Protocol for an integrated data request of test results from the laboratories of pathological anatomy

CODAP - users version May 2022

Cancer diagnoses & early detection of cancer
(breast, colorectal and cervix)

Belgian Cancer Registry

Table of contents

Introduction

This document will provide a set of instructions on how to transfer data on cancer diagnosis and test results of early cancer detection to the Belgian Cancer Registry. The aim is to provide a clear description of a standardized and integrated protocol describing how data should be transferred, allowing us to process this information and enabling the use of your data e.g. for national and international descriptive statistics on cancer incidence.

Please transfer this document to your IT service responsible for assembling the dataset(s) and/or also to all the pathologists who deliver data.

The legal basis for the work of the Belgian Cancer Registry can be found in: The law of 13 December 2006 called:

'Wet houdende diverse bepalingen betreffende gezondheid (1), hoofdstuk VI, Artikel 39'
'Loi portant dispositions diverses en matière de santé (1), chapitre VI, Article 39'

Changes in this law relevant to this data request were published in the 'Belgisch Staatsblad' / 'Moniteur Belge' on June 2nd, 2010 (art. 29).

A Royal Decree, published in the 'Belgisch Staatsblad' / 'Moniteur Belge' on February 13th, 2012, links the ratification of the laboratories for pathological anatomy to the participation in the cancer registration.

Contact information

For additional information or support, please contact the Belgian Cancer Registry at:

02/250 10 10 or info@kankerregister.org / info@registreducancer.org

or – by preference - your contact person in the Belgian Cancer Registry.

Additional information can also be found at :

www.kankerregister.org / www.registreducancer.org
http://www.kankerregister.org/downl-vr-pathologen
http://www.kankerregister.org/downl-pour-pathologistes

1. Data transfer: general principles

1.1 Which data should be transferred?

The Belgian Cancer Registry kindly asks you to transfer all data concerning these 4 topics:

1. One structured file containing all encoded **cancer diagnoses** and a separate file with the written reports (i.e. 'protocols');

2. One structured file containing the encoded test results of all
breast specimens and a separate file with the written reports (i.e. 'protocols');

3. One structured file containing the encoded test results of all
colorectal specimens and a separate file with the written reports (i.e. 'protocols');

4. One structured file containing the encoded test results of all
cervical smears and biopsies and a separate file with the written reports (i.e. 'protocols').

A detailed description of each data set is stated below.

Remark: following these procedures, it is normal that if a cancer is diagnosed, it may result in double registration: once in the 'classic cancer' file and once in the 'breast', 'colorectal' or 'cervical' file.

Analyses done on request of other laboratories have to be delivered by either the laboratory that executed these tests OR by the laboratory that asked for the tests. This should be a mutual consent between laboratories, but the applicant of the test has to guarantee the information reaches the BCR.

1.2   Data format

A. The format of the structured file is a tab separated text.

B. The anonymous protocols should preferably be submitted in one file as a tab separated text format with a unique and clear delimiter between the different protocols. This delimiter should not appear in the text of the protocol. The specimen number should be mentioned in the protocol. Only .doc and .txt files will be accepted. Separated .dot, .pdf, .html and other files are to be avoided. An example will be provided as attachment.

1.3   Means of delivery

Data should be delivered by uploading on the sFTP-server of the Belgian Cancer Registry. Please read the sFTP-manual in which the simple procedure is explained. Once the data are ready to be sent, please call your contact in the Cancer Registry who will provide you with *a username and password (temporary).* The data you'll deliver by sFTP must be protected by a password (chosen by yourself) that you can communicate by telephone when you inform your contact that data have been placed on the sFTP-server.

Datatransfer by e-mail (even if the file is secured by a password) is not allowed. E-mail can only be used to transfer protocol-numbers or anonymized protocols. Once data allow identification of the patient, e-mail cannot be accepted!

1.4   When a laboratory has several activity centres

-   Separate delivery of the data of the different activity centres is possible when the name of the specific activity centre, responsible for the analysis and registration of the samples, is clearly mentioned.

