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PAEREWA PĀRONGO HAUORA

Bowel Screening Histology Data Standard

HISO 10072.1:2022

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1 Introduction

The National Bowel Screening Programme[1] (NBSP) is a free programme for men and women aged 60–74 years who are eligible for publicly funded health care. The primary objective of bowel screening is to reduce the mortality rate by diagnosing and treating bowel cancer at an earlier, more treatable stage. The introduction of the NBSP in New Zealand followed a successful six-year pilot.

The new NBSP information technology system is called the National Screening Solution (NSS). This system will enable easy management of the bowel screening pathway, support planning and management of participants, monitor safety and quality, and enable ongoing evaluation of the programme. The NSS is a long-term strategic solution that can be extended to support future population health initiatives.

1.1 Purpose

The HISO 10072.1:2019 Bowel Screening Histology Data Standard (the standard) identifies and describes the data elements that the laboratories contracted to perform NBSP histology services need to capture in their information systems. This data will support the monitoring, operation and quality of the NBSP and may also be used for research and education purposes.

The standard is designed to ensure that consistent information is sent from various laboratories to the NSS.

Laboratory information systems must provide the data described in this standard to the NSS in a way that does not make the work of laboratory pathologists significantly more difficult (ie, pathologists should not be expected to manually enter SNOMED CT codes into their information systems).

1.2 Scope

This standard defines the data required to be sent to the NSS. It does not define the data sent from the laboratory to the physician responsible for the patient's care.

[1] **www.timetoscreen.nz/bowel-screening/about-the-national-bowel-screening-programme**

1.3 Implementation

Laboratories performing NBSP histology services must update their information systems to ensure that they can capture the data specified in this standard.

1.4 SNOMED CT

SNOMED CT is the endorsed terminology standard for clinical information systems and electronic health records in New Zealand. SNOMED CT is developed by SNOMED International, of which New Zealand is a member country.

1.5 Legislation and regulations

The following Acts of Parliament and regulations have specific relevance to this standard:

- **Health Act 1956**
- **Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996**
- **Health Information Privacy Code 2020**
- **Health Practitioners Competence Assurance Act 2003**
- **Privacy Act 2020**
- **Public Records Act 2005**
- **Health (Retention of Health Information) Regulations 1996.**

Readers must consider other Acts and regulations and any amendments that are relevant to their own organisation when implementing or using this standard.

1.6 Related specifications

Other specifications used in developing this standard, or referenced in its operation, offer additional clarification if needed. These are:

- **HISO 10072.2:2019 Bowel Screening Messaging Implementation Guide**
- **HISO 10005:2008 Health Practitioner Index (HPI) Data Set**
- **HISO 10006:2008 Health Practitioner Index (HPI) Code Set**
- **HISO 10046 Consumer Health Identity Standard**
- **Digestive System Tumours: WHO Classification of Tumours, 5th edition, Volume 1**
- **ICCR Colorectal Excisional Biopsy (Polypectomy) Histopathology Reporting Guide**

1.7 Revision history

Updated	Details
November 2021	Update to Figure 1, logical model Data elements added to support reporting: **Polyp profile** **Extent of invasion** **Invasion into the adjacent structure/organ details** **Tumour budding assessment indicator** **Number of tumour buds** **Tumour budding score** **Loss of nuclear expression for MMR proteins** Measurement requirements added to: **Deep margin status** **Peripheral margin status** **Depth of invasion**
May 2022	Update to data elements: **Tumour budding score** **Loss of nuclear expression for MMR proteins** **Margin – polypectomy** **Haggitt level** **Nuclear expression of MLH1** **Nuclear expression of PMS2** **Nuclear expression of MSH2** **Nuclear expression of MSH6BRAFV600E mutation status** **MLH1 promoter methylation testing**

1.8 Data element template

Data element specifications in this standard conform to the requirements of *ISO/IEC 11179 Information Technology – Metadata Registries (MDR)*.[2]

Definition	A statement that expresses the essential nature of the data element and its differentiation from other elements in the data standard.		
Source standards	Established data definitions or guidelines pertaining to the data element.		
Data type	Alphabetic (A) Date Date/time Numeric (N) Alphanumeric (X) Boolean	**Representational class**	Code, free text, value or identifier. For date and time data types, use full date or partial date.
Field size	Maximum number of characters	**Representational layout**	The formatted arrangement of characters in alphanumeric elements, eg: • 'A(50)' means up to 50 alphabetic characters • 'NNAAAA' means two numeric followed by four alphabetic characters.
Data domain	The valid values or codes that are acceptable for the data element. Each coded data element has a specified code set.		
Obligation	Indicates if the data element is mandatory or optional in the context, or whether its appearance is conditional.		
Guide for use	Additional guidance to inform the use of the data element.		
Verification rules	Quality control mechanisms that preclude invalid values.		

[2] See **https://standards.iso.org/ittf/PubliclyAvailableStandards/index.html**

2 Data elements

This section describes the set of histology data that laboratories need to send to the NSS for use by the NBSP. The messages sent to the NSS are in addition to and different from histology messages that laboratories already send to requesting physicians.

Each report must have one or more specimens. For each specimen, in addition to the main diagnosis, there can be up to five other pathological findings. Each report must include at least one set of 'Result sent to' information and at least one pathologist identifier. Figure 1 gives an overview of these relationships. The subsections that follow provide more detail on the data elements. For instructions on how to create HL7 messages that align to this logical structure, see the HISO 10072.2 Bowel Screening Messaging Implementation Guide.

