Bowel Screening Histology Data Standard

Draft for public comment

HISO 10072.2: 2019

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Contents

1 Introduction 1

1.1 Purpose 1

1.2 Scope 1

1.3 Implementation 2

1.4 SNOMED CT 2

1.5 New Zealand legislation 2

1.6 Data element definitions 3

2 Data elements 4

2.1 Report 5

2.2 Specimen 11

2.3 Other pathological findings 27

# Introduction

The National Bowel Screening Programme[[1]](#footnote-1) (NBSP) is a free programme for men and women aged 60 – 74 years eligible for publically 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 is capable of being extended to support future population health initiatives.

## Purpose

The standard identifies and describes the data elements that need to be captured in information systems of the laboratories contracted to perform NBSP histology services. 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 into the NSS.

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

## Scope

The standard defines the data required to be sent to the NSS. This standard 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 the data specified in this standard is able to be captured accordingly.

## 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 one of a number of member countries.

## New Zealand legislation

The following Acts of Parliament and Regulations have specific relevance to this standard. Readers must consider other Acts and Regulations and their amendments that are relevant to their own organisation, in the implementation or use of this standard:

* Health Act 1956
* Health and Disability Commissioner (Code of Health and Disability Services Consumers’ Rights) Regulations 1996
* Health Information Privacy Code 1994
* Health Practitioners Competence Assurance Act 2003
* Privacy Act 1993 (revised 2008)
* Public Records Act 2005
* Retention of Health Information Regulations 1996.

## Data element definitions

Each data element in this standard is defined according to a set of metadata components from ISO/IEC 11179 *Information Technology – Specification and standardization of data elements* 2003.

|  |  |  |  |
| --- | --- | --- | --- |
| **Definition** | A statement that expresses the essential nature of the data element and its differentiation from all other data elements in this standard | | |
| **Source standards** | Established data definitions or guidelines pertaining to the data element | | |
| **Data type** | Alphabetic (A)  Numeric (N)  Alphanumeric (X)  Boolean  Date | **Representational class** | Code, free text, value or identifier  For date and time data types, use full date or partial date  Does not apply to Boolean types |
| **Field size** | Maximum number of characters | **Representational layout** | The arrangement of characters in the data element – eg,   * ‘A(50)’ means up to 50 alphabetic characters * ‘NNAAAA’ means two numeric followed by four alphabetic characters.   Full date/time representation is YYYYMMDD hh:mm:ss. |
| **Obligation** | Indicates if the data element is mandatory or optional for the entity being discussed. It can include conditional obligations of the data element. | | |
| **Data domain** | The valid values or codes that are acceptable for the data element.  The data elements contained in this standard are dates, free text or coded.  Each coded data element has a specified code set. | | |
| **Guide for use** | Additional guidance about using the data element. | | |
| **Verification rules** | Quality control mechanisms that preclude invalid values. | | |

# Data elements

This section describes the set of histology data that needs to be sent to the NSS for use by the NBSP. The messages sent to the NSS are in addition and different to the existing 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.



## Report

This section 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** | Information on the Health Provider Index is available at <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 |
| **Obligation** | Mandatory | | |
| **Data domain** | A valid HPI Facility ID | | |
| **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. The current list is available at <https://www.health.govt.nz/nz-health-statistics/data-references/code-tables/common-code-tables/facility-code-table>. | | |
| **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 specimens or episode is documented in the laboratory information system. | | |
| **Source standards** | N/A | | |
| **Data type** | Alphanumeric | **Representational class** | Identifier |
| **Field size** | 30 | **Representational layout** | X(30) |
| **Obligation** | Mandatory | | |
| **Data domain** | As defined by the laboratory. | | |
| **Guide for use** | N/A | | |
| **Verification rules** | Each laboratory report identifier must be unique for all reports 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 who extracted the samples which this histology report relates to. | | |
| **Source standards** | HPI documentation: [www.health.govt.nz/our-work/health-identity/health-practitioner-index](http://www.health.govt.nz/our-work/health-identity/health-practitioner-index)  See also:   * HISO 10005:2008 Health Practitioner Index Data Set: [www.health.govt.nz/publication/hiso-100052008-health-practitioner-index-hpi-data-set](http://www.health.govt.nz/publication/hiso-100052008-health-practitioner-index-hpi-data-set) * HISO 10006:2008 Health Practitioner Index Code Set: [www.health.govt.nz/publication/hiso-100062008-health-practitioner-index-hpi-code-set](http://www.health.govt.nz/publication/hiso-100062008-health-practitioner-index-hpi-code-set) | | |
| **Data type** | Alphanumeric | **Representational class** | Identifier |
| **Field size** | 6 | **Representational layout** | NNAAAA |
| **Obligation** | Mandatory | | |
| **Data domain** | HPI Common Person Number (CPN) generated by the HPI system. | | |
| **Guide for use** | This field uses the Health Provider Index (HPI) CPN, a unique identifying number for the health practitioner delivering the service. This field is only for use where the practitioner is a member of a Responsible Authority under the Health Practitioners Competence Assurance Act 2003. | | |
| **Verification rules** | CPN can be obtained from the clinician but must be validated with the HPI system. | | |

