



ANATOMICAL PATHOLOGY : A GUIDE TO CODING

The following guidelines have been agreed by consensus of Anatomical Pathologists who are members of the Anatomical Pathologist's Group and the National Association of Pathologists (National Pathology Group) and Pathologists in full time Academic Practice:

The *guidelines* have been formulated in order to achieve a uniform coding policy applicable to all histo-pathology investigations.

Examination of appropriate tissue sections, special stains or techniques are relevant to establishing a diagnosis or staging a disease process.

The guide does not refer to any value to be ascribed to any procedure as performed by an Anatomical Pathologist but only gives guidance on the utilisation of the correct codes.

This guideline does not stipulate methods of specimen dissection but such methods as are recommended or described in recognized and appropriate surgical pathology text books, including, but not limited to, Ackerman's Surgical Pathology, Surgical Pathology Dissection by William H. Westra, and the Manual for Gross Sample Examination and Sectioning as published by the Anatomical Pathology Department of the University of the Witwatersrand, which may be used.

1 DEFINITIONS

1.1 SPECIMEN

A specimen is defined as an individual portion of tissue irrespective of its size, submitted as a biopsy or surgical resection which is individually identified by the referring doctor, or is identifiable by macroscopic or microscopic examination by a pathologist.

1.2 SAMPLE

A sample is the tissue submitted for processing in the laboratory which may either be a specimen or may be portions of a specimen selected in the laboratory for microscopic examination and diagnosis.

1.3 TISSUE SECTION

A single tissue section is a thinly cut portion of a sample that is mounted in a paraffin block contained in a cassette. The tissue section is mounted on a glass slide, appropriately stained, and is examined by a pathologist.

1.4 SERIAL STEP SECTIONS

This is the process of slide preparation and subsequent examination of multiple tissue sections cut as a ribbon or from deeper levels from a sample, which is mounted in a cassette. Probable tissue sources for such an examination would include tissue from the gastro-intestinal tract, prostate, skin, uterine cervix, bladder, oral mucosa, kidney and liver, but also other sources where the biopsy material is small.

1.5 SPECIAL STAINS

Routine examination of a tissue section is by use of a standard Haematoxylin and Eosin stain. Should the disease process require further examination or analysis then different stains may be used to identify tissue component types, pathological processes or organisms. Such stains are termed Special Stains. Special stains are distinct from Immunofluorescent or immunoperoxidase stains.

2 GUIDELINES FOR CODING TO BE USED ON CLAIMS

- 2.1 When a single tissue section from a sample is mounted on a single slide for examination, the procedural code 4567 is used. If more than one sample has been selected from the specimen then the code 4571 is used for the second and subsequent sections which may be used as a multiple to indicate the number of further samples examined from a single specimen i.e., the first code used is 4567 for a single specimen, and the second code 4571 is for the second and any subsequent samples.
- 2.2 Any specimen that is individually identified by the referring doctor, or is identified as separate, either by macroscopic or microscopic examination, is coded using the process as outlined above in paragraph 2.1.
- 2.3 When a specimen from which a sample is prepared requires examination of multiple tissue sections mounted on a slide, code for serial step sections 4582 is used.
- 2.4 Should several specimens from the same anatomical site, which do not require detailed individual orientation, be examined and which are mounted on separate glass slides, then code 4584 is used for the second and subsequent samples and may be used as a multiple to indicate the number of such samples examined. i.e., the first code used is 4582 when serial step sections are prepared from a single specimen, and 4584 for the second and any subsequent samples.
- 2.5 When the codes for Serial Step Sections are used, codes 4567 and 4571 cannot be used for the same sample, as code 4582 is inclusive of code 4567 and code 4584 is inclusive of code 4571.
- 2.6 When biopsies are submitted which contain multiple small tissue fragments in a single specimen container which do not require individual orientation, these multiple tissue fragments should be treated as a single specimen and should be coded according to the number of tissue sections (as defined in paragraph 2.3) examined with the use of progression of coding as is set out in codes 4567 and 4571; or if serial sections have been prepared, then codes 4582 and 4584 should be used, according to the number of tissue sections examined. Such specimens would

include endometrial curettings, transurethral prostatic resections or bladder tumour curettings. Such specimens should not be processed or coded as is set out in paragraph 2.7.