-   One delivery, containing the activity of all centres, is also allowed provided that an extra variable is added, in particular the name of the activity centre that was responsible for the analysis and registration of the sample.

-   Only the main laboratory will receive a financial reimbursement for the collaboration with the Belgian Cancer Registry (no longer every single activity centre).

2. Data transfer: detailed overview

2.1. Datasets

2.1.A. Dataset for cancer diagnoses

	Variable	Compulsory (C) Optional (O) Highly Recommended (HR)	Format	Short comment (for details see further)
1	INSZ/NISS	C	11 characters, text format without space	Leading zero's should be conserved! ('TEXT' format therefore necessary)
2	Last name	O/C	Free text field	Compulsory if INSZ/NISS unknown
3	First name	O/C	Free text field	Compulsory if INSZ/NISS unknown
4	Sex	C	Male or Female F-M-U*	
5	Date of birth	C	yyyymmdd DD/MM/YYYY*	
6	Date of death	O	yyyymmdd DD/MM/YYYY*	Only if applicable
7	Postal code	C	Free text field	
8	Country code	C	2 characters, text format	ISO-code of the legal residence of the patient
9	Specimen number	C	Free text field	Should match the specimen number in the protocol
10	Date specimen was taken	C	yyyymmdd DD/MM/YYYY*	
11	Requesting hospital/laboratory	O	Free text field	Name of the hospital/laboratory that requests the pathological examination.
12	Diagnostic procedure	O/HR	Free text field	Please provide the significance of your codes in a separate file or mail
13	Organ	C	Free text field	All organ codes (Only use valid CODAP organ codes) **
14	Laterality	O/HR	1 = left 2 = right	Only if applicable and not already included in the organ code
15	Lesion	C	Free text field	Range to select: all lesion codes >=60 + AINH, CBB5, CIN2, CIN3, FBC5, FTH4, FTH5, FTH6, GIN3, GINH, GL02, GL03, GL04, GL05, GL06, GL07, GL08, GL09, GL10, HSIL, KL5, KR, KZ, PIN3, PINH, SINH, TY5, VIN3 ** (Only use valid CODAP lesion codes)
16	Differentiation grade	O	Free text field	Histological grading and differentiation
17	pT	O/C*	Free text field	TNM 8th edition from 2017 onwards
18	pN	O/C*	Free text field	TNM 8th edition from 2017 onwards
19	pM	O/C*	Free text field	TNM 8th edition from 2017 onwards
20	Degree of certainty (about lesion code)	O	1 = uncertain 2 = differential diagnosis 3 = certain	This field can be replaced by a comment field

O=Optional; C=Compulsory; O/C=Compulsory if INSZ/NISS unknown; O/C*=Compulsory if applicable; HR=highly recommended

* This format is to be used when data will be transferred through the Healthdata.be-platform

** See also 'Coding manual For registration - CODAP version 2017' and 'Code Book CODAP version 2017' (http://kankerregister.org/downl-vr-pathologen)

