Fact Sheet

Pathology Laboratory Quick Facts for Cancer Reporting to the California Cancer Registry

Reporting Requirements

It is the responsibility of the original pathologist and pathology laboratory to report all cancer diagnoses (AB 2325 [Bonilla, 2016], SB 344 [Rubio, 2023]). Any slide review, second opinion, report correction, addendums, etc. related to the original specimen diagnosis that either change the original incidence of cancer (i.e., reportable to non-reportable, or vice versa) or changes the histology and/or behavior of the original specimen is to be electronically transmitted to California Cancer Registry (CCR) by the original pathologist and pathology laboratory within two weeks of finalizing the revised pathology documentation.

Is Your Laboratory Information Current?

- Update Or Re-Register: **The CCR requests that pathology laboratories and/or facilities update or re-register organization or lab information. This includes specific contact information, lead physician contact, lab management contact, technical interface contact, as well as LIS and/or EHR vendor information.**
- Register Today: **Electronic Pathology Registration Portal (https://pathreporting.ccr.ca.gov/registration/).**
- Avoid Non Compliance Fines: **Register to report and start submitting your data today.**

What is the Registration Process?

Facilities and/or Pathology labs are required to register for reporting on behalf of represented pathologists within an organization or lab.

Registration information includes:

- Lead physician contact
- Lab management contact
- Technical interface contact
- LIS and/or EHR vendor information for the purpose of providing a certificate for submission to the web service where applicable.

What are the Transmission Methods?

CCR will accept electronic pathology reports through four methods of transmission:

- A web service
- Secure File Transfer Protocol (SFTP)
- Minimal Lower Layer Protocol (MLLP)
- Direct Data Entry Web Portal.

In What Formats can Pathology Laboratories Send their Data?

CCR is limiting the formatting of pathology reports to four options:

- Simple Narrative
- Synoptically Structured Health Level Seven (HL7)
- Synoptically Structured HL7 using College of American Pathologists (CAP) Electronic Cancer Checklist (eCC)
- CAP eCC Structured Data Captured (SDC) Extensible Markup Language (XML)

What are the Reportable Diagnoses Criteria?

- All reportable neoplasms meeting the criteria as outlined in the Electronic Pathology Reporting Standards Manual, Volume V are to be transmitted to CCR. Neoplasms outlined under the Non-Reportable Diagnoses are not to be transmitted.
- In the event an ambiguous term(s) precede a reportable cancer diagnoses, the case is to be considered reportable. Examples of ambiguous terminology include, but are not limited to the following: apparently, appear to, suspicious, likely or most likely, favors, comparable, consistent with, typical (of), probable, presumed, malignant appearing.

For more information contact us at cdsrbhelp@cdph.ca.gov or go to our website to submit your question: https://www.ccrcal.org/submit-data/

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Reportable Diagnoses

Refer to the reportability guide below for information on specific histologies and sites for tumors that are reportable to the CCR.