- 2.7 If several specimens are submitted in a single specimen container from a single anatomical site and require individual detailed orientation and examination, then each of these specimens should be separately embedded and coded according to the number of tissue sections examined with the use of progression of coding as is set out in codes 4567 and 4571; or if serial sections have been prepared then codes 4582 and 4584 may be used according to the number of tissue sections examined. Only biopsy samples that require individual orientation and examination of the individual fragments submitted are coded in this way.
- 2.8 Specimens from different organs are treated as individual specimens and coded utilising the primary codes 4567 and 4571, or using codes 4582 and 4584 should serial step sections be prepared.
- 2.9 Lymph node dissections, as part of a surgical resection for malignant disease, are treated as separate specimens. The code to be used for each of this is per the number of samples examined.
- 2.10 When individual (anatomically distinct) organs are resected en bloc, each organ is treated as an individual specimen and coded as per the number of samples examined. Examples include but are not limited to splenectomy as part of gastrectomy, prostatectomy as part of radical cystectomy, ovaries or uterine adnexa as part of hysterectomy.

2.11 **FROZEN SECTIONS**

- 2.11.1 Frozen sections that are performed are coded using code 4577 for the first frozen section on a single specimen, and as multiples of code 4578 according to the number of samples examined in theatre.
- 2.11.2 If a further specimen, that is anatomically distinct from the first, is examined the further specimen, in turn, is coded as a separate sample specimen according to the system outlined above in paragraph 2.11.1.
- 2.11.3 In the laboratory frozen section specimens, are submitted for selection of tissue samples for permanent paraffin sections, and are reported separately, and coded as is set out above in paragraphs 2.6 and 2.7.

2.12 **SPECIFIC EXAMINATIONS**

The examinations referred to below are set out in this guideline merely for clarification for coding purposes and for medical schemes to understand the best practice processes used in respect of the examinations referred to in this section. The examinations referred to in this section are those examinations that occur more frequently than any other examination with reference to benefits offered by medical schemes:

2.12.1 **Cone biopsy cervix:**

Complete radial samples should be selected and examined.

2.12.2 **Breast lumpectomy:**

If the specimen is small, all relevant tissue is processed. If large, two thirds of all tissue excluding fat is selected.

2.12.3 **Skins:**

Samples more than 5mm in diameter should be bisected and serial sections cut. Larger specimens may require several samples to be prepared and examined in order to diagnose or to assess resection margins.

2.12.4 **Surgical operative excision specimens including major resections for malignancy:**

2.12.4.1 Charges as set out above in paragraph 2.10 apply for the number of samples selected and examined.

2.12.4.2 Complete and adequate examination will differ according to pathological processes identified macroscopically and possibly following microscopic examination.

2.12.4.3 In some resections for malignant disease or other pathology, sample selections may vary according to diagnosis and the need to stage the disease process. This may necessitate the preparation and examination of multiple samples, which may differ from guidelines as set out in dissection manuals, according to the pathological process present. The multiple samples will be coded accordingly.

2.12.5 **Prostate needle biopsies:**

Each core should be separately embedded in a cassette and serial sections cut.

2.12.6 **Transurethral Prostatic or Bladder resections:**

2.12.6.1 Where the specimens are submitted to a pathologist are composed of large numbers of tissue fragments, the number samples utilised is dependent on the total weight of tissue submitted. Such samples should be placed in cassettes of 2.0 grams per cassette for up to 8 cassettes and thereafter an additional 1 cassette for each 10 grams *provided* that no abnormality or malignancy is detected.

2.12.6.2 Should any abnormality or malignancy be detected, then all reserve tissue should be embedded, so that the volume of the malignancy in the entire tissue may be established or, in the case of pre-neoplastic conditions, so that the possibility of neoplasia or infiltration may be excluded.

2.12.7 **Special stains, immunoperoxidase and immunofluorescence studies:**

The number of special stains and immunohistochemical or immunofluorescent studies that are performed is dependent on the pathological diagnosis or differential diagnosis. The type and number of such special procedures will vary according to the tissue type and pathological processes that are observed or diagnosed. Such special investigations are used to diagnose and stage disease processes and also to exclude pathological processes.

