Bowel Screening Histology Data Standard

HISO 10072.1:2022

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# Introduction

The National Bowel Screening Programme[[1]](#footnote-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.

## 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).

## 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.

## Implementation

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

## 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.

## Legislation and regulations

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

* [Health Act 1956](https://www.legislation.govt.nz/act/public/1956/0065/latest/DLM305840.html)
* [Health and Disability Commissioner (Code of Health and Disability Services Consumers’ Rights) Regulations 1996](https://www.legislation.govt.nz/regulation/public/1996/0078/latest/whole.html)
* [Health Information Privacy Code 2020](https://www.privacy.org.nz/privacy-act-2020/codes-of-practice/hipc2020/)
* [Health Practitioners Competence Assurance Act 2003](https://www.legislation.govt.nz/act/public/2003/0048/latest/DLM203312.html)
* [Privacy Act 2020](https://www.legislation.govt.nz/act/public/2020/0031/latest/LMS23223.html)
* [Public Records Act 2005](https://www.legislation.govt.nz/act/public/2005/0040/latest/DLM345529.html)
* [Health (Retention of Health Information) Regulations 1996.](https://www.legislation.govt.nz/regulation/public/1996/0343/latest/DLM225616.html)

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

## 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](https://www.health.govt.nz/publication/hiso-1007222019-bowel-screening-messaging-implementation-guide)
* [HISO 10005:2008 Health Practitioner Index (HPI) Data Set](https://www.health.govt.nz/publication/hiso-100052008-health-practitioner-index-hpi-data-set)
* [HISO 10006:2008 Health Practitioner Index (HPI) Code Set](https://www.health.govt.nz/publication/hiso-100062008-health-practitioner-index-hpi-code-set)
* [HISO 10046 Consumer Health Identity Standard](https://www.health.govt.nz/publication/hiso-100462021-consumer-health-identity-standard)
* [Digestive System Tumours: WHO Classification of Tumours, 5th edition, Volume 1](https://publications.iarc.fr/579)
* [ICCR Colorectal Excisional Biopsy (Polypectomy) Histopathology Reporting Guide](C://Users/skerruis/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/I1JVX3ME/ICCR-Poly-1st-edn-v1-0-hyperlink.pdf)

## Revision history

|  |  |
| --- | --- |
| **Updated** | Details |
| November 2021 | Update to Figure 1, logical model  Data elements added to support reporting:  [Polyp profile](#_Polyp_profile)  [Extent of invasion](#_Extent_of_invasion)  [Invasion into the adjacent structure/organ details](#_Invasion_into_the)  [Tumour budding assessment indicator](#_Tumour_budding_assessment)  [Number of tumour buds](#_Number_of_tumour)  [Tumour budding score](#_Tumour_budding_score)  [Loss of nuclear expression for MMR proteins](#_Loss_of_nuclear)  Measurement requirements added to:  [Deep margin status](#_Deep_margin_status)  [Peripheral margin status](#_Peripheral_margin_status)  [Depth of invasion](#_Depth_of_invasion) |
| May 2022 | Update to data elements:  [Tumour budding score](#_Tumour_budding_score)  [Loss of nuclear expression for MMR proteins](#_Loss_of_nuclear)  [Margin – polypectomy](#_Margin_–_polypectomy)  [Haggitt level](#_Haggitt_level)  [Nuclear expression of MLH1](#_Nuclear_expression_of)  [Nuclear expression of PMS2](#_Nuclear_expression_of_1)  [Nuclear expression of MSH2](#_Nuclear_expression_of_2)  [Nuclear expression of MSH6](#_Nuclear_expression_of_3)[BRAFV600E mutation status](#_BRAFV600E_mutation_status)  [MLH1 promoter methylation testing](#_MLH1_promoter_methylation) |

## Data element template

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

# 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



## Report

This subsection lists the relevant data elements for a report.

### Laboratory facility identifier

|  |  |  |  |
| --- | --- | --- | --- |
| **Definition** | The unique identifier for the facility (laboratory) that performed the pathology work. | | |
| **Source standards** | [Health Provider Index](https://www.health.govt.nz/our-work/health-identity/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](https://www.health.govt.nz/nz-health-statistics/data-references/code-tables/common-code-tables/facility-code-table) to identify the relevant HPI Facility ID. | | |
| **Verification rules** | A valid HPI Facility ID | | |

### 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.

### 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](https://www.health.govt.nz/publication/hiso-100052008-health-practitioner-index-hpi-data-set) | | |
| **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. | | |

### Patient identifier

This is the identifier, recorded in the [National Health Index (NHI)](https://www.health.govt.nz/our-work/health-identity/national-health-index) 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](https://www.health.govt.nz/publication/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.

### 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](https://www.health.govt.nz/system/files/documents/publications/hiso-10046-consumer-health-identity-standard-update-oct2017.pdf).

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

### 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](https://www.health.govt.nz/publication/hiso-10046-consumer-health-identity-standard).