### Patient identifier

|  |  |  |  |
| --- | --- | --- | --- |
| **Definition** | National Health Index (NHI) number – a unique identifier assigned by the NHI system to a patient. | | |
| **Source standards** | HISO 10046 Consumer Health Identity Standard: www.health.govt.nz/publication/hiso-10046-consumer-health-identity-standard  See also NHI data dictionary: www.health.govt.nz/publication/national-health-index-data-dictionary. | | |
| **Data type** | Alphanumeric | **Representational class** | Identifier |
| **Field size** | 7 | **Representational layout** | AAANNNN |
| **Obligation** | Mandatory | | |
| **Data domain** | NHI numbers | | |
| **Guide for use** | Only the NHI system generates the NHI number assigned to a patient.  NHI numbers are not reused once assigned to a patient.  Where more than one number exists for a patient, one number is declared ‘live’ and all other numbers are made ‘dormant’ and attached to the live record.  The NHI number is the primary key for patients’ records. | | |
| **Verification rules** | See the source standards for the check digit algorithm and NHI number validation rules. | | |

### Patient name

This is the name of the NSS participant whose specimens are being examined and reported on. This is a complex field, and the report must contain the data elements identified in the ‘Patient name’ section 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).

### Patient birth date

|  |  |  |  |
| --- | --- | --- | --- |
| **Definition** | The date when the patient was born. | | |
| **Source standards** | HISO 10046 Consumer Health Identity Standard: www.health.govt.nz/publication/hiso-10046-consumer-health-identity-standard | | |
| **Data type** | Date | **Representational class** | Full or partial date |
| **Field size** | Max: 8 | **Representational layout** | CCYY[MM[DD]] |
| **Obligation** | The year component of the date is mandatory.  Month is conditional and to be used if known.  Day is conditional and to be used if known and month has been recorded. | | |
| **Data domain** | A valid date. | | |
| **Guide for use** | Year of birth must be recorded as a minimum. | | |
| **Verification rules** | The date of birth must be a valid day, month and year combination and cannot be in the future.  For a partial date, the month of birth can be left blank if unknown. In this case, the day of birth must be blank. | | |