2.12.8 Each special stain and additional deeper serial sections or level is coded using the code 4589.

2.12.8.1 When multiple tissue sections are prepared utilising the same stain, such as for the identification of scanty micro-organisms, these are coded as individual special stains using code 4589.

2.12.8.2 Immunoperoxidase stains are coded using code 4592.
Immunofluorescent stains are coded using code 4591.

2.12.8.3 When the same immunoperoxidase or immunofluorescent stain is prepared on several samples then each of these is coded as an individual item, i.e. as multiples of code 4592 or 4591 (for immunofluorescent stains).

2.12.8.4 When the same special stain is prepared on several samples then each of these is coded as an individual item, i.e. multiples of 4589.

2.12.8.5 When additional single tissue sections or additional serial sections are required in order to look at deeper levels of an existing paraffin embedded sample then multiples of the code 4589 can be used for each additional slide prepared. The codes 4584 and 4571 cannot be used for this purpose.

2.13 Examination of FNA Cytology In Theatre (4565):

The code 4565 is used as multiples based on the number of FNA passes examined.
If one pass results in one good smear: 4565x01 and 4561x01.

2.14 Performance of FNA By Pathologist (4564):

The code 4564 is used in addition to 4565 (as multiples) based on the number of FNA passes performed by the pathologist. This applies to pathologists who offer an FNA service where the pathologist performs and examines the FNA specimen themselves.
If one pass results in one good smear = 4564x01 and 4565x01.

4565 must also be used when intra-operative smears are made outside the context of an FNA (such as smears on brain tumour tissue).

2.15 Special Procedures (4590):

The code 4590 is used for special procedures as listed below:

Polarization - billed per slide polarized

Decalcification - billed per block decalcified

Use of fat revealing agent - billed per specimen

Submission of blocks or specimen for radiological examination - billed per block or specimen examined (to identify microcalcifications/radiologic markers)

3. MOLECULAR TESTING IN ANATOMICAL PATHOLOGY

Advances in the understanding of solid tumours has lead to rapid growth in the development of molecularly-targeted therapies. Patients with tumours harbouring specific mutations may be candidates for specific therapies. Additionally, molecular testing can aid in prognostic stratification or identification of treatment-resistant tumours. Due to these advances, molecular testing has been incorporated into international oncology and pathology guidelines¹⁻⁴. In addition, molecular testing (germline testing) may also be used to identify hereditary cancer syndromes.

Testing of molecular markers for the more common solid tumours (somatic testing) such as colorectal cancer (CRC) or non-small-cell lung carcinoma (NSCLC) can follow one of two approaches: Broad panel-based testing of multiple genes by next generation sequencing (NGS) technology or a step-wise testing approach of single gene markers by real-time PCR (rtPCR) or FISH. Molecular testing of stage III/IV melanoma has traditionally been limited to BRAF analysis, however, broader testing for other molecular targets and prognostic indicators (such as NRAS, KIT, NTRK, ROS-1 and ALK⁵) are likely to become of value.

Molecular pathology laboratories can facilitate the following testing approaches:

3.1 NGS testing:

The NGS assay offered by most laboratories is a 52-gene based assay to test for most relevant targetable genes of interest (see table below).

NGS testing is appropriate and recommended by most international guidelines as the test of choice in cancers where analysis of multiple genes is appropriate. These include NSCLC (analysis of EGFR, ROS-1, ALK, BRAF & MET) and colorectal cancer (KRAS, NRAS & BRAF).

DNA Panel				RNA Panel	
Hotspot analysis - 35 genes		Copy Number Variant (CNV) analysis - 19 genes		Fusion driver analysis - 23 genes	
AKT1	IDH1	ALK	FGFR3	ABL1	FGFR2
ALK	IDH2	AR	FGFR4	AKT3	FGFR3
AR	JAK1	BRAF	KIT	ALK	MET
BRAF	JAK2	CCND1	KRAS	AXL	NTRK1
CDK4	JAK3	CDK4	MET	BRAF	NTRK2
CTNNB1	KIT	CDK6	MYC	ERG	NTRK3
DDR2	KRAS	EGFR	MYCN	ETV1	PDGFRA
EGFR	MAP2K1	ERBB2	PDGFRA	ETV4	PPARG
ERBB2	MAP2K2	FGFR1	PIK3CA	ETV5	RAF1
ERBB3	MET	FGFR2		EGFR	RET
ERBB4	MTOR			ERBB2	ROS1
ESR1	NRAS			FGFR1	
FGFR2	PDGFRA				
FGFR3	PIK3CA				
GNA11	RAF1				
GNAQ	RET				
HRAS	ROS1				
	SMO				