Figure 1: Logical model

2.1 Report

This subsection lists the relevant data elements for a report.

2.1.1 Laboratory facility identifier

Definition	The unique identifier for the facility (laboratory) that performed the pathology work.		
Source standards	**Health Provider Index**		
Data type	Alphanumeric	**Representational class**	Identifier
Field size	8	**Representational layout**	FXXNNN-C
Data domain	A valid HPI Facility ID		
Obligation	Mandatory		
Guide for use	This must be the HPI Facility ID for the laboratory that performed the pathology work. For organisations using the Ministry of Health's legacy Health Facility Codes, refer to the Ministry's **current list of mappings** to identify the relevant HPI Facility ID.		
Verification rules	A valid HPI Facility ID		

2.1.2 Laboratory report identifier

Definition	A laboratory's unique accession number or 'day number' for the report, ie, the number under which the specimen(s) or episode is documented in the laboratory information system.		
Source standards			
Data type	Alphanumeric	**Representational class**	Identifier
Field size	30	**Representational layout**	X(30)
Data domain	As defined by the laboratory		
Obligation	Mandatory		
Guide for use			
Verification rules	Each laboratory report identifier must be unique to each report sent from that laboratory.		

The laboratory report identifier will be stored within the NSS to enable communication with a laboratory about a particular report.

2.1.3 Pathologist identifier

Definition	A unique identifier for the pathologist responsible for the analysis of the samples that this histology report relates to.		
Source standards	**Health Practitioner Index data standards**		
Data type	Alphanumeric	**Representational class**	Identifier
Field size	6	**Representational layout**	NNAAAA
Data domain	HPI Common Person Number (CPN) generated by the HPI system		
Obligation	Mandatory		
Guide for use	This field uses the Health Provider Index Common Person Number (HPI_CPN), a unique identifying number for the health practitioner delivering the service.		
Verification rules	CPN can be obtained from the clinician but must be validated with the HPI system.		

2.1.4 Patient identifier

This is the identifier, recorded in the **National Health Index (NHI)** for the NSS participant's (patient) whose specimens are being examined and reported on.

The NHI for the patient should be captured according to section **2.1 NHI number** of the **HISO 10046 Consumer Health Identity Standard**.

This record should be populated from the patient record in the NHI system, and any updated information copied back into the NHI system.

2.1.5 Patient name

Patient name is the name of the NSS participant (patient) whose specimens are being examined and reported on. This is a complex field, and the report must contain the data elements identified in section **2.2 Person name** of the HISO 10046 Consumer Health Identity Standard.

See also the 'PID-5 – patient name' section of the HISO 10072.2:2019 Bowel Screening Messaging Implementation Guide for message implementation guidance.

2.1.6 Patient birth date

The date the patient was born.

The patient's date of birth should be captured according section **2.3 Birth date and place** of the **HISO 10046 Consumer Health Identity Standard**.

2.1.7 Programme identifier

Definition	This will be 'NBSP' for histology sent to NSS as part of the National Bowel Screening Programme.		
Source standards			
Data type	Alphabetic	**Representational class**	Code
Field size	4	**Representational layout**	A(4)
Data domain	**Code** / **Description** NBSP / National Bowel Screening Programme		
Obligation	Mandatory		
Guide for use	This is used by the NSS to determine what screening programme the pathology results relate to.		
Verification rules	This must be NBSP.		

2.1.8 Requesting clinic identifier

Definition	This is the HPI Facility ID of the endoscopy clinic that performed the colonoscopy, or other screening procedure, during which the specimens were taken.		
Source standards	**Health Provider Index | Ministry of Health NZ**		
Data type	Alphanumeric	**Representational class**	Identifier
Field size	8	**Representational layout**	FXXNNN-C
Data domain	Valid HPI number only		
Obligation	Mandatory		
Guide for use	Use the HPI Facility ID of the endoscopy clinic, hospital or surgery that sent the specimens to the laboratory. Use the most specific HPI Facility ID available. For organisations using the Ministry of Health's legacy Health Facility Codes, refer to the Ministry's **current list of mappings** to identify the relevant HPI Facility ID.		
Verification rules	A valid HPI Facility ID.		

2.1.9 Requesting clinician identifier

Definition	Identifier for the endoscopist who performed the colonoscopy – this should appear on the histology request form sent to the laboratory.		
Source standards	**Health Practitioner Index data standards**		
Data type	Alphanumeric	**Representational class**	Identifier
Field size	6	**Representational layout**	NNAAAA
Data domain	CPN numbers as generated by the HPI system		

Obligation	Mandatory
Guide for use	This field uses the Health Provider Index Common Person Number (HPI_CPN), which is a unique identifying number for the health provider that is delivering the service where that health practitioner is a member of a Responsible Authority as set out in the Health Practitioners Competence Assurance Act 2003.[3]
Verification rules	The CPN can be obtained from the clinician but must be validated by the HPI system.

2.1.10 Facility report sent to

Definition	This is the HPI Facility ID of the endoscopy clinic, hospital or other facility that the laboratory sent the results to.		
Source standards	**Health Provider Index | Ministry of Health NZ**		
Data type	Alphanumeric	**Representational class**	Identifier
Field size	8	**Representational layout**	FXXNNN-C
Data domain	Valid HPI number only		
Obligation	Mandatory		
Guide for use	Use the HPI Facility ID of the endoscopy clinic, hospital or surgery that the laboratory sent the results to. Use the most specific HPI Facility ID available. This field can be repeated if the laboratory has sent the results to more than one facility. For organisations using the Ministry of Health's legacy Health Facility Codes, refer to the Ministry's **current list of mappings** to identify the relevant HPI Facility ID.		
Verification rules	A valid HPI Facility ID.		