### Programme identifier

|  |  |  |  |
| --- | --- | --- | --- |
| **Definition** | This will be ‘NBSP’ for histology sent to NSS as part of the National Bowel Screening Programme. | | |
| **Source standards** | N/A | | |
| **Data type** | Alpha | **Representational class** | Code |
| **Field size** | 4 | **Representational layout** | A(4) |
| **Obligation** | Mandatory | | |
| **Data domain** | |  |  | | --- | --- | |  |  | | **Code** | **Description** | | NBSP | National Bowel Screening Programme | |  |  | | | |
| **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** | Information on the Health Provider Index is available at <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 |
| **Obligation** | Mandatory | | |
| **Data domain** | Valid HPI number only. | | |
| **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. The current list is available at <https://www.health.govt.nz/nz-health-statistics/data-references/code-tables/common-code-tables/facility-code-table>. | | |
| **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** | HPI documentation: [www.health.govt.nz/our-work/health-identity/health-practitioner-index](http://www.health.govt.nz/our-work/health-identity/health-practitioner-index)  See also:   * HISO 10005:2008 Health Practitioner Index Data Set: [www.health.govt.nz/publication/hiso-100052008-health-practitioner-index-hpi-data-set](http://www.health.govt.nz/publication/hiso-100052008-health-practitioner-index-hpi-data-set). * HISO 10006:2008 Health Practitioner Index Code Set: [www.health.govt.nz/publication/hiso-100062008-health-practitioner-index-hpi-code-set](http://www.health.govt.nz/publication/hiso-100062008-health-practitioner-index-hpi-code-set). | | |
| **Data type** | Alphanumeric | **Representational class** | Identifier |
| **Field size** | 6 | **Representational layout** | NNAAAA |
| **Obligation** | Mandatory | | |
| **Data domain** | HPI CPN numbers generated by the HPI system. | | |
| **Guide for use** | This field uses the Health Provider Index (HPI) Common Person Number (HPI\_CPN): A unique identifying number pertaining to 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.[[2]](#footnote-2)  This field is only for use where the practitioner is a member of a Responsible Authority under the Health Practitioners Competence Assurance Act 2003. | | |
| **Verification rules** | CPN can be obtained from the clinician but must be validated with the HPI system. | | |

### Date of order

|  |  |  |  |
| --- | --- | --- | --- |
| **Definition** | The date when the histology order was made, as provided on the request form, which should match the date of the endoscopy. | | |
| **Source standards** | N/A | | |
| **Data type** | Date | **Representational class** | Date |
| **Field size** | 8 | **Representational layout** | CCYYMMDD |
| **Obligation** | Mandatory | | |
| **Data domain** | A valid date | | |
| **Guide for use** | Use the date when the histology order was made | | |
| **Verification rules** | A valid date that is less than or equal to the current date | | |

### Date specimens received

|  |  |  |  |
| --- | --- | --- | --- |
| **Definition** | The date when the specimen(s) were received in the laboratory | | |
| **Source standards** | RCPA guideline and policy (8.2.l): <https://www.rcpa.edu.au/Library/College-Policies/Guidelines/Turnaround-Time-in-Anatomical-Pathology> | | |
| **Data type** | Date | **Representational class** | Date |
| **Field size** | 8 | **Representational layout** | CCYYMMDD |
| **Obligation** | Mandatory | | |
| **Data domain** | A valid date. | | |
| **Guide for use** | Use the date when the tissue was received in the laboratory.  The interim quality standards require that turnaround times are accordant with the RCPA guideline and policy (8.2.l). | | |
| **Verification rules** | A valid date that is less than or equal to the current date. | | |

### Date of report

|  |  |  |  |
| --- | --- | --- | --- |
| **Definition** | The date when the laboratory report was finalised. | | |
| **Source standards** | N/A | | |
| **Data type** | Date | **Representational class** | Date |
| **Field size** | 8 | **Representational layout** | CCYYMMDD |
| **Obligation** | Mandatory | | |
| **Data domain** | A valid date. | | |
| **Guide for use** | Use the date when the laboratory report was finalised. | | |
| **Verification rules** | A valid date that is less than or equal to the current date. | | |

### Clinical details

|  |  |  |  |
| --- | --- | --- | --- |
| **Definition** | Additional clinical information provided by the endoscopist. | | |
| **Source standards** | N/A | | |
| **Data type** | Alphanumeric | **Representational class** | Free text |
| **Field size** | 2000 | **Representational layout** | X(2000) |
| **Obligation** | Conditional. Required where the information is provided on the laboratory request form. | | |
| **Data domain** | Free text. | | |
| **Guide for use** | A free-text description of the pathology or any details about it, not already catered for by the elements in this report. | | |
| **Verification rules** | N/A | | |

## Specimen

There are one or more specimens for each report. The following identified the data elements for a specimen.