2.1.B. Dataset for breast and colorectal specimens

	Variable	Compulsory (C) Optional (O) Highly Recommended (HR)	Format	Short comment (for details see further)
1	INSZ/NISS	C	11 characters, text format without space	Leading zero's should be conserved! ('TEXT' format therefore necessary)
2	Last name	O/C	Free text field	Compulsory if INSZ/NISS unknown
3	First name	O/C	Free text field	Compulsory if INSZ/NISS unknown
4	Sex	C	Male or Female F-M-U*	
5	Date of birth	C	yyyymmdd DD/MM/YYYY*	
6	Date of death	O	yyyymmdd DD/MM/YYYY*	Only if applicable
7	Postal code	C	Free text field	
8	Country code	C	2 characters, text format	ISO-code of the legal residence of the patient
9	Specimen number	C	Free text field	Should match the specimen number in the protocol
10	Date specimen was taken	C	yyyymmdd DD/MM/YYYY*	
11	Requesting hospital/laboratory	O	Free text field	Name of the hospital/laboratory that requests the pathological examination.
12	RIZIV/INAMI number of the applicant of the test	C	11 numbers text format without space	
13	Diagnostic procedure	O/HR	Free text field	Please provide the significance of your codes in a separate file/mail
14	Organ	C	Free text field	File colorectal: 41XX, 42XX, 43XX File breast: 69XX (Only use valid CODAP organ codes)**
15	Laterality	O/HR for breast	1 = left 2 = right	Only if applicable and not already included in the organ code
16	Lesion	C	Free text field	All test results including negative tests (Only use valid CODAP lesion codes)**
17	Degree of certainty (about lesion code)	O	1 = uncertain 2 = differential diagnosis 3 = certain	This field can be replaced by a comment field
18	Nomenclature number(s)	O	Text format without space	Different numbers to be entered separated by commas ","

O=Optional; C=Compulsory; O/C=Compulsory if INSZ/NISS unknown; HR=highly recommended

*This format is to be used when data will be transferred through the Healthdata.be-platform

** See also 'Coding manual For registration - CODAP version 2017' and 'Code Book CODAP version 2017'

(http://kankerregister.org/downl-vr-pathologen)

2.1.C. Dataset for test results of cervical/vaginal smears and biopsies

	Variable	Compulsory (C) Optional (O) Highly Recommended (HR)	Format	Short comment (for details see further)
1	INSZ/NISS	C	11 characters, text format without space	Leading zero's should be conserved! ('TEXT' format therefore necessary)
2	Last name	O/C	Free text field	Compulsory if INSZ/NISS unknown
3	First name	O/C	Free text field	Compulsory if INSZ/NISS unknown
4	Sex	C	Female F-M-U*	
5	Date of birth	C	yyyymmdd DD/MM/YYYY*	
6	Date of death	O	yyyymmdd DD/MM/YYYY*	Only if applicable
7	Postal code	C	Free text field	
8	Country code	C	2 characters, text format	ISO-code of the legal residence of the person
9	Specimen number	C	Free text field	Should match the specimen number in the protocol
10	Date specimen was taken	C	yyyymmdd DD/MM/YYYY*	
11	Requesting hospital/laboratory	O	Free text field	Name of the hospital/laboratory that requests the pathological examination.
12	RIZIV/INAMI number of the applicant of the test	C	11 numbers text format without space	
13	Quality of the specimen	C	SUF & INSU	Only for pap smears
14	Diagnostic procedure	HR	Free text field	Please provide the significance of your codes in a separate file/mail
15	Organ	C	Free text field	64XX, 65XX (Only use valid CODAP organ codes)**
16	Lesion	C	Free text field	All test results including negative tests, benign and premalignant lesions (Only use valid CODAP lesion codes or CERVIBASE)**
17	Degree of certainty (about lesion code)	O	1 = uncertain 2 = differential diagnosis 3 = certain	This field can be replaced by a comment field
18	HPV **high risk** test results	C if HPV test performed	HPV-, HPV+, HPVi	
19	HPV **high risk** types detected	C if genotyping performed	HP16, HP18, ... Free text field	Different HPV genotypes to be entered separated by commas ","
20	Nomenclature number(s)	O***	**Text format** without space	Different numbers to be entered separated by commas ","

O=Optional; C=Compulsory; O/C =Compulsory if INSZ/NISS unknown; HR=highly recommended

*This format is to be used when data will be transferred through the Healthdata.be-platform

** See also 'Coding manual For registration - CODAP version 2017' and 'Code Book CODAP version 2017' (http://kankerregister.org/downl-vr-pathologen)

*** From 01/01/2015 on, nomenclature numbers for cervical/vaginal samples are optional (Only applicable if certain conditions are fulfilled; see chapter 2.3.D)