■ Hotspots only
 ■ CNVs only
 ■ Fusions only
 ■ Hotspot & CNVs
■ Hotspot & CNVs & Fusions
 ■ Hotspot & Fusions
 ■ CNV & Fusions

3.2 Single gene testing by rtPCR:

Single-gene testing for EGFR, KRAS, NRAS, BRAF is also offered by most laboratories. Mutations in these genes predict response or resistance to targeted treatments and also have prognostic implications. The following relevant mutations/variants should be covered for each gene tested:

- **BRAF** (BRAF V600E/E2/D and V600K/R/M mutations)
- **KRAS** (KRAS mutations in codons 12, 13, 59, 61, 117 or 146v)
- **NRAS** (NRAS mutations in codons 12, 13, 59, 61, 117, 146)
- **EGFR** (exon 18 (G719A/C/S), exon 21 (L858R, L861Q) exon 20 (T790M, S768I) mutations, exon 19 deletions and exon 20 insertions in the EGFR oncogene)

3.3 Single gene testing by fluorescence in situ hybridisation (FISH):

FISH testing allows for evaluation of gene significant gene rearrangements and copy number variants. These may have diagnostic or prognostic value or predict response to targeted treatments. Common examples would be:

- **Her2 amplification** in breast cancer (predicts response to Her2 inhibitors).
- **ALK & ROS-1 rearrangements** in NSCLC (predicts response to targeted treatments)
- **MYC, Bcl-2 & Bcl-6 rearrangements** in lymphoma (predicts prognosis and alters therapy)
- **MDM2 amplification** in well differentiated liposarcoma (assists in confirming the diagnosis)
- **EWSR-1 and SS18 rearrangements** in soft tissue tumours (assists in confirming the diagnosis)

For FISH and ISH testing on solid tumours and lymphomas the following codes may be used:

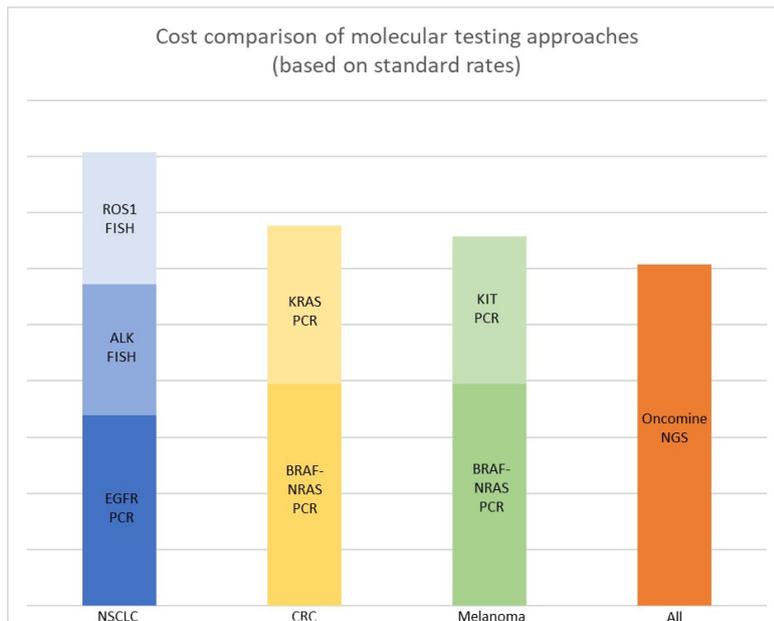
4760: Preparation of the sample for FISH analysis

4761: Per probe used

The charge code **4757** will be added to all samples received as paraffin wax sections or bone marrow sections as the analysis of these samples is more labour intensive and time consuming.

Cost comparison between single gene testing and NGS testing of multiple genes:

If two or more gene tests are to be analyzed, eg. in the case of NSCLC (EGFR, ALK & ROS-1) or colorectal carcinoma (KRAS, NRAS & BRAF), it is more cost effective to request an NGS panel rather than multiple sequential single gene tests. The NGS panel also allows for the most conservative use of your patient's specimen.



