

<b>Product name</b>	ColoNode (IVDD)		
<b>Product Composition</b>			
<b>ColoNode Reagent Kit</b>	<b>REF</b>	CN 20201604	
	<b>Box 1 of 2</b>	<b>SKU</b>	CN 2020160410
		<i>Contents:</i>	
		<i>Mastermix 1</i>	REF 50100
		<i>Mastermix 2</i>	REF 50101
		<i>25 mM MnAc</i>	REF 50108
		<i>Negative control</i>	REF 50109
	<b>Box 2 of 2</b>	<b>SKU</b>	CN 2020160420
		<i>Contents:</i>	
		<i>Standard A</i>	REF 50102
		<i>Standard B</i>	REF 50103
		<i>Standard C</i>	REF 50104
<i>Standard D</i>		REF 50105	
	<i>Standard E</i>	REF 50106	
	<i>Standard F</i>	REF 50107	
<b>ColoNode Analysis Software</b>	ColoNode Software		
	In combination with QuantStudio 5 Design and Analysis Software		
<b>Manufacturer</b>	<b>HiloProbe AB</b> Tvistevägen 48C SE-90736 Umeå Sweden		
<b>Kit shelf life</b>	CN 20201604	6 months	
<b>Kit shipping conditions</b>	CN 20201604	Cold shipment – dry ice	
<b>Kit storage conditions</b>	CN 2020160410	-20°C ± 5 °C	
	CN 2020160420	-80°C ± 10 °C	
<b>Box 1 &amp; 2 Dimensions</b>	Width: 130 mm, Height: 60 mm, Depth: 48 mm		
<b>Instructions for use</b>	www.colonode.se		
<b>Safety Data Sheet</b>	www.colonode.se		
<b>Intended use</b>	<p>The intended use is for detection of tumor cells in lymph nodes (LNs) of colorectal cancer (CRC) patients and determination of CRC tumor aggressiveness to aid when decisions are to be made about adjuvant chemotherapy and follow-up.</p> <p>ColoNode® is a test intended for measurement of mRNA expression levels of five biomarker genes, i.e. CEACAM5 (carcinoembryonic antigen), KLK6 (kallikrein-related peptidase 6), SLC35D3 (solute carrier family 35 member D3), POSTN (periostin) and MUC2 (mucin 2), as well as expression levels of 18S rRNA (18S ribosomal RNA) in total RNA extracted from LNs of CRC patients. The results are to be used as complementary information to the outcome of histopathology.</p>		
<b>Targeted genes</b>	CEACAM5, KLK6, POSTN, SLC35D3, MUC2, 18S rRNA		
<b>Accepted criteria</b>	Positive control	Standards serves as positive controls. Criteria for acceptance; Standard Ct- and slope-values approved by the ColoNode Software.	
	Negative control	No signals above thresholds are accepted.	
<b>Commercial website</b>	www.colonode.se		