2.1.D. Summary of all datasets

	VARIABLES FOR CODAP users	DATASET FOR CANCER DIAGNOSES	DATASET FOR BREAST AND COLON PREVENTION FILE	DATASET FOR CERVIX PREVENTION FILE
		Following international guidelines for cancer registries	According to the need of the Centers for Cancer Detection in Belgium	
1	INSZ/NISS	C	C	C
2	Last name	O/C	O/C	O/C
3	First name	O/C	O/C	O/C
4	Sex	C	C	C
5	Date of birth	C	C	C
6	Date of death	O	O	O
7	Zip code = postal code	C	C	C
8	Country code	C	C	C
9	Specimen number	C	C	C
10	Date specimen was taken	C	C	C
11	Requesting hospital/laboratory	O	O	O
12	RIZIV/INAMI number of the applicant of the test		C	C
13	Quality of the specimen			C
14	Diagnostic procedure	O / HR	O / HR	O / HR
15	Organ	C	C	C
16	Laterality	O / HR	O / HR for breast	
17	Lesion	C	C	C
18	Differentiation grade	O		
19	pT	O/C*		
20	pN	O/C*		
21	pM	O/C*		
22	Degree of certainty (about lesion code)	O	O	O
23	HPV **high risk** test results			C if HPV test performed
24	HPV **high risk** types detected			C if genotyping performed
25	Nomenclature number(s)		O	O if diagnostic procedure deducible from other variables

O=Optional; C=Compulsory; O/C=Compulsory if INSZ/NISS unknown; HR=highly recommended

2.2. Inclusion criteria per project

2.2.A. Inclusion criteria for the classic CANCER-file

SELECTION BASED ON <u>LESION</u>-CODE

Range to select:

CODAP: all lesion codes equal or greater than 60 + AINH, CBB5, CIN2, CIN3, FBC5, FTH4, FTH5, FTH6, GIN3, GINH, GL02, GL03, GL04, GL05, GL06, GL07, GL08, GL09, GL10, HSIL, KL5, KR, KZ, PIN3, PINH, SINH, TY5, VIN2, VIN3 (Equivalent for ICD-O-3: 8000/0-9999/9). CIN2 is no longer considered as an obsolete code (see section 2.3.D), and should be added to the cancer-file inclusion criteria if used. Please take care that all records for which pTNM-variables are coded, are selected!

- All malignant tumours, invasive or in situ (inclusive severe dysplasia and high-grade intraepithelial neoplasia).
- All hematological tumours including the myelodysplastic syndromes and myeloproliferative diseases.
- All tumours of the central nervous system whatever the behaviour of the tumour (benign, low malignant potential, malignant).
- All urothelial cell tumours (low malignant potential, in situ, invasive).
- Ovary: malignant and borderline malignant tumours.

If analyses of the skin are executed by a separate <u>laboratory for dermatopathology</u>, please transfer this mail with annexes to your colleagues so they can learn how to transfer their data (if you do not already deliver this data).

> *These data are currently asked <u>three times per year</u>*
> *(data from the first four-month period to be delivered by end of May*
> *data from the second four-month period to be delivered by end of September*
> *full year data to be delivered by mid-February)*

2.2.B. Inclusion criteria for the BREAST & COLON-file

The datasets for the breast and colorectal specimens are almost identical; however, the structured files and protocols should be delivered in **separate files**.

SELECTION BASED ON <u>ORGAN</u>-CODE

Range to select:

1. For the structured file containing the encoded (structured) test results of all

    breast specimens:

    CODAP: organ codes **69XX**

    (Equivalent for ICD-O-3: C50.X)

    All encoded test results of breast specimens, including negative results, benign and (pre)malignant lesions.

    In July 2015 coding guidelines for breast samples were communicated through a newsletter sent to laboratories. This newsletter can be downloaded at the following link: http://www.kankerregister.org/downloads

2. For the structured file containing the encoded (structured) of all

    colorectal specimens:

    CODAP: organ codes 41XX, 42XX, 43XX

    (equivalent for ICD-O-3: C18.X, C19.X, C20.X, C21.X)

    All encoded test results of colorectal specimens, including negative results, benign and (pre)malignant lesions.