- Invasive Malignancies
- In-situ Malignancies (See Appendix C for a list of in-situ terms)
- Severe or High-grade Dysplasia documented as synonymous with carcinoma
- High grade squamous intraepithelial lesion
- Intraepithelial neoplasia, grades II and III
- Lymphangioleiomyomatosis, dx 01/01/2023+
- Malignant perivascular epithelioid cell tumor (PEComa)
- Mesothelioma in situ, 9050/2, dx 01/01/2023+
- Urine Cytology - Positive for Malignancy
- All hematopoietic and lymphoid neoplasms as outlined in the following link: http://seer.cancer.gov/seertools/hemelymph
- Appendix:
  - Carcinoid tumors, NOS with malignant behavior /3, dx 01/01/2015+
  - Low-grade appendiceal mucinous neoplasm (LAMN), dx 01/01/2022+
  - High grade appendiceal mucinous neoplasm (HAMN), dx 01/01/2022+
- Bones, Joints, and Articular Cartilage: Chondrosarcoma, grade 1, dx 01/01/2022+
- Brain:
  - Diffuse leptomeningeal glioneuronal tumor, dx 01/01/2023+
  - High-Grade astrocytoma with Piloid features (HGAP), dx 01/01/2023+
  - Benign and borderline Intracranial and/or Central Nervous System (CNS) tumors, dx 01/01/2001+
    - Diffuse astrocytoma, MYB- or MYBL1algered and diffuse low-grade glioma, MAPK pathway altered, dx 01/01/2023+
    - Hemangioma, NOS 9121/0 and cavernous hemangioma
    - Note: For cavernous sinus hemangioma, code site to C700 cerebral meninges.
    - Lhermitte-Duclos disease is synonymous with dysplastic gangliocytoma per WHO classification of CNS tumors, dx 01/01/2018+
    - Multinodular and vacuolating neuronal tumor, dx 01/01/2023+
    - Juvenile xanthogranuloma, 01/01/2023+
    - Pilocytic astrocytoma/juvenile pilocytic astrocytoma for all sites, dx 01/01/2023+
- Gastrointestinal Stromal Tumors (GIST): ALL GIST tumors are reportable with a malignant behavior /3 in ICD-O-3.2, dx 01/01/2021+
- Ovary: Noninvasive low grade (Micropapillary) serous carcinoma
- Pancreas: Neuroendocrine tumor when diagnosis is insulinoma; cystic pancreatic endocrine neoplasm (CPEN); cystic pancreatic endocrine specified as neuroendocrine tumor, grades 1 and 2; solid pseudopapillary neoplasm of pancreas; or non-invasive mucinous cystic neoplasm (MCN) of pancreas with high-grade dysplasia
- Pituitary: Rathke pouch tumor
- Post Transplant Lymphoproliferative Disorder (PTLD), dx 01/01/2025+
- Testis: Mature teratoma of the testes in adult (adult defined as post-puberty)
- Thymoma: All except: Microscopic thymoma or thymoma, benign; Micronodular thymoma with lymphoid stroma; Ectopic hamartomatous thymoma
- Skin: Invasive, In-Situ, Early or evolving melanoma of any type; Basal and squamous cell carcinoma of skin of genital organs (vagina, clitoris, labium, vulva, prepuce, penis and scrotum; adnexal carcinomas (sweat glands, sebaceous gland, ceruminous gland and hair follicle); adenocarcinomas, lymphomas, melanomas, sarcomas and Merkel cell tumors of the skin (regardless of site); any carcinoma arising in a hemorrhoid is reportable as hemorrhoids arise in mucosa, not skin.
- Stomach and Small Intestine:
  - Intestinal-Type adenoma, high grade
  - Adenomatous polyp, high grade dysplasia
  - Serrated dysplasia, high grade

Reportable Non-Malignant Diagnoses

- All benign and borderline intracranial and/or Central Nervous System (CNS) tumors

Non-Reportable Diagnoses

- Skin: Basal and squamous cell carcinomas of the skin unless it occurs on genital organs. Non-reportable skin cancers include the following
- Neoplasms, malignant, NOS of the skin
- Epithelial carcinomas of the skin
- Papillary and squamous cell carcinomas of the skin
- Basal cell carcinomas of the skin
- Benign and Borderline neoplasms that are not primary intracranial and or CNS neoplasm
- Cervix: Carcinoma in-situ (CIS) or intraepithelial neoplasia grade III (CIN III)
- Lymphoma In-situ
- Prostate: Prostatic intraepithelial neoplasia, Grade III (PIN III)
- Thyroid: Non-invasive follicular thyroid neoplasm with papillary like nuclear features

What are the Reportable Pathology Report Types?

The following types of pathology reports that provide information on reportable neoplasms are to be transmitted to CCR:

Surgical Pathology Reports:

- Biopsy (Needle Core, Excisional, Incisional, Bone Marrow Aspirates)
- Surgical Resection
- Surgical Re-excision

NOTE: All pathology reports for Surgical Resection or Surgical Reexcision of malignant melanoma or lentigo should be submitted. This includes both positive and negative findings (i.e., Wide Re-Excision: No residual melanoma; or negative for melanoma, etc.)

Cytology Reports:

- Biopsy (fine needle aspiration)
- Brushings (e.g., endoscopic evaluation of pancreas, Papanicolaou (PAP) smear)
- Fluids (Urine, Peritoneal, Pleural, Cerebrospinal Fluid, Bronchioalveolar lavage)
- Hematologic Specific Reports
  - Immunohistochemistry (IHC)
  - Peripheral Blood Count
  - Flow Cytometry
- Molecular Reports
  - Molecular Diagnosis Polymerase Chain Reaction (PCR)
  - Reverse Transcription (RT)-PCR
  - Sequencing (Next-Generation Sequencing [NGS], Pyrosequencing, etc.)
  - In-situ Hybridization (ISH)
  - Fluorescent In-situ Hybridization (FISH)
  - Gene Array

Consults
Slide Reviews
Biomarker Results
Pathology Report Addenda

What are the Required Data Elements?