3.4 Circulating tumour DNA (liquid biopsy):

In recent years, liquid biopsies have emerged as a promising tool in the fields of molecular oncology and precision medicine. Liquid biopsy methodology typically analyses genomic DNA isolated from circulating tumour cells (CTCs) or circulating cell-free tumour DNA (cfDNA/ctDNA) in a peripheral blood sample, to gain insight into the genomic profile of the patients' tumour. Since liquid biopsy only requires a routine blood draw, it can overcome many of the limitations associated with tissue biopsies, such as limited accessibility to tumour tissue or risks of adverse effects due to invasive sampling methods.

Currently analysis of circulating tumour DNA (so called liquid biopsy) for EGFR mutations is available at South African labs with analysis of a broader panel of genes being available as send away tests overseas.

The following EGFR mutations are usually covered:

- **EGFR** (exon 18 (G719A/C/S), exon 21 (L858R, L861Q), exon 20 (T790M, S768I) mutations, exon 19 deletions and exon 20 insertions in the EGFR oncogene)

Analysis of cell free DNA for EGFR mutations is appropriate or is usually indicated in the following contexts:

- Physicians may use cfDNA methods to identify EGFR T790M mutations in lung adenocarcinoma patients that have developed **secondary clinical resistance to an EGFR-targeted TKI**.
- In some clinical settings in which **tissue is limited and/or insufficient** for molecular testing or when a **biopsy of a tumour is not possible**, physicians may use a cfDNA assay to identify EGFR mutations.

A liquid biopsy has high specificity (83.3-99%), however, only has intermediate sensitivity (60-80%). A negative result must therefore always be followed by an attempt at a tissue biopsy for EGFR analysis before a patient is accepted as being negative⁶.

3.5 **Testing for BRCA1 & BRCA2 & other Homologous recombination repair (HRR) genes:**

Evaluation of tumour specimens for alterations in BRCA1, BRCA2 and other HRR genes is useful in predicting response to PARP inhibitor therapy and platinum-based chemotherapy in a number of tumour types, as discussed below:

Ovarian cancer	Advanced ovarian cancer carrying somatic or germline mutations in <i>BRCA1</i> or <i>BRCA2</i> who have responded to front line platinum-based therapy ⁵⁻⁶ or recurrent cancer (previously responding to platinum-based therapy) have been shown to benefit from maintenance PARP inhibitor therapy (SOLO1/2, NOVA, ARIEL3 trials). Deficiencies in other HRR pathway genes have been found to show responses to PARP inhibitors similar to those with <i>BRCA1</i> or <i>BRCA2</i> variants.
Breast cancer	The FDA has approved PARP inhibitors (Olaparib and Talazoparib) for patients with germline <i>BRCA1</i> or <i>BRCA2</i> pathogenic variants and HER2-negative breast cancer who have previously been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting (OlympiAD and EMBRACA trials).
Prostate cancer	A prospective case series showed that 23% of advanced prostate cancers had potentially actionable somatic alterations in an HRR pathway-related gene ¹⁴ . All men with advanced castration-resistant prostate cancer who have received prior taxane therapy and who may have access to PARP inhibitor therapy should undergo germline or tumour (somatic) testing for alterations in the genes involved in the HRR pathway.
Pancreatic cancer	Pathogenic variants in <i>BRCA1</i> , <i>BRCA2</i> or <i>PALB2</i> are present in approximately 10% of pancreas cancer specimens, 5% of which will have a germline variant and 5% a somatic variant only. Regimens that include a platinum agent should be considered standard regimens in all patients with somatic or germline variants in HRR related genes ¹⁶ . Furthermore, these alterations also select those patients who are likely to benefit from maintenance therapy with PARP inhibitors after response to an initial period of platinum containing chemotherapy. Based on the results of the POLO trial, the FDA approved Olaparib for first-line maintenance therapy in patients with germline <i>BRCA1</i> or <i>BRCA2</i> pathogenic variants.