    In April 2014 and October 2020 coding guidelines for colorectal samples were communicated through newsletters sent to laboratories. These newsletters can be downloaded at the following link: http://www.kankerregister.org/downloads

---

These data are currently asked <u>three times per year</u>
(data from the first four-month period to be delivered by end of May
data from the second four-month period to be delivered by end of September
full year data to be delivered by mid-February)

2.2.C. Inclusion criteria for the CERVIX-file

SELECTION BASED ON ORGAN-CODE

Range to select:

CODAP: organ codes **64XX, 65XX**.

(Equivalent for ICD-O-3: C52.X, C53.X)

- All cervical and vaginal <u>cytology test results</u> including negative tests (no abnormalities), light or moderate cell abnormalities and (pre)malignancies.
- All cervical <u>histology test results</u> including negative tests (no abnormalities), light or moderate cell abnormalities and (pre)malignancies.
- Results of <u>high risk HPV tests</u>.

<u>**HPV-analyses**</u> **done on request of other laboratories have to be delivered by <u>either</u> the laboratory that executed these tests <u>OR</u> by the laboratory that asked for the tests. This should be a mutual consent between laboratories, but the applicant of the test has to guarantee the information reaches the BCR.**

These data are currently asked <u>three times per year</u>
(data from the first four-month period to be delivered by end of May
data from the second four-month period to be delivered by end of September
full year data to be delivered by mid-February)

2.3. Additional information regarding the variables

2.3.A. Additional information regarding the COMMON variables

- **'National Social Security Number (INSZ/NISS)'**

  This variable is used for patient identification. In case the INSZ/NISS is lacking, the last name, first name, sex, date of birth and postal code must be delivered.

  Complete and correct administrative data are essential to establish high-quality databases. Therefore, we recommend making the necessary efforts to deliver the INSZ/NISS for each patient. TAKE CARE: this variable should always contain 11 characters and be a TEXT format, since otherwise leading zero's will be lost.

- **'Country code'**

  Please use the correct codes you can find on:

  http://www.iso.org/iso/home/standards/country_codes/country_names_and_code_elements.htm

  The country code refers to the country in which the patient is officially residing. The country code is a compulsory variable since malignancies are only taken into account for the incidence numbers for Belgium if the person has his/her legal residence in Belgium. Missing information about people residing outside Belgium will never be asked.

- **'Date specimen was taken'**

  Take care to fill in the date **the specimen was taken**. Only if this date is unknown, **the date of reception of the specimen** or **the date of analysis** can be used. When date is missing, data cannot be treated!

- **'Requesting hospital/laboratory'**

  Fill in the "hospital/laboratory" that sent the specimen, requested the pathological examination and to which the result is reported.

  If you use abbreviations, please provide us with a conversion table.

  If there is no requesting hospital/laboratory and the request originates from a private person, please mention "PRIVATE" for this variable. By providing us with this information, some missing or additional data can be asked (immediately) to the applicant of the analysis instead of the laboratory that performed the analysis.

- **'Diagnostic procedure'**

The variable 'diagnostic procedure' indicates if it concerns a cytology or histology. This variable is not compulsory, but highly recommended when the diagnostic procedure cannot be deduced from other variables as the organ-code (e.g. 64**CY** = cervical cytology, 64**HI*** = cervical histology) or nomenclature.

* new code that can be used from 25/10/2014 onwards.

Specifying the diagnostic procedure only within the protocol number is not feasible (e.g. 14-**C**-98765 for **c**ytology or 14-**B**-28956 for **b**iopsy) since different formats are used by each source and multiple samples could be described in one protocol.