### Specimen identifier

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

### Site

|  |  |  |  |
| --- | --- | --- | --- |
| **Definition** | This is the location the tissue was taken from | | |
| **Source standards** | N/A | | |
| **Data type** | Numeric | **Representational class** | Code |
| **Field size** | 18 | **Representational layout** | N(18) |
| **Obligation** | Mandatory | | |
| **Data domain** | |  |  | | --- | --- | |  |  | | **Clinical term** | **SNOMED CT** | | 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 canal | 34381000 | | Colon (NOS) | 71854001 | | Unknown body region | 87100004 | |  |  | | | |
| **Guide for use** | ‘Unknown body region’ should only be used when the histology request form is not filled in correctly.  If the location where the specimen was removed from cannot categorically be identified by the endoscopist, the distance from the anal verge should be recorded instead on the histology request form. This should then be provided in the ‘Distance from anal verge’ element and the site documented as ’Colon (NOS)’. | | |
| **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** | N/A | | |
| **Data type** | Numeric | **Representational class** | Number |
| **Field size** | 2 | **Representational layout** | N(2) |
| **Obligation** | Conditional. Required when provided on laboratory request form. | | |
| **Data domain** | An integer. | | |
| **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 is Colon (NOS) then the distance from the anal verge should be provided. | | |

### Sample procedure

|  |  |  |  |
| --- | --- | --- | --- |
| **Definition** | This identifies how the specimen was removed. | | |
| **Source standards** | N/A | | |
| **Data type** | Numeric | **Representational class** | Code |
| **Field size** | 18 | **Representational layout** | N(18) |
| **Obligation** | Mandatory | | |
| **Data domain** | |  |  |  | | --- | --- | --- | |  |  | | | **Clinical term** | **SNOMED CT** | | Biopsy | 274323008 | | Polypectomy | 274025005 | | Unknown procedure | 428119001 | | Other procedure on large intestine | 118838009 | |  |  | | | | |
| **Guide for use** | Refer to information in the histology request form. | | |
| **Verification rules** | One of the provided options. | | |

### Size

|  |  |  |  |
| --- | --- | --- | --- |
| **Definition** | This is the size of the specimen in millimetres. | | |
| **Source standards** | N/A | | |
| **Data type** | Numeric | **Representational class** | Number |
| **Field size** | 2 | **Representational layout** | N(2) |
| **Obligation** | Conditional. Required if documented. | | |
| **Data domain** | An integer. | | |
| **Guide for use** | According to programme’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 largest dimension should be measured by the reporting pathologist to the nearest millimetre on the haematoxylin and eosin slide.  Provided in mm. | | |
| **Verification rules** | An integer. | | |