2.1.11 Clinician report sent to

Definition	Identifier for the clinician who the report was sent to.		
Source standards	**Health Practitioner Index data standards**		
Data type	Alphanumeric	**Representational class**	Identifier
Field size	6	**Representational layout**	NNAAAA
Data domain	CPN numbers generated by the HPI system		
Obligation	Mandatory		

[3] **www.health.govt.nz/our-work/regulation-health-and-disability-system/health-practitioners-competence-assurance-act/responsible-authorities-under-act**

Guide for use	This field can be repeated if the laboratory has sent the results to more than one clinician. This field uses the Health Provider Index Common Person Number (HPI_CPN), which is a unique identifying number for the health provider practitioner that is delivering the service where that health practitioner is a member of a Responsible Authority as set out in the Health Practitioners Competence Assurance Act 2003.[4]
Verification rules	The CPN can be obtained from the clinician but must be validated by the HPI system.

2.1.12 When specimens collected

Definition	The date and time when the specimens were collected, as provided on the request form.		
Source standards			
Data type	Date/time	**Representational class**	Full date
Field size	14	**Representational layout**	CCYYMMDD hh:mm
Data domain	A valid date		
Obligation	Mandatory		
Guide for use	Use the data and time provided on the histology request form.		
Verification rules	A valid date and time that is less than or equal to the current date and time.		

2.1.13 When specimens received

Definition	The date and time when the specimen(s) were received in the laboratory,		
Source standards	Royal College of Pathologists of Australasia (RCPA) guideline and policy (8.2.l): **www.rcpa.edu.au/Library/College-Policies/Guidelines/Turnaround-Time-in-Anatomical-Pathology**		
Data type	Date/time	**Representational class**	Full date
Field size	14	**Representational layout**	CCYYMMDD hh:mm
Data domain	A valid date		
Obligation	Mandatory		
Guide for use	Use the date and time when the tissue was received in the laboratory. The interim quality standards require that turnaround times accord with the RCPA guideline and policy (8.2.l).		
Verification rules	A valid date and time that is less than or equal to the current date and time.		

[4] **www.health.govt.nz/our-work/regulation-health-and-disability-system/health-practitioners-competence-assurance-act/responsible-authorities-under-act**

2.1.14 When report released

Definition	The date and time when the laboratory report was released.		
Source standards			
Data type	Date/time	**Representational class**	Full date
Field size	14	**Representational layout**	CCYYMMDD hh:mm
Data domain	A valid date and time		
Obligation	Mandatory		
Guide for use	Use the date and time the laboratory report was released.		
Verification rules	A valid date and time that is less than or equal to the current date and time.		

2.1.15 Number of specimens received

Definition	Number of specimens received		
Source standards			
Data type	Numeric	**Representational class**	Value
Field size	3	**Representational layout**	N(3)
Data domain	An integer		
Obligation	Mandatory		
Guide for use	Use the number of specimens that the laboratory received.		
Verification rules	Greater than zero.		

2.1.16 Clinical details

Definition	Additional clinical information provided by the endoscopist.		
Source standards			
Data type	Alphanumeric	**Representational class**	Free text
Field size	2000	**Representational layout**	X(2000)
Data domain	Free text		
Obligation	Optional		
Guide for use	A free-text description of the pathology, or any details about it, that the elements in this report have not already catered for.		
Verification rules			

2.2 Specimen

Each report concerns one or more specimens. This subsection identifies the data elements for each specimen.

2.2.1 Specimen identifier

Definition	The identifier for the specimen.		
Source standards			
Data type	Alphanumeric	**Representational class**	Identifier
Field size	30	**Representational layout**	X(30)
Data domain			
Obligation	Mandatory		
Guide for use	This is the same as the Pot ID provided on the pot that contained the specimen, and on the laboratory request form. Laboratories may use their own internal identifiers for the pot(s) in any order, but the identifier used in the report must match that used to originally label the pot.		
Verification rules			

2.2.2 Site

Definition	This is the location the tissue was taken from.		
Source standards	SNOMED International		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)

Data domain

Clinical term	**SNOMED Concept (SCTID)**
Caecum	32713005
Appendiceal orifice	83856002
Ileocaecal valve	23153004
Ileum *(excluding terminal ileum)*	34516001
Terminal ileum	85774003
Right (ascending) colon	9040008
Hepatic flexure	48338005
Transverse colon	485005
Splenic flexure	72592005
Left (descending) colon	32622004
Sigmoid colon	60184004
Rectosigmoid junction	49832006
Rectum	34402009
Anal structure	53505006
Colon (not further specified)	71854001
Unknown body region	87100004

Obligation	Mandatory
Guide for use	'Unknown body region' should only be used when the histology request form is not filled in correctly. If the endoscopist cannot categorically identify the location where the specimen was removed from, the distance from the anal verge should be recorded instead on the histology request form. This should then be provided in the 'Distance from the anal verge' element (Section 2.2.3) and the site documented as 'Colon (not further specified)'.
Verification rules	One of the options must be provided.