You can also use the following <u>BD-codes (BD = Basis for Diagnosis)</u>:

Possible codes	Meaning of the codes
1	Autopsy, found by hazard
2	Histology of the primary tumour
3	Histology of the metastasis
4	Cytology/haematology

Important: if the diagnostic procedure is not clearly provided by means of organ, nomenclature or BD-code: unspecified cervical organ codes such as **64, 64NS** and non-existing **64XX** codes will be considered as cervical cytology. For breast samples, all organ codes will be considered as histological samples except for 69CT and 69CY.

- **'Organ'**

Please use the code of the sample in which the diagnosis is made, regardless of the organ in which the tumour takes its origin.

Please use always (when applicable) 4 characters and official CODAP 2017 codes to encode the organ as precisely as possible. For instance, coding sub-localisation for colon and skin and laterality for breast is important.

You can download the list with CODAP 2017 codes from our website:

www.kankerregister.org / www.registreducancer.org

Whenever possible please encode <u>laterality</u> (left or right). This information can be included in the organ code and/or in a separate field (see below).

We accept official CODAP-organ codes followed by LI or RE to indicate the laterality (only this kind of CODAP-codes can contain 6 characters).

> E.g.   Left axilla: 07AXLI
>
> Skin of the right arm: 80ARRE

Without an organ code, the record cannot be extracted for the prevention files (breast/colon and cervix), following the BCR-rules for extraction and cannot be treated by the Cancer Registry.

If possible, you can include information about the diagnostic procedure within this variable (e.g. 64**CY** = cervical cytology; 64**HI** = cervical histology).

- **'Laterality'**

If possible, always mention the laterality. When not encoded by the use of a specific organ code from which laterality can be deduced (e.g. 69LI for the left breast), there are other possibilities to provide us with the laterality:

- by making 2 registrations (e.g. 80BB 91MG and 06BR 91MG)

- add LI/RE (6 characters: e.g. 80BB**RE** 91MG) to the original organ code (see above)

- by means of a variable 'Laterality' for which you can use the following codes:

Possible codes	Meaning of the codes
1	Left
2	Right
#NK	Not known
#NA	Not applicable

- **'Lesion'**

For prevention files (breast/colon and cervix), please encode also negative, benign and (pre)malignant lesions.

Please use always (when applicable) 4 characters and official CODAP 2017 codes to encode the lesion as precisely as possible.

If no information on the lesion is available or only an additional test is performed without histological diagnosis (e.g. KRAS, HPV, EGFR, FISH, ...), the value #NA (= not applicable) can be mentioned for the variable 'Lesion'.

Also see section 2.3.D (additional information regarding the variables of the dataset cervix).

Without a lesion code, a cancer record cannot be extracted for the Cancer-file following the extraction rules of the BCR-protocol and cannot be treated by the Cancer Registry. Please pay attention to always fill in the variable 'Lesion'.

- **'Degree of certainty'**

For cervix samples, this applies to the certainty about the lesion and not about the HPV-test.

- *Missing information*

If certain information is not present in your database, you can fill out the column with:

#NS	not stated or not present
#NK	unknown
#NA	not applicable

2.3.B. Additional information regarding the specific CANCER variables

- **'Differentiation grade'**

  When not specified in the lesion code (e.g. 93GG: well differentiated adenocarcinoma) this optional variable can be delivered in a separate field:

  Histological grading and differentiation

Possible codes	Meaning of the codes
1	Well differentiated
2	Moderately differentiated
3	Poorly differentiated
4	Undifferentiated / anaplastic
#NA	Not applicable
#NK	Not known
#NS	Not stated

- **'pTNM-variables'**

  Please use different, separate fields to deliver these variables. Use the TNM 8th edition (see http://www.wileyanduicc.com) from 2017 onwards and take care of possible errata as for the previous editions.

  The TNM is not applicable for every tumour or specimen. That is the reason why these variables cannot be made compulsory for every registration. However, when applicable (and present in the report), the TNM-variables should also be present in the structured file, and not only in the protocol. Extraction of these variables out of the protocols by means of text-recognition is possible but this procedure is time-consuming and is always accompanied by a loss of quality, what must be avoided as much as possible.