CCR requires various facility and patient information in order to successfully match pathology information to existing patients in its database and/or to match

to the criteria for research studies/clinical trials. With the implementation of SB 344, if the required information in Appendix A -Constraints Document is missing, the CCR will return the report to the pathologist or pathology laboratory to either provide the information or for an explanation as to why the information was not included. Other patient demographic items are also essential for epidemiological incidence and mortality research. CCR recognizes that not all facility/patient information may be available to all pathologists and pathology laboratories. Thus, to help CCR serve its public health mission to improve cancer patient outcomes, a cooperative effort is encouraged to provide this kind of data. It is likely that ordering facility/office EHR systems will contain many of these facility/patient data elements, so CCR recommends that LIS vendors work with ordering facilities/offices and their EHR vendors to enable these kinds of data elements to be transmitted to CCR. Given different workflows and different levels of integration between EHR systems and LIS systems, there may be multiple facility-specific methods to achieve this goal.

Vendor Self-Initiated Testing

CCR has developed a web page and associated service to upload test files for automatic evaluation and feedback on pathology reports with any identified issues. The self-testing tool will validate test messages for structure and format. The file will be checked to determine that it is parsable, and that the required fields are completed. Edits will then be run against the submitted file. Multiple record types from pathology laboratory vendors may be needed. If the files pass, the service will update their user account allowing them to send that version of the record to CCR. If the file fails, a list of errors will be returned and/or displayed. Vendor Self-Initiated Testing Link: https://pathreporting.ccr.ca.gov/selftesting/

On-Boarding Process

CCR will conduct outreach to entities registering to begin pathology reporting to the CCR and conduct organization and laboratory specific testing. Organization and laboratory specific testing will require a defined method of reporting to be finalized. Depending upon the method of reporting, subsequent tasks involved to create and establish a direct connection with CCR may be required. Pathology laboratories submitting data on behalf of pathologists will be required to participate in a testing and validation process with CCR. CCR will work with pathology laboratories and their representatives and/or vendor representatives to ensure the data being submitted to CCR meets formatting and completeness requirements.

Top Two Questions Asked Regarding Electronic Pathology Cancer Reporting to CCR:

1. ***Will use of the College of American Pathologist's (CAP) Electronic Cancer Checklists (eCC) be a requirement for pathologists to use to meet the California reporting mandate? No. CAP eCC is not a requirement of the state to meet the California pathology reporting requirement. However, use of software which supports discrete data capture, such as CAP eCC, is highly encouraged in order for CCR to efficiently process cancer incidence data and achieve future uses of data envisioned by CCR. For more information please download a copy of the Electronic Pathology Reporting Standards Manual, Volume V.***

2. ***If my pathology department or lab already reports to CCR, will the requirements for reporting change? Pathology laboratories currently submitting data to CCR electronically utilizing National Cancer Institute (NCI) or Centers for Disease Control and Prevention (CDC) supported methods for electronic reporting (AIM, PHIN MS), or Office of the National Coordinator (ONC) HL7 standard for Structured Data Capture (SDC) using CAP eCC, meet the transmission methods for submitting data. However, all pathology departments and laboratories should reference the Electronic Pathology Reporting Standards Manual, Volume V and review the reporting requirements to ensure the required data is being transmitted.***

Working together to provide Californians the most accurate cancer information:

Research outcomes and future advancements in cancer treatment depend on the quality of the data provided to cancer registries. As a pathology laboratory, the information you provide to CCR is of critical importance because it raises the level of diagnostic accuracy. Your participation in reporting all the data items listed below and outlined in the Quality section of the *Pathology Reporting Completeness, Timelines, and Quality* report are important and without this data, underserved populations in our area may not be accurately represented. Electronic reporting can further drive the standardization of cancer reporting and can also increase the efficiency and timeliness of reporting.

Crucial Demographic Data Items:	
Social Security Number	**Street Address**
First Name	**City**
Last Name	**State**
Birth Date	**Zip Code**
Sex	**Race**

With the passage of SB 344 (Rubio, 2023) CCR can now work with pathology laboratories to collect crucial demographic data. CCR currently receives cancer incidence case electronically in near-time (AB 2325 [Bonilla, 2016]), which allows a broader use of the data, including responding to community cancer concerns with more timely data, identifying data for research studies requiring rapid identification of cancer cases, and clinical trials matching.