2.2.3 Distance from the anal verge

Definition	The measurement, in millimetres, of the distance between the anal verge and where the specimen was taken from.		
Source standards			
Data type	Numeric	**Representational class**	Value
Field size	3	**Representational layout**	N(3)
Data domain	An integer		
Obligation	Conditional. Required when provided on laboratory request form.		
Guide for use	In some situations, it may not be possible to categorically specify the name of the site where the specimen was taken from. In such cases, the endoscopist may provide the distance from the anal verge instead of the location in the large bowel. If the distance from the anal verge is provided on the laboratory request form for the specimen, then it should be provided here.		
Verification rules	If the site value of 'Colon (not further specified)' is provided (Section 2.2.2), then the distance from the anal verge should be provided.		

2.2.4 Sample procedure

Definition	This identifies how the specimen was removed.		
Source standards	SNOMED International		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Data domain			

Clinical term	**SNOMED Concept (SCTID)**
Biopsy	274323008
Polypectomy	274025005
Not specified *(SNOMED preferred term: 'Procedure not indicated')*	428119001
Other procedure on large intestine	118838009

Obligation	Mandatory
Guide for use	Refer to information in the histology request form.
Verification rules	One of the provided options.

2.2.5 Size

Definition	The size of the specimen in millimetres.		
Source standards			
Data type	Numeric	**Representational class**	Value
Field size	2	**Representational layout**	N(2)
Data domain	An integer		
Obligation	Conditional. Required if documented.		
Guide for use	According to the NBSP's interim quality standard 8.2.c, the size of lesions is generally accepted as that measured by the endoscopist and provided on the request form. However, if there is a major discrepancy between the provided size and the size of the lesion microscopically, the reporting pathologist should measure the largest dimension to the nearest millimetre on the haematoxylin and eosin slide. Provided in millimetres.		
Verification rules	An integer		

2.2.6 Main diagnosis

Definition	This identifies the pathologist's diagnosis of the specimen.		
Source standards	The diagnosis options include and expand on: • **Digestive System Tumours: WHO Classification of Tumours, 5th edition, Volume 1** • NHS Bowel Cancer Screening Programme: Guidance on reporting lesions, **https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/694063/bowel_cancer_screening_programme_guidance_on_reporting_lesions.pdf**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Data domain			

	Clinical term	SNOMED Concept (SCTID)
Normal diagnosis and unsatisfactory specimen	Normal	30389008
	Specimen unsatisfactory for diagnosis	112631006
Cancers	Adenocarcinoma of large intestine	408645001

	Adenocarcinoma in adenomatous polyp	43233001
	Suspicious of adenocarcinoma *(SNOMED CT term: 'Atypia suspicious for malignancy')*	44085002
	Squamous cell carcinoma	28899001
	Neuroendocrine carcinoma (NEC), small cell	719105002
	Neuroendocrine carcinoma (NEC), large cell	128628002
	Undifferentiated carcinoma	38549000
	Mixed adenoneuroendocrine carcinoma *(WHO term: 'Mixed neuroendocrine-non-neuroendocrine neoplasm')*	51465000
	Secondary malignant neoplasm *(including metastasis or direct spread to the colon/rectum)*	781076008
	Other primary malignant neoplasm of bowel	86049000
	Adenosquamous carcinoma	59367005
Polyps	Tubular adenoma	19665009
	Tubulovillous adenoma	61722000
	Villous adenoma	128859003
	Hyperplastic polyp	62047007
	Sessile serrated adenoma/polyp/lesion	443157008
	Traditional serrated adenoma	443734007
	Serrated adenoma (not further specified)	128653004
	Inflammatory polyp	76235005
	Mucosal prolapse	29696001
	Mesenchymal tumours – Leiomyoma	44598004
	Mesenchymal tumours – Lipoma	46720004
	Mesenchymal tumours – Gastrointestinal stromal tumour	128755003
	Hamartomatous polyp (including juvenile polyp)	27391005
	Well differentiated neuroendocrine tumour (including grades 1 to 3, typical and atypical carcinoids) *(SNOMED CT term: 'Neuroendocrine tumour')*	55937004
	Lymphoid polyp	80297003
	Benign neoplasm of large intestine	92170008
Other pathology	Ulcerative colitis	64766004
	Crohn's disease	34000006
	Chronic idiopathic inflammatory bowel disease, unclassified	359664009
	Inflammation, unspecified	23583003
	Intestinal infectious disorder	266071000

	Ischaemic colitis	30588004
Obligation	Mandatory	
Guide for use	The members in this code set cover both polyps and cancers. The main diagnosis for the specimen must be provided. Any additional pathological findings can be provided using 'Other pathological findings' data elements (Section 2.3). The pathologist should be able to enter the diagnosis in the same manner as they always have or in an intuitive manner when the laboratory information systems are upgraded. Colorectal adenocarcinoma is coded as 'Adenocarcinoma of large intestine'. Malignant tumours from other sites (such as ovarian or prostate adenocarcinoma) should be coded as 'Secondary malignant neoplasm'.	
Verification rules	The value must be one of the agreed options.	

2.2.7 Dysplasia

Definition	This describes the presence or absence of dysplasia and, where present, the degree of dysplasia.		
Source standards	**National Bowel Screening Programme Interim Quality Standards**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Data domain	**Clinical term** / **SNOMED Concept (SCTID)** Low grade dysplasia — 43185009 High grade dysplasia — 55237006 Dysplasia (not further specified) — 25723000		
Obligation	Conditional. Required to be captured if the predisposing adenoma is present.		