### 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. | | |

### 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](https://www.health.govt.nz/our-work/health-identity/health-provider-index) | | |
| **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](https://www.health.govt.nz/nz-health-statistics/data-references/code-tables/common-code-tables/facility-code-table) to identify the relevant HPI Facility ID. | | |
| **Verification rules** | A valid HPI Facility ID. | | |

### 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](https://www.health.govt.nz/publication/hiso-100052008-health-practitioner-index-hpi-data-set) | | |
| **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]](#footnote-3) | | |
| **Verification rules** | The CPN can be obtained from the clinician but must be validated by the HPI system. | | |

### 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](https://www.health.govt.nz/our-work/health-identity/health-provider-index) | | |
| **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](https://www.health.govt.nz/nz-health-statistics/data-references/code-tables/common-code-tables/facility-code-table) to identify the relevant HPI Facility ID. | | |
| **Verification rules** | A valid HPI Facility ID. | | |

### Clinician report sent to

|  |  |  |  |
| --- | --- | --- | --- |
| **Definition** | Identifier for the clinician who the report was sent to. | | |
| **Source standards** | [Health Practitioner Index data standards](https://www.health.govt.nz/publication/hiso-100052008-health-practitioner-index-hpi-data-set) | | |
| **Data type** | Alphanumeric | **Representational class** | Identifier |
| **Field size** | 6 | **Representational layout** | NNAAAA |
| **Data domain** | CPN numbers generated by the HPI system | | |
| **Obligation** | Mandatory | | |
| **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]](#footnote-4) | | |
| **Verification rules** | The CPN can be obtained from the clinician but must be validated by the HPI system. | | |

### 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. | | |

### 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](https://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. | | |

### 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. | | |

### 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. | | |

### 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** |  | | |

## Specimen

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

### 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** |  | | |

### 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. | | |

### 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. | | |

### 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. | | |

### 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 | | |

### 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](file:///C:\Users\skerruis\Downloads\Digestive%20System%20Tumours:%20WHO%20Classification%20of%20Tumours,%205th%20edition,%20Volume%201) * 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. | | | | | |

### 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](https://www.nsu.govt.nz/resources/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** |  | | |

### 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. | | |

### 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 | | |

### 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](https://publications.iarc.fr/579) | | |
| **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** |  | | |

### 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](https://www.rcpa.edu.au/getattachment/777b2f36-3b54-4d97-94c0-040a31f97b2b/Protocol-Polypectomy-local-resections-CR.aspx) | | |
| **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. | | |

### 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. | | |

### 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. | | |

### 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** |  | | |

### 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** |  | | |

### 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 | | |

### 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](C://Users/skerruis/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/I1JVX3ME/ICCR-Poly-1st-edn-v1-0-hyperlink.pdf) | | |
| **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 | | |

### 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** |  | | |

### 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** |  | | |

### 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 | | |

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

### 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** |  | | |

### 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. | | |

### 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. | | |

### 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. | | | |

### 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)  [Nuclear expression of PMS2](#_Nuclear_expression_of_1)  [Nuclear expression of MSH2](#_Nuclear_expression_of_2)  [Nuclear expression of MSH6](#_Nuclear_expression_of_3) | | |
| **Verification rules** | Valid value only | | |

### 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](https://www.health.govt.nz/system/files/documents/publications/molecular-testing-colorectal-cancer-nz-jun18.pdf) | | |
| **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. | | |

### 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:](https://www.health.govt.nz/system/files/documents/publications/molecular-testing-colorectal-cancer-nz-jun18.pdf) | | |
| **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. | | |

### 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](https://www.health.govt.nz/system/files/documents/publications/molecular-testing-colorectal-cancer-nz-jun18.pdf) | | |
| **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. | | |

### 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](https://www.health.govt.nz/system/files/documents/publications/molecular-testing-colorectal-cancer-nz-jun18.pdf) | | |
| **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. | | |

### 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](https://www.health.govt.nz/system/files/documents/publications/molecular-testing-colorectal-cancer-nz-jun18.pdf) | | |
| **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. | | |

### 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** |  | | |

### 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](https://www.health.govt.nz/system/files/documents/publications/molecular-testing-colorectal-cancer-nz-jun18.pdf) | | |
| **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** |  | | |

## Other pathological findings

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

### 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. | | |

1. [www.timetoscreen.nz/bowel-screening/about-the-national-bowel-screening-programme](https://www.timetoscreen.nz/bowel-screening/about-the-national-bowel-screening-programme/) [↑](#footnote-ref-1)
2. See <https://standards.iso.org/ittf/PubliclyAvailableStandards/index.html> [↑](#footnote-ref-2)
3. [www.health.govt.nz/our-work/regulation-health-and-disability-system/health-practitioners-competence-assurance-act/responsible-authorities-under-act](http://www.health.govt.nz/our-work/regulation-health-and-disability-system/health-practitioners-competence-assurance-act/responsible-authorities-under-act) [↑](#footnote-ref-3)
4. [www.health.govt.nz/our-work/regulation-health-and-disability-system/health-practitioners-competence-assurance-act/responsible-authorities-under-act](http://www.health.govt.nz/our-work/regulation-health-and-disability-system/health-practitioners-competence-assurance-act/responsible-authorities-under-act) [↑](#footnote-ref-4)