### Main diagnosis

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Definition** | This identifies the pathologist’s diagnosis of the specimen | | | | | |
| **Source standards** | The diagnosis options include and expand upon the WHO classification of tumours of the colon and rectum (2010). The options are coded in SNOMED CT. | | | | | |
| **Data type** | Numeric | | **Representational class** | Code | | |
| **Field size** | 18 | | **Representational layout** | N(18) | | |
| **Obligation** | Mandatory | | | | | |
| **Data domain** |  |  | | |  |  |
|  | **Clinical term** | | | **SNOMED CT** |  |
| **Normal diagnosis and unsatisfactory specimen** |  | Normal | | | 30389008 |  |
|  | Specimen unsatisfactory for diagnosis | | | 112631006 |  |
| **Cancers** |  | Adenocarcinoma of large intestine | | | TBD |  |
|  | Adenocarcinoma in adenomatous polyp | | | 43233001 |  |
|  | Suspicious of adenocarcinoma | | | 315274008 |  |
|  | Mucinous adenocarcinoma | | | 72495009 |  |
|  | Signet ring cell carcinoma | | | 87737001 |  |
|  | Serrated adenocarcinoma | | | 450948005 |  |
|  | Cribriform comedo type adenocarcinoma | | | 733838009 |  |
|  | Medullary carcinoma | | | 32913002 |  |
|  | Micropapillary carcinoma | | | 450895005 |  |
|  | Squamous cell carcinoma | | | 28899001 |  |
|  | Neuroendocrine carcinoma (NEC) | | | TBD |  |
|  | Undifferentiated carcinoma | | | 38549000 |  |
|  | Mixed adenoneuroendocrine carcinoma | | | 51465000 |  |
|  | Adenocarcinoma (non-colorectal) | | | TBD |  |
|  | Malignant tumour (non bowel) | | | TBD |  |
|  | Malignant tumour (other, primary in bowel) | | | TBD |  |
|  | Benign neoplasm (other primary bowel) | | | TBD |  |
|  | Adenosquamous carcinoma | | | 59367005 |  |
|  | Neuroendocrine tumour (NET) | | | TBD |  |
| **Polyps** |  | Tubular adenoma | | | 19665009 |  |
|  | Tubulovillous adenoma | | | 61722000 |  |
|  | Villous adenoma | | | 128859003 |  |
|  | Hyperplastic polyp | | | 62047007 |  |
|  | Sessile serrated adenoma /polyp | | | 443157008 |  |
|  | Traditional serrated adenoma | | | 443734007 |  |
|  | Serrated polyp (not otherwise specified) | | | 449854009 |  |
|  | Inflammatory polyp | | | 76235005 |  |
|  | Mucosal prolapse | | | 29696001 |  |
|  | Mesenchymal tumours – Leiomyoma | | | 44598004 |  |
|  | Mesenchymal tumours – Lipoma | | | 46720004 |  |
|  | Mesenchymal tumours – Gastrointestinal stromal tumour | | | 128755003 |  |
|  | Hamartomatous polyp | | | 27391005 |  |
|  | Lymphoid polyp | | | 80297003 |  |
| **Other pathology** |  | Ulcerative colitis | | | 64766004 |  |
|  | Crohn’s disease | | | 34000006 |  |
|  | Chronic idiopathic inflammatory bowel disease, unclassified | | | 359664009 |  |
|  | Inflammation, unspecified | | | 23583003 |  |
|  |  | | |  |  |
| **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.  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.  *Guidance is currently being refined on how adenocarcinomas known to be from other sites (such as ovarian or prostate adenocarcinoma) should be coded.*  *Guidance is currently being refined on how malignant neoplasms such as a high risk GIST should be coded*. | | | | | |
| **Verification rules** | The value must be one of the agreed options. | | | | | |

### Dysplasia

|  |  |  |  |
| --- | --- | --- | --- |
| **Definition** | Describes the presence or not of dysplasia and where present the degree. | | |
| **Source standards** | 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. | | |
| **Data type** | Numeric | **Representational class** | Code |
| **Field size** | 18 | **Representational layout** | X(18) |
| **Obligation** | Conditional. Required to be if the predisposing adenoma is present. | | |
| **Data domain** | |  |  | | --- | --- | |  |  | | **Clinical term** | **SNOMED CT** | | Low grade dysplasia | 43185009 | | High grade dysplasia | 55237006 | | Dysplasia (NOS) | 25723000 | |  |  | | | |
| **Guide for use** | Low-grade dysplasia describes unequivocal neoplasia confined to the epithelial glands, while high grade dysplasia incorporates architectural changes with supporting cytologic changes.  Dysplasia must be graded for tubular adenomas, tubulovillous adenomas and villous adenomas. It is not required to grade the dysplasia in sessile serrated adenomas/polyps or traditional serrated adenomas. The ‘Dysplasia (NOS)’ option should be used for sessile serrated adenomas/polyps. | | |
| **Verification rules** | Required if the predisposing adenoma is present. | | |

### Margin –polypectomy

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Definition** | This identifies whether there is dysplasia present at the margin of the polyp, and what grade that dysplasia is. | | | |
| **Source standards** | N/A | | | |
| **Data type** | Numeric | **Representational class** | | Code |
| **Field size** | 1 | **Representational layout** | | N |
| **Obligation** | Conditional. Required for all specimens except biopsies. | | | |
| **Data domain** | Involvement by low grade | | 1 | |
| Involvement by high grade | | 2 | |
| No involvement | | 3 | |
| Not assessable | | 4 | |
| **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. | | | |