Guide for use	The interim quality standards require that no more than 10% of adenomata (including sessile serrated adenomata/polyps) are reported as 'High grade dysplasia' by a pathologist. 'Low grade dysplasia' describes unequivocal neoplasia confined to the epithelial glands, while 'High grade dysplasia' incorporates marked architectural changes visible at low power with supporting cytologic changes. In tubular adenomas, tubulovillous adenomas and villous adenomas, the dysplasia is graded. In sessile serrated lesions, the heterogeneity means that the dysplasia is not subtyped into low or high grade so record as Dysplasia (not further specified). Traditional serrated adenomas (TSA) are considered to have low grade dysplasia inherently. When high grade dysplasia is present, this should be documented as a TSA with high grade dysplasia. Occasionally benign polyps like a juvenile polyp can have dysplasia and this should be recorded. If an inflammatory polyp shows dysplasia, consider inflammatory bowel disease.
Verification rules	

2.2.8 Margin – polypectomy

Definition	This identifies whether there is dysplasia, including its grade, or residual sessile serrated adenoma/polyp is present at the margin of the polyp.		
Source standards			
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)

Data domain	

Clinical term	Code
No involvement by dysplasia (SNOMED CT term: Surgical margin not involved by adenoma with dysplasia)	161861000210109
Not assessable	369712006
Involvement by low grade dysplasia (SNOMED CT term: Surgical margin involved by adenoma with low grade dysplasia)	161831000210100
Involvement by high grade dysplasia (SNOMED CT term: Surgical margin involved by adenoma with high grade dysplasia)	161841000210108
Involvement by sessile serrated adenoma/polyp (SNOMED CT term: Surgical margin involved by sessile serrated lesion)	161851000210106

Obligation	Conditional. Required for all specimens except biopsies.
Guide for use	If the margin cannot be determined because the specimen is in fragments or the margin cannot be identified, use 'Not assessable'.
Verification rules	Not applicable for biopsies. For adenocarcinomas arising in polyps, the peripheral and deep margin fields also apply.

2.2.9 Polyp profile

Definition	The type of polyp removed during a procedure.		
Source standards			
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain			

Agreed term	SCTID
Sessile polyp	103679000
Pedunculated polyp	103680002
Unavailable *(to be used when the details of the type of polyp have not been provided?*	103329007

Obligation	Conditional. Required for all polyps removed
Guide for use	
Verification rules	Valid code

2.2.10 Histological grade (tumour differentiation)

Definition	The histological grade or differentiation describes how much an adenocarcinoma resembles the normal tissue from which it arose.		
Source standards	**Digestive System Tumours: WHO Classification of Tumours, 5th edition, Volume 1**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Data domain			

Clinical term	SCTID
Low grade *(SNOMED CT term: 'Low grade (well to moderately differentiated)')*	395529007
High grade *(SNOMED CT term: 'High grade (poorly differentiated to undifferentiated)')*	395530002

Obligation	Conditional. Required for polypectomy specimens showing adenocarcinomas.
Guide for use	Grading is based on the least differentiated component but not the invasive front where tumour budding and poorly differentiated clusters at the epithelial-mesenchymal transition point occur.
Verification rules	

2.2.11 Poor/undifferentiated tumour

Definition	The presence of any degree of poor differentiation/undifferentiated tumour must be recorded.		
Source standards	**RCPA structured reporting protocol for polypectomies**		
Data type	Numeric	**Representational class**	Identifier
Field size	18	**Representational layout**	N(18)
Data domain			

Clinical term	SNOMED Concept (SCTID)
Present	52101004
Absent	2667000
Not applicable	385432009

Obligation	Conditional. Required for polypectomy specimens with a diagnosis of adenocarcinoma.
Guide for use	
Verification rules	One of the options provided.

2.2.12 Lymphatic invasion

Definition	This identifies whether there is lymphatic invasion.		
Source standards			
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Data domain			

Clinical term	SNOMED Concept (SCTID)
Present *(SNOMED CT term: 'Lymphatic (small vessel) invasion by tumour present')*	395717001
Not present *(SNOMED CT term: 'Lymphatic (small vessel) invasion by tumour absent')*	395716005
Cannot be determined *(SNOMED CT term: 'Lymphatic (small vessel) invasion by tumour indeterminate')*	395720009

Obligation	Conditional. This is required for polypectomy specimens showing adenocarcinoma.
Guide for use	This is required for polypectomy specimens showing adenocarcinoma.
Verification rules	One of the options provided.

2.2.13 Venous invasion

Definition	This identifies whether there is venous invasion.		
Source standards			
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Data domain			

Clinical term	SNOMED Concept (SCTID)
Present *(SNOMED CT term: 'Vascular invasion by tumour present')*	372287009
Absent *(SNOMED CT term: 'No vascular invasion by tumour')*	127494000
Indeterminate *(SNOMED CT term: 'Vascular invasion by tumour is indeterminate')*	127495004

Obligation	Conditional. Required for polypectomy specimens showing adenocarcinoma.
Guide for use	This is required for polypectomy specimens showing adenocarcinoma.
Verification rules	One of the options provided.