2.3.C. Additional information regarding the specific BREAST/COLON variables

- **'RIZIV/INAMI number of the applicant of the test'**

  A 'fail-safe' system is a back-up mechanism which ensures that patients with an abnormal screening result will have the appropriate follow-up. Within this 'fail-safe' mechanism, the variables 'requesting hospital/laboratory' and 'RIZIV/INAMI number of the applicant of the test' are necessary to be able to contact the persons responsible for the follow-up of the patient.

  Take care: this variable should be a **TEXT format** and should by preference contain 11 characters.

- **'Nomenclature number(s)'**

  Nomenclature can be useful to provide us with the information about the diagnostic procedure (difference between cytology/histology), especially for breast specimens.

  From 01/01/2014 on, delivery of nomenclature numbers for **breast and colorectal samples** is no longer compulsory but optional. The use of non-official nomenclature codes is allowed. Please provide the meaning of these codes.

  In case of more than one nomenclature number, they should be separated by a comma (",").

  Take care: this variable should be a **TEXT format**.

2.3.D. Additional information regarding the specific CERVIX variables

- **'RIZIV/INAMI number of the applicant of the test'**

See section 2.3.C.

- **'Quality of the specimen'**

This variable is obligatory for **cervical smears** (cytology), not for histological samples.

Possible codes	Meaning of the codes
SUF	**Sufficient:** The sample is of sufficient quality to result in a reliable diagnosis.
INSU	**Insufficient:** No reliable test result could be determined, or the specimen could not be evaluated at all because it was broken or incorrectly labelled

Since **01/01/2013**, the codes 'SUF+' and 'SUF-' are no longer used. Both codes are pooled into only **one code 'SUF'** which indicates the sample is of sufficient quality to result in a reliable diagnosis.

The code **'INSU'** should only be used if no reliable diagnosis can be established. This implies that a new smear should be taken.

- **'Lesion'**

Also see section 2.3.A.

For correct coding of the cervical smears (cytology) and biopsies (histology), please follow the systematic overview of diagnostic codes as mentioned on our website. By coding the test results, **always take care to make a clear distinction between cytology and histology.**

According to the WHO classification of tumours of female reproductive organs (4th Edition, 2014, page 172), a two tier system of low- and high-grade intraepithelial lesions is more biologically relevant and histologically more reproducible than the three-tier CIN1, CIN2 and CIN3 [1,2] and is therefore recommended. According to the 5th Edition of the WHO classification of Female Genital Tumours published in 2020, HSIL may be subdivided into HSIL (CIN 2) and HSIL (CIN 3), particularly for young women below the age of 30 years. The reason for this is the evidence that adolescents and young women show significantly higher regression rates of HSIL (CIN 2) compared to older women [3].

If for a patient both a cytological and a histological analysis have been performed and described in the same protocol, both the cytological and the histological diagnosis should be delivered in different records with the same sample/reference number.

If the cytological and histological results are mentioned in different protocols, both the cytological and histological diagnosis should be delivered in different records with the appropriate reference number and the correct sample date.

For screening programs, it is important to know which cytological exams are followed by a histological confirmation.

- **'HPV high risk test results'**

HPV high risk test results: select only one code	
Possible codes	**Meaning of the codes**
HPV-	Test performed, but no high risk HPV detected. If only low risk or intermediate risk HPV genotypes are detected, also code with HPV-
HPV+	Test performed, HPV high risk detected
HPVi	Test performed, no analysis or no reliable test result possible

- **'HPV high risk types detected'**

Specific HPV high risk types detected	
Possible codes	**Meaning of the codes**
HP16	HPV Type 16
HP18	HPV Type 18
HP39	HPV Type 39
HPOT	HPV high risk genotype different from HPV16/HPV18, if no genotyping other than HPV16/HPV18 is possible

Following 13 HPV-types are considered by the BCR as 'high risk HPV-types: HP16,HP18,HP31,HP33,HP35,HP39,HP45,HP51,HP52,HP56,HP58,HP59,HP68

These include the 12 HPV types currently classified as carcinogenic to humans and one type (HP68) classified as probably carcinogenic to humans in the IARC monograph series [4,5].