### Histological grade (tumour differentiation)

|  |  |  |  |
| --- | --- | --- | --- |
| **Definition** | The histologic grade or differentiation describes how much an adenocarcinoma resembles the normal tissue from which it arose. | | |
| **Source standards** | Based on the 2010 WHO classification which uses the degree of gland formation to grade an adenocarcinoma. | | |
| **Data type** | Numeric | **Representational class** | Code |
| **Field size** | 18 | **Representational layout** | X(18) |
| **Obligation** | Conditional | | |
| **Data domain** | |  |  |  | | --- | --- | --- | |  |  | | | **Clinical term** | **SNOMED CT** | | Well differentiated | 263933003 | | Moderately differentiated | 384812005 | | Poorly differentiated | 263843001 | | Undifferentiated | 263918006 | |  |  | | | |
| **Guide for use** | This is required for polypectomy specimens showing adenocarcinomas. It is not required for special variants of adenocarcinoma such as mucinous, medullary, micropapillary, serrated or signet-ring cell carcinoma. | | |
| **Verification rules** | One of the options provided. | | |

### 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** | Number |
| **Field size** | 18 | **Representational layout** | N(18) |
| **Obligation** | Conditional | | |
| **Data domain** | |  |  |  | | --- | --- | --- | |  |  | | | **Clinical term** | **SNOMED CT** | | Present | 52101004 | | Absent | 2667000 | | Not applicable | 385432009 | |  |  | | | |
| **Guide for use** | This is required for polypectomy specimens with a diagnosis of adenocarcinoma. It is not required for special variants of adenocarcinoma such as mucinous, medullary, micropapillary, serrated or signet-ring cell carcinoma. | | |
| **Verification rules** | One of the options provided. | | |

### Lymphatic invasion

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Definition** | This identifies whether there is lymphatic invasion. | | | |
| **Source standards** | N/A | | | |
| **Data type** | Numeric | **Representational class** | Code | |
| **Field size** | 18 | **Representational layout** | X(18) | |
| **Obligation** | Conditional. This is required for polypectomy specimens showing adenocarcinoma. | | | |
| **Data domain** | Present (SNOMED CT term: Lymphatic tumour invasion finding) | | | 385414009 |
| Not present (SNOMED CT term: No tumour invasion) | | | 370049004 |
| Cannot be determined (SNOMED CT term: Tumour invasion cannot be assessed) | | | 370048007 |
| **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** | N/A | | |
| **Data type** | Numeric | **Representational class** | Code |
| **Field size** | 18 | **Representational layout** | X(18) |
| **Obligation** | Conditional. This is required for polypectomy specimens showing adenocarcinoma. | | |
| **Data domain** | |  |  | | --- | --- | |  |  | | **Clinical term** | **SNOMED CT** | | Present (SNOMED CT term: Vascular invasion by tumour present) | 372287009 | | Not present (SNOMED CT term: No tumour invasion) | 370049004 | | Cannot be determined (SNOMED CT term: Tumour invasion cannot be assessed) | 370048007 | |  |  | | | |
| **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 from the deep margin (in mm). | | |
| **Source standards** | N/A | | |
| **Data type** | Numeric | **Representational class** | Numeric |
| **Field size** | 2 | **Representational layout** | N(2) |
| **Obligation** | Conditional. See guide for use. | | |
| **Data domain** | An integer. | | |
| **Guide for use** | This can be used to identify whether the deep margin of the polyp is involved.  The distance from the deep margin (in mm) 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** | N/A | | |

### Peripheral margin status

|  |  |  |  |
| --- | --- | --- | --- |
| **Definition** | This field records the distance of the tumour from the peripheral (mucosal) margin (in mm). | | |
| **Source standards** | N/A | | |
| **Data type** | Numeric | **Data type** | Numeric |
| **Field size** | 2 | **Field size** | N(2) |
| **Obligation** | Conditional. See guide for use. | | |
| **Data domain** | An integer. | | |
| **Guide for use** | This can be used to identify whether the peripheral margin of the polyp is involved.  This 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** | N/A | | |

### Depth of invasion

|  |  |  |  |
| --- | --- | --- | --- |
| **Definition** | This is the maximum depth of an invasive adenocarcinoma from the muscularis mucosae in millimetres. | | |
| **Source standards** | N/A | | |
| **Data type** | Numeric | **Representational class** | Number |
| **Field size** | 3 | **Representational layout** | N(3) |
| **Obligation** | Optional | | |
| **Data domain** | An integer. | | |
| **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. | | |
| **Verification rules** | N/A | | |