3.6 Comprehensive Genomic Profiling:

Comprehensive Genomic Profiling (CGP) is a next-generation sequencing (NGS) technique that simultaneously evaluates hundreds of genes (>500 genes) for a variety of alterations, including single nucleotide variants (SNVs), insertions/deletions (indels), copy number variations (CNVs), gene fusions, tumour mutational burden (TMB), microsatellite instability (MSI) and homologous recombination deficiency (HRD). The motivation for its widespread adoption is compelling and multi-faceted, supported by a growing body of clinical evidence. An example of a CGP assay would be the OncoPrint Comprehensive Assay Plus.

The advantages of CGP are as follows:

Unlocking Additional Targeted Therapy Opportunities and Improving Outcomes

CGP allows for the identification of rare genomic alterations that can be targeted with specific therapies beyond the traditional genes tested for by smaller NGS panels.

Tumour-Agnostic Therapy

Perhaps the most powerful argument for CGP is its ability to identify biomarkers that are effective across diverse cancer types. The most notable examples are:

Microsatellite Instability-High (MSI-H): Tumours with this biomarker, regardless of origin, respond exceptionally well to immune checkpoint inhibitors (pembrolizumab, dostarlimab). This led to the first-ever tissue-agnostic FDA approval in 2017⁷.

NTRK Gene Fusions: While rare, fusions involving NTRK1/2/3 are highly actionable with TRK inhibitors (larotrectinib, entrectinib), producing dramatic and durable responses in a wide array of cancers⁵.

Informing Prognosis and Understanding Resistance Mechanisms

CGP provides a holistic view of the tumour genome, offering insights beyond simple "actionable" hits.

Tumour Mutational Burden (TMB): TMB, measured by the number of somatic mutations per megabase of DNA, has emerged as a robust predictive biomarker for response to immunotherapy. High TMB (TMB-H) is associated with improved outcomes on checkpoint inhibitors in multiple cancer types, leading to its FDA approval as a companion diagnostic in solid tumours⁸.

Understanding Resistance: When a patient's disease progresses on a targeted therapy, CGP on a new biopsy (or liquid biopsy) can reveal the mechanism of resistance allowing clinicians to strategically select the next line of treatment⁹.

Facilitating patient enrolment into drug trials

CGP may help facilitate patient enrolment into drug trials by matching their tumour's genomic profile to specific trial arms¹⁰.

References:

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DESCRIPTORS USED IN THIS DOCUMENT

CODE	DESCRIPTOR
4430	RECOMBINANT DNA TECHNIQUE
4439	QUANTITATIVE PCR – VIRAL LOAD (NOT HIV) – HEPATITIS B & C, CMV, ETC
4567	FOR EACH HISTOLOGY PER SAMPLE
4571	HISTOLOGY ADDITIONAL SAMPLE/S FROM INDIVIDUAL SPECIMEN
4575	FROZEN SECTION HISTOLOGY AND MACROSCOPIC EXAMINATION IN LABORATORY
4577	FROZEN SECTION HISTOLOGY AND MACROSCOPIC EXAMINATION IN THEATRE
4578	SECOND AND SUBSEQUENT FROZEN SECTION IN THEATRE
4579	ATTENDANCE IN THEATRE; NO EXAMINATION
4582	HISTOLOGY SERIAL STEP SECTIONS FROM INDIVIDUAL SAMPLE
4584	HISTOLOGY ADDITIONAL SERIAL STEP SECTIONS FROM INDIVIDUAL SPECIMEN
4587	FOR EACH HISTOLOGY CONSULTATION PER SPECIMEN
4589	SPECIAL STAIN PREPARATION FOR IDENTIFICATION OF TISSUE COMPONENT TYPES, PATHOLOGY OR ORGANISMS
4590	SPECIAL PROCEDURES
4591	FOR EACH IMMUNOFLUORESCENCE STUDIES
4592	FOR EACH IMMUNOPEROXIDASE STUDIES
4593	ELECTRON MICROSCOPY
4595	FOETAL AUTOPSY EXCLUDING HISTOLOGY

CODE	DESCRIPTOR
4760	FISH PROCEDURE, INCLUDING CELL CULTURE
4761	FISH ANALYSIS PROBE SYSTEM
4757	SPECIFIED ADDITIONAL ANALYSIS eg MOSAICISM, FANCONI ANAEMIA, FRA X, ADDITIONAL STAINING METHODS.