This variable is not required to be filled out when no search for specific HPV high risk genotypes is performed by you or another laboratory or when only a range of **possible** HPV-types can be given. If your HPV test can only discriminate between the genotypes HPV 16, HPV 18 and a range of several high risk genotypes, the code **HPOT** should be used if high risk HPV types other than type 16 or 18 are detected (see table above).

Multiples HPV can be entered and must be separated by commas ",".

Examples:

* HP16,HP18,HP45: HPV types 16, 18 and 45.

* HPOT,HP16: HPV16 in combination with another high risk type

As cervical cancer is **HPV**-related and prevention campaigns include vaccination of young girls, data on HPV test results are very useful to evaluate the effect of the vaccination program.

- **'Nomenclature number(s)'**

In case of more than one nomenclature number, they should be entered separated by a comma (","). Take care: this variable should be a **TEXT format** to allow correct treatment of the data.

From 01/01/2015 on, delivery of nomenclature numbers for **cervical/vaginal samples** is not longer compulsory **BUT** if your laboratory decides not to deliver this variable, it is **obligatory** to indicate very clearly the difference between cytology and histology by means of the 'organ code' or the 'diagnostic procedure'.

Important: if the diagnostic procedure is not clearly provided by means of organ code, nomenclature or diagnostic procedure-code: unspecified organ codes such as **64, 64NS** and non-existing **64XX** codes will be considered by default as CERVICAL CYTOLOGY.

If your laboratory will continue to deliver this variable, the field of the nomenclature codes must be filled in as completely as possible according to the following recommendations.

    a. Official nomenclature code: if reimbursed by RIZIV/INAMI

    b. Non-official (dummy) code: if not reimbursed by RIZIV/INAMI (please provide us with the meaning of each used dummy code)

    c. #NK: if the reimbursement by the RIZIV/INAMI is uncertain

It is recommended to send all the samples of the requested period even when no certainty exists about the nomenclature. Delivery of an incomplete file in which a lot of *samples* are missing has to be avoided.

- **Additional information about cervical smears**

For the cervical smears we want to know the following information:

    o Which laboratory performs the HPV tests?

    o Which test is used for HPV detection?

These questions are repeated every year in order to have the most up to date information. If changes in the treatment of HPV testing took place during the year, please inform us.

References

[1] Thomas, C. Wright Jr., Pathology of HPV infection at the cytologic and histologic levels: Basis for a 2-tiered morphologic classification system: International Journal of Gynecology and Obstetrics (2006) **94** (Supplement 1), S22-S31

[2] Alan G. Waxman, MD, MPH, David Chelmow, MD, Teresa M. Darragh, MD, Herschel Lawson, MD, and Anna-Barbara Moscicki, MD, Revised Terminology for Cervical Histopathology and Its Implications for Management of High-Grade Squamous Intraepithelial Lesions of the Cervix: Obstet Gynecol. 2012 December; 120(6): 1465–1471

[3] WHO Classification of Tumours Editorial Board. Female genital tumours [Internet]. Lyon (France): International Agency for Research on Cancer; 2020 [cited 2021 Oct 21]. (WHO classification of tumours series, 5th ed.; vol. 4). Available from: https://tumourclassification.iarc.who.int/chapters/34.

[4] V. Bouvard, R. Baan, K. Straif, Y. Grosse, B. Secretan, F. El Ghissassi, L. Benbrahim-Tallaa, N. Guha, C. Freeman, L. Galichet, V. Cogliano, A review of human carcinogens-Part B: biological agents, Lancet Oncol. 10(4) (2009) 321–322.

[5] IARC, Monographs on the Evaluation of Carcinogenic Risks to Humans Volume 100B: A Review of Human Carcinogens: Biological Agents, International Agency for Research on Cancer, Lyon, 2012.