2.2.14 Deep margin status

Definition	This field records the distance of the tumour (invasive carcinoma) from the deep margin (in mm).		
Source standards			
Data type	Numeric	**Representational class**	Value
Field size	3	**Representational layout**	NN.N
Data domain	Value		
Obligation	Conditional		
Guide for use	This can be used to identify whether the deep margin of the polyp is involved. The distance from the deep margin (**specify in millimetres or distance to nearest 0.1mm**) is required for adenocarcinoma arising in polypectomy specimens. If the tissue is received piecemeal, then it is not assessable, and a measurement is not required.		
Verification rules			

2.2.15 Peripheral margin status

Definition	This field records the distance of the tumour (invasive carcinoma) from the peripheral (mucosal) margin (in mm).		
Source standards			
Data type	Numeric	**Representational class**	Value
Field size	3	**Representational layout**	NN.N
Data domain	Value		
Obligation	Conditional		
Guide for use	This can be used to identify whether the peripheral margin of the polyp is involved. The distance from the peripheral margin (**specify in millimetres or distance to nearest 0.1mm**) is required for adenocarcinoma arising in polypectomy specimens. If the tissue is received piecemeal, then it is not assessable, and a measurement is not required.		
Verification rules			

2.2.16 Depth of invasion

Definition	This is the maximum depth of an invasive adenocarcinoma from the muscularis mucosae in millimetres.		
Source standards			
Data type	Numeric	Representational class	Value
Field size	4	Representational layout	NNN.N
Data domain	Value		
Obligation	Conditional. Required for polypectomy specimens showing adenocarcinoma.		
Guide for use	This is required for adenocarcinomas arising in polypectomy specimens. If the muscularis mucosae is destroyed, then the maximum tumour thickness will suffice. In piecemeal resections, the maximum dimension of invasive adenocarcinoma in any one piece should be recorded. **Specify in millimetres or distance to nearest 0.1mm.**		
Verification rules	Valid value		

2.2.17 Extent of invasion

Definition	The extent of the tumour invasion as determined by an assessment of the specimen.		
Source standards	**ICCR Colorectal Excisional Biopsy (Polypectomy) Histopathology Reporting Guide**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)

Value domain

Clinical term	SCTID
Non-invasive neoplasia/high grade dysplasia (SNOMED CT term: 'No tumour invasion')	370049004
Invasion into submucosa (SNOMED CT term: 'Tumour invasion into submucosa')	370059003
Invasion into muscularis propria (SNOMED CT term: 'Tumour invasion into muscularis propria)	370060008
Invasion through the muscularis propria into pericolorectal connective tissue	370070005
Invasion into the surface of the visceral peritoneum (SNOMED CT term: Invasion of neoplasm to visceral peritoneum)	443766002
Invasion into the adjacent structure(s)/organ(s) (SNOMED CT term: Tumour invasion by direct extension to other structures)	370054008
Depth of invasion not accessible	397376003

Obligation	Conditional. Required for polypectomy specimens showing adenocarcinoma
Guide for use	Further details are required if **Invasion into the adjacent structure(s)/organ(s)** is selected.
Verification rules	Valid code

2.2.18 Invasion into the adjacent structure/organ details

Definition	Additional details that specify the invasion into an adjacent structure(s)/organ(s).		
Source standards			
Data type	Alphanumeric	**Representational class**	Free text
Field size	250	**Representational layout**	X(250)
Value domain			
Obligation	Mandatory if **Invasion into the adjacent structure(s)/organ(s)** is identified.		
Guide for use			
Verification rules			

2.2.19 Tumour budding assessment indicator

Definition	Indication of whether a tumour budding was able to be assessed		
Source standards			
Data type	Boolean	**Representational class**	N/A
Field size	1	**Representational layout**	N(1,0)
Value domain			

Value	Meaning
1	Yes, can be assessed
0	No, cannot be assessed

Obligation	Mandatory for non-mucinous and non-signet ring cell adenocarcinoma areas
Guide for use	
Verification rules	

2.2.20 Number of tumour buds

Definition	The number of tumour buds that were assessed		
Source standards			
Data type	Numeric	**Representational class**	Value
Field size	3	**Representational layout**	N(3)
Value domain	An integer		
Obligation	Mandatory if **Yes** is selected for **Tumour budding assessment indicator**.		
Guide for use	Should only be reported in non-mucinous and non-signet ring cell adenocarcinoma areas		
Verification rules	Valid value		

2.2.21 Tumour budding score

Definition	The score determined by the assessment of the tumour bud.		
Source standards			
Data type	Alphanumeric	**Representational class**	Code
Field size	3	**Representational layout**	X(3)
Value domain			
Obligation	Optional		
Guide for use	Tumour budding should be scored as per international guidelines such as the RCPA Polypectomy and Local Resections of the Colorectum Structured Reporting Protocol (2nd Edition) or the International Collaboration on Cancer Reporting Colorectal excision Biopsy Guide 2020 (1,2). Tumour budding is not scored or reported in mucinous and signet-ring cell areas of adenocarcinoma. A system should be able to auto populate the value from the number of tumour buds identified in **2.2.20 Number of tumour buds**.		
Verification rules			

Clinical term		**Code**
Low budding	(0-4 buds)	Bd1
Intermediate budding	(5-9 buds)	Bd2
High budding	(≥10 buds)	Bd3

2.2.22 Width of tumour

Definition	This is the maximum width of the invasive adenocarcinoma in millimetres.		
Source standards			
Data type	Numeric	**Representational class**	Value
Field size	3	**Representational layout**	N(3)
Data domain	An integer		
Obligation	Conditional. Required for adenocarcinomas.		
Guide for use	This is required for adenocarcinomas in intact polypectomy specimens.		
Verification rules			

2.2.23 Haggitt level

Definition	This identifies the Haggitt level for polypoid (pedunculated) tumours as determined by the pathologist.		
Source standards			
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Data domain			

Clinical term	Code
Level 1 = carcinoma invades submucosa; limited to head of polyp	277733009
Level 2 = carcinoma invades neck of polyp	277734003
Level 3 = carcinoma invades any part of the stalk	277735002
Level 4 = carcinoma invades submucosa of bowel wall, below polyp stalk but above muscularis propria	277736001
Cannot be determined	1156316003

Obligation	Conditional. Required for adenocarcinomas arising in pedunculated polyps removed by polypectomy (not biopsies).
Guide for use	Haggitt level can only be determined for a resected polyp, not for a biopsy. It is a four-level system. This is required for adenocarcinomas removed by polypectomy (not biopsies). The level cannot be determined if the tissue is received piecemeal.
Verification rules	Valid code.