### Width of tumour

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

### Haggitt level

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Definition** | This identifies the Haggitt level for polypoid (pedunculated) tumours as determined by the pathologist. Haggitt level can only be determined for a resected polyp and not for a biopsy. It is a four level system. | | | |
| **Source standards** | N/A | | | |
| **Data type** | Numeric | **Representational class** | Code | |
| **Field size** | 1 | **Representational layout** | N | |
| **Obligation** | Conditional. This is required for adenocarcinomas arising in pedunculated polyps removed by polypectomy (not biopsies). | | | |
| **Data domain** | Level 1 = carcinoma invades submucosa; limited to head of polyp | | | 1 |
| Level 2 = carcinoma invades neck of polyp | | | 2 |
| Level 3 = carcinoma invades any part of the stalk | | | 3 |
| Level 4 = carcinoma invades submucosa of bowel wall, below polyp stalk but above muscularis propria | | | 4 |
| Cannot be determined | | | 0 |
| **Guide for use** | This is required for adenocarcinomas removed by polypectomy (not biopsies). The level cannot be determined if the tissue is received piecemeal. | | | |
| **Verification rules** | One of the options provided. | | | |

### 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. Kikuchi levels can only be determined for resected intact polyps and not for biopsies. | | | |
| **Source standards** | N/A | | | |
| **Data type** | Alphanumeric | **Representational class** | Code | |
| **Field size** | 3 | **Representational layout** | XXX | |
| **Obligation** | Conditional. This is required for sessile adenocarcinomas removed by polypectomy (not biopsies). | | | |
| **Data domain** | Slight submucosal invasion (200–300um (0.2–0.3mm) | | | 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 | | | X |
| **Guide for use** | 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). | | | |
| **Verification rules** | One of the options provided. | | | |

### Nuclear expression of MLH1

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Definition** | 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. | | | |
| **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** | 1 | **Representational layout** | | N |
| **Obligation** | Conditional. Required for adenocarcinoma. | | | |
| **Data domain** | Intact nuclear expression | | 1 | |
| Loss of nuclear expression | | 2 | |
| Other abnormal pattern | | 3 | |
| Equivocal | | 4 | |
| Test failed | | 5 | |
| Not performed | | 6 | |
| **Guide for use** | Other abnormal pattern includes but 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** | 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 MSH2 (usually accompanied by loss of MSH6) raises the possibility of Lynch syndrome. | | | |
| **Source standards** | National Bowel Cancer Working Group proposal for standards in molecular testing of CRC. | | | |
| **Data type** | Numeric | **Representational class** | | Code |
| **Field size** | 1 | **Representational layout** | | N |
| **Obligation** | Conditional. Required for adenocarcinoma. | | | |
| **Data domain** | Intact nuclear expression | | 1 | |
| Loss of nuclear expression | | 2 | |
| Other abnormal pattern | | 3 | |
| Equivocal | | 4 | |
| Test failed | | 5 | |
| Not performed | | 6 | |
| **Guide for use** | Other abnormal pattern includes but 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 MSH6

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Definition** | 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. Isolated loss of expression raises the possibility of Lynch syndrome. | | | |
| **Source standards** | National Bowel Cancer Working Group proposal for standards in molecular testing of CRC. | | | |
| **Data type** | Numeric | **Representational class** | | Code |
| **Field size** | 1 | **Representational layout** | | N |
| **Obligation** | Conditional. Required for adenocarcinoma | | | |
| **Data domain** | Intact nuclear expression | | 1 | |
| Loss of nuclear expression | | 2 | |
| Other abnormal pattern | | 3 | |
| Equivocal | | 4 | |
| Test failed | | 5 | |
| Not performed | | 6 | |
| **Guide for use** | Other abnormal pattern includes but 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 PMS2 protein

