificate Screening Checklist:								
Cert # (new):		Cert Revisions / Comments (If Applicable):						
Cert. # (old):								
Replacing Existing Cert on File (Y/N):								
Criteria		conforms		Comments	/info for M	DS		
Issued to full name of manufacturer as it appears on application/licence and label.								
Issued to complete civic address matching application/licence and label.								
Criteria are ISO 13485:2016 and Medical Dev Regulations – Part 1 – SOR 98/282	ices							
Scope activities limited to design, developme manufacture, production, servicing, installation distribution.								
Activities include "manufacture" or "production" Activities include "design" or "development and development" for class III/IV devices.								
Scope is unambiguous and covers app./lic. devices. Does not contain product names/models/licence numbers.								
Auditing Organisation is Authorized or Recognized								
Statement of Authorization or Recognition.								
Field labelled "Effective Date"								
Field labelled "Expiry Date"								
Validity period ≤ 3 years								
Unique identification code labelled "certification umber" or "certification document number"	I .			\square new	☐ revise	d		
Name, title, and signature of certification authority								
Pagination (page x or y) included on all pages . All pages present.								
Method to verify validity								
Screening Decision								
Accept						-		
Giovanni Di Rienzo			Date : 2020)-05-07				
Device Licensing Services Division Medical Devices Bureau								



Health	Canada
1)-

Santé Canada Check GMDN

Reference Material Regulatory Action **Action for Screener** Issue **GMDN Description** GMDN Code **GMDN Name**