2.2.24 Kikuchi level

Definition	This identifies the Kikuchi level for sessile tumours as determined by the pathologist. It is used for describing the degree of infiltration of a sessile early invasive colorectal cancer.		
Source standards			
Data type	Alphanumeric	**Representational class**	Code
Field size	3	**Representational layout**	X(3)

Clinical term	Code
Slight submucosal invasion (200–300 um (0.2–0.3 mm))	sm1
Invasion of the middle one-third of the submucosa or intermediate between sm2 and sm3	sm2
Invasion of the deep one-third of the submucosa	sm3
Cannot be determined	XXX

Obligation	Conditional. Required for sessile adenocarcinomas removed by polypectomy (not biopsies).
Guide for use	Kikuchi levels can only be determined for resected intact polyps, not for biopsies. This is required for adenocarcinomas arising in sessile polyps removed by polypectomy (not biopsies). The level cannot be determined if the tissue is received piecemeal. The definitions are based on the RCPA Polypectomy and Local Resections of the Colorectum Structured Reporting Protocol (2013). If the level of invasion is considered to be 'at least sm2', then this should be coded as sm2.
Verification rules	Valid code.

2.2.25 Perineural invasion

Definition	This identifies the presence or absence of perineural invasion.		
Source standards			
Data type	Alphanumeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Data domain			

	Clinical term	SNOMED Concept (SCTID)
	Present *(SNOMED CT term: 'Perineural invasion by tumour present')*	369731000
	Not identified *(SNOMED CT term: 'Perineural invasion by tumour not identified')*	385001000
	Indeterminate *(SNOMED CT term: 'Perineural invasion by tumour indeterminate')*	396393005
Obligation	Conditional and optional. This is required for adenocarcinomas and optional for specimens with a main diagnosis of adenocarcinoma of large intestine.	
Guide for use		
Verification rules	One of the options provided.	

2.2.26 Loss of nuclear expression for MMR proteins

Definition	An indication that a loss of nuclear expression has been identified for one or more mismatch repair proteins (MMR).		
Source standards			
Data type	Numeric	**Representational class**	Code
Field size	1	**Representational layout**	N
Value domain	**Clinical term**		**Code**
	For **all four** MMR proteins, **no** loss of nuclear expression has been identified		0
	In **one or more** of the MMR proteins, a loss of nuclear expression has been identified		1
Obligation	Conditional. Mandatory if no response is captured for **all** of the mismatch repair proteins (MMR).		
Guide for use	For reporting purposes, this information is only to be submitted in an HL7 massage when a response of '0' is recorded and a code has not been captured in any of the following fields: **Nuclear expression of MLH1** **Nuclear expression of PMS2** **Nuclear expression of MSH2** **Nuclear expression of MSH6**		
Verification rules	Valid value only		

2.2.27 Nuclear expression of MLH1

Definition	This details the outcome of the test for MLH1 by immunohistochemistry.		
Source standards	**National Bowel Cancer Working Group proposal for standards in molecular testing of colorectal cancer**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Data domain			

Clinical term	Code
Intact nuclear expression	161871000210103
Loss of nuclear expression	161881000210101
Other abnormal pattern	161901000210103
Equivocal	280414007
Test failed	161891000210104
Not performed	373121007

Obligation	Conditional. Required for adenocarcinoma.
Guide for use	Mismatch repair protein (MMR) immunohistochemistry helps identify one of four potentially defective MMR genes responsible for a hereditary form of colorectal cancer called Lynch syndrome. In addition, MMR status may predict response to chemotherapy and provide information regarding prognosis. Loss of nuclear expression of MLH1 indicates a need for further testing. Other abnormal patterns include but are not limited to unequivocally weak or subclonal (partial) loss of nuclear expression. 'Equivocal' is used when the staining is difficult to interpret, whether it is normal or abnormal.
Verification rules	Valid code.

2.2.28 Nuclear expression of PMS2

Definition	This details the outcome of the test for PMS2.		
Source standards	**National Bowel Cancer Working Group proposal for standards in molecular testing of colorectal cancer:**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)

Data domain	

Clinical term	Code
Intact nuclear expression	161871000210103
Loss of nuclear expression	161881000210101
Other abnormal pattern	161901000210103
Equivocal	280414007
Test failed	161891000210104
Not performed	373121007

Obligation	Conditional. Required for adenocarcinoma.
Guide for use	Mismatch repair protein (MMR) immunohistochemistry helps identify one of four potentially defective MMR genes responsible for a hereditary form of colorectal cancer called Lynch syndrome. In addition, MMR status may predict response to chemotherapy and provide information about prognosis. Isolated loss of expression suggests Lynch syndrome. Other abnormal patterns include but are not limited to unequivocally weak or subclonal (partial) loss of nuclear expression. 'Equivocal' is used when the staining is difficult to interpret, whether it is normal or abnormal.
Verification rules	One of the options provided.