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Definition** | 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. Isolated loss of expression suggests Lynch syndrome. | | | |
| **Source standards** | National Bowel Cancer Working Group proposal for standards in molecular testing of CRC. | | | |
| **Data type** | Numeric | **Representational class** | | Code |
| **Field size** | 1 | **Representational layout** | | N |
| **Obligation** | Conditional. Required for adenocarcinoma. | | | |
| **Data domain** | Intact nuclear expression | | 1 | |
| Loss of nuclear expression | | 2 | |
| Other abnormal pattern | | 3 | |
| Equivocal | | 4 | |
| Test failed | | 5 | |
| Not performed | | 6 | |
| **Guide for use** | Other abnormal pattern includes but 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** | 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. | | | |
| **Source standards** | NBCWG proposal for standards in molecular testing of CRC. | | | |
| **Data type** | Numeric | **Representational class** | | Code |
| **Field size** | 1 | **Representational layout** | | N |
| **Obligation** | Conditional. Required in those colorectal adenocarcinomas with MLH1 loss, microsatellite instability or stage IV colorectal disease. | | | |
| **Data domain** | BRAFV600E mutation present | | 1 | |
| BRAFV600E mutation absent | | 2 | |
| Not tested | | 3 | |
| Test failed | | 4 | |
| **Guide for use** | Lynch syndrome is unlikely if BRAFV600E mutation is present in adenocarcinoma with loss of MLH1. | | | |
| **Verification rules** | Required in those colorectal adenocarcinomas with MLH1 loss, microsatellite instability or stage IV colorectal disease. | | | |

### BRAF method of testing

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Definition** | This indicates the means by which BRAFV600E mutation status was determined. | | | |
| **Source standards** | N/A | | | |
| **Data type** | Numeric | **Representational class** | Code | |
| **Field size** | 18 | **Representational layout** | N(18) | |
| **Obligation** | Conditional. Required if BRAFV600E mutation status documented as present, absent or failed. | | | |
| **Data domain** | Immunohistochemistry | | | 117617002 |
| Non-immunohistochemical assay (eg, RT-PCR, Sanger sequencing, NGS, FA test etc) (SNOMED clinical term: Molecular genetics procedure) | | | 116148004 |
| **Guide for use** | Only required if BRAFV600E mutation status documented as present, absent or failed. | | | |
| **Verification rules** | Only required if BRAFV600E mutation status documented as present, absent or failed. | | | |

### MLH1 promoter methylation testing

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Definition** | Analysis for MLH1 promoter methylation should be performed when BRAFV600E mutation is absent in adenocarcinoma with loss of MLH1. | | | |
| **Source standards** | National Bowel Cancer Working Group proposal for standards in molecular testing of colorectal cancer. | | | |
| **Data type** | Numeric | **Representational class** | | code |
| **Field size** | 1 | **Representational layout** | | N |
| **Obligation** | Conditional. Required if MLH1 and PMS2 show absent nuclear expression and BRAFV600E mutation is absent. | | | |
| **Data domain** | MLH1 promoter hypermethylation present | | 1 | |
| MLH1 promoter hypermethylation absent | | 2 | |
| Not tested | | 3 | |
| Test failed | | 4 | |
| **Guide for use** | Lynch syndrome is unlikely if MLH1 promoter hypermethylation is present in adenocarcinoma with loss of MLH1. | | | |
| **Verification rules** | Only required if: MLH1 and PMS2 show absent nuclear expression and BRAFV600E mutation is absent. | | | |

## Other pathological findings

For each specimen, in addition to a main pathological finding, there can be up to five other pathological findings, 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** | The diagnosis options include and expand upon the WHO classification of tumours of the colon and rectum (2010). The options are coded in SNOMED CT. | | |
| **Data type** | Numeric | **Representational class** | Code |
| **Field size** | 18 | **Representational layout** | N(18) |
| **Obligation** | Optional | | |
| **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’. | | |
| **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.  Colorectal adenocarcinoma is coded as adenocarcinoma of large intestine, while adenocarcinomas known to be from other sites (such as ovarian or prostate adenocarcinoma) should be coded as adenocarcinoma, no subtype for the purposes of this data. Malignant neoplasms such as a high risk GIST should be coded as ‘malignant, tumour, other’. | | |
| **Verification rules** | The value must be one of the agreed options. | | |

1. [National Bowel Screening Programme: https://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. [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-2)