2.2.29 Nuclear expression of MSH2

Definition	This details the outcome of the test for MSH2.		
Source standards	**National Bowel Cancer Working Group proposal for standards in molecular testing of colorectal cancer**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Data domain			

Clinical term	Code
Intact nuclear expression	161871000210103
Loss of nuclear expression	161881000210101
Other abnormal pattern	161901000210103
Equivocal	280414007
Test failed	161891000210104
Not performed	373121007

Obligation	Conditional. Required for adenocarcinoma.
Guide for use	Mismatch repair protein (MMR) immunohistochemistry helps identify one of four potentially defective MMR genes responsible for a hereditary form of colorectal cancer called Lynch syndrome. In addition, MMR status may predict response to chemotherapy and provide information about prognosis. Loss of MSH2 (usually accompanied by loss of MSH6) raises the possibility of Lynch syndrome. Other abnormal patterns include but are not limited to unequivocally weak or subclonal (partial) loss of nuclear expression. 'Equivocal' is used when the staining is difficult to interpret, whether it is normal or abnormal.
Verification rules	Valid code.

2.2.30 Nuclear expression of MSH6

Definition	This details the outcome of the test for MSH6.		
Source standards	**National Bowel Cancer Working Group proposal for standards in molecular testing of colorectal cancer**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)

Data domain	

Clinical term	Code
Intact nuclear expression	161871000210103
Loss of nuclear expression	161881000210101
Other abnormal pattern	161901000210103
Equivocal	280414007
Test failed	161891000210104
Not performed	373121007

Obligation	Conditional. Required for an adenocarcinoma.
Guide for use	Mismatch repair protein (MMR) immunohistochemistry helps identify one of four potentially defective MMR genes responsible for a hereditary form of colorectal cancer called Lynch syndrome. In addition, MMR status may predict response to chemotherapy and provide information about prognosis. Isolated loss of expression raises the possibility of Lynch syndrome. Other abnormal patterns include but are not limited to unequivocally weak or subclonal (partial) loss of nuclear expression. 'Equivocal' is used when the staining is difficult to interpret, whether it is normal or abnormal.
Verification rules	One of the options provided.

2.2.31 BRAFV600E mutation status

Definition	This details the outcome of the test for BRAFV600E mutation.		
Source standards	**National Bowel Cancer Working Group proposal for standards in molecular testing of colorectal cancer**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Data domain			

Clinical term	Code
BRAFV600E mutation present (SNOMED term: Present)	52101004
BRAFV600E mutation absent (SNOMED term: Absent)	2667000
Test failed	161891000210104
Not performed	373121007

Obligation	Conditional. Required in those colorectal adenocarcinomas with MLH1 loss, microsatellite instability or stage IV colorectal disease.

Guide for use	BRAFV600E mutational analysis is performed when there is a loss of expression of MLH1 and PMS2 to rule out the methylation pathway to colorectal cancer. The oncologists may also use this for prognosis and treatment selection. Lynch syndrome is unlikely if BRAFV600E mutation is present in adenocarcinoma with loss of MLH1.
Verification rules	Valid code.

2.2.32 BRAF method of testing

Definition	This indicates the means by which BRAFV600E mutation status was determined.		
Source standards			
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Data domain			

Clinical term	**SNOMED Concept (SCTID)**
Immunohistochemistry	117617002
Non-immunohistochemical assay (eg, RT-PCR, Sanger sequencing, NGS, FA test) *(SNOMED term: 'Molecular genetics procedure')*	116148004

Obligation	Conditional. Required if BRAFV600E mutation status documented as present, absent or failed.
Guide for use	
Verification rules	

2.2.33 MLH1 promoter methylation testing

Definition	This indicates the outcome of the analysis for MLH1 promoter methylation.		
Source standards	**National Bowel Cancer Working Group proposal for standards in molecular testing of colorectal cancer**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)

Data domain	

Clinical term	Code
MLH1 promoter hypermethylation present (SNOMED CT term: Present)	52101004
MLH1 promoter hypermethylation absent (SNOMED CT term: Absent)	2667000
Inconclusive/equivocal	280414007
Test failed	161891000210104
Not performed	373121007

Obligation	Conditional. Required if MLH1 and PMS2 show absent nuclear expression and BRAFV600E mutation is absent.
Guide for use	Analysis for MLH1 promoter methylation should be performed when BRAFV600E mutation is absent in adenocarcinoma with loss of MLH1. Lynch syndrome is unlikely if MLH1 promoter hypermethylation is present in adenocarcinoma with loss of MLH1.
Verification rules	

2.3 Other pathological findings

For each specimen, in addition to a main pathological finding, there can be up to five or no other pathological findings.

2.3.1 Other pathological finding

Definition	This identifies the pathologist's other pathological finding(s) in addition to the main diagnosis of the specimen. The members in this code set cover both polyps and cancers.		
Source standards			
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Data domain	The clinical terms and corresponding SNOMED CT values that are used for this field are the same as those used in the 'Main diagnosis' field (Section 2.2.6).		
Obligation	Optional		
Guide for use	This field can be used to provide a pathological finding in addition to the main diagnosis for a specimen. There can be up to five instances of this field for each specimen. The pathologist should be able to enter the diagnosis in the same manner as they always have or in an intuitive manner when the laboratory information systems are upgraded. This field can be repeated.		
Verification rules	The value must be one of the agreed options.		