Providing Facilities Information on their Reporting Requirements:

CCR provides reporting facilities a facility-specific summary of their data transmits. The report contains information about the number of reports received monthly, timeliness, and the quality of data. The goal of this report is to provide confirmational feedback to entities reporting to CCR as well as to provide a detailed guide about which aspects of their reporting performance may be in need of improvement. This report will be generated and distributed to facililities on a monthly time frame. Below are examples of what information will be included in the report:

SENDING FACILITY NAME

Pathology Reporting
Completeness, Timeliness, and Quality

Introduction: The information presented below depicts the completeness of records submitted to the California Cancer Registry (CCR) for the current Specimen Year and utilizes previous Specimen Year as a comparison. The Reporting Summary provides an overview of your submissions for the most recent reporting period. Subsequent pages provide an in-depth view of your submission. The total record distribution; which, is broken down by reportability, provides the approximate percentages of total records the registry determined to meet CCR reportability requirements based on the classification of cancer.

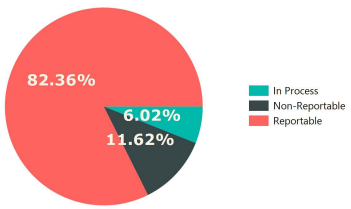
Reporting Summary

Total Path Reports	Reportable[1]	Not reportable	In Process[2]	On Time	Avg. Time to Report
15,415	12,696	1,791	0	7,434	0.20 Day(s)

Completeness by Specimen Year and Months

WorkflowActivity	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
2025	440	480	553	546	552	525	609	221	0	0	0	0	3,926
Reportable	370	380	448	401	400	355	402	109	0	0	0	0	2,865
Non-Reportable	17	14	21	20	19	18	15	11	0	0	0	0	135
In Process	53	86	84	125	133	152	192	101	0	0	0	0	926
2024	484	460	508	489	541	491	481	556	472	545	453	438	5,918
Reportable	384	361	430	397	439	407	425	475	423	517	422	420	5,100
Non-Reportable	100	99	78	91	102	84	56	81	49	28	31	18	817
In Process	0	0	0	1	0	0	0	0	0	0	0	0	1
2023	379	370	508	449	506	515	469	548	507	481	410	429	5,571
Reportable	379	370	465	364	405	429	361	452	390	388	374	354	4,731
Non-Reportable	0	0	43	85	101	86	107	96	117	93	36	75	839
In Process	0	0	0	0	0	0	1	0	0	0	0	0	1
Total Received	1,303	1,310	1,569	1,484	1,599	1,531	1,559	1,325	979	1,026	863	867	15,415

Total Path Reports by Workflow Activity



1. Reportable and not reportable neoplasms are defined under Section 5.4 of CCR Volume V. In the event an ambiguous term(s) precedes a reportable cancer diagnoses, the case is to be considered reportable and transmitted to the CCR.

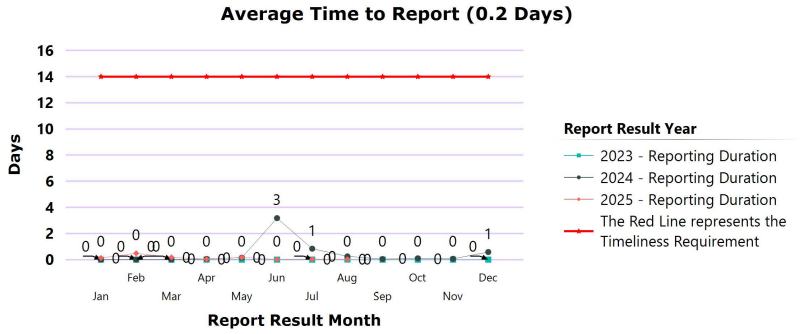
2. In Process is defined as pathology reports that have not been classified by the CCR and final determination of reportability is pending.

SENDING FACILITY NAME

Timeliness

The information presented below depicts the timeliness of data submitted to the CCR. For this section, timeliness is measured as the length of time between date of finalized pathology report to date transmitted to CCR. The timeliness standard is two weeks (14 days).

Workflow Activity	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
2025 Reported	440	480	553	546	552	525	609	221	0	0	0	0	3926
Avg. Time to report (days)	0.1	0.5	0.2	0.0	0.2	0.0	0.0	0.0					0.1
On Time*	439	478	552	546	551	525	609	221					3,921
2024 Reported	484	460	508	489	541	491	481	556	472	545	453	438	5918
Avg. Time to report (days)	0.0	0.0	0.0	0.1	0.1	3.2	0.8	0.2	0.0	0.1	0.1	0.6	0.4
On Time*	1	1	9	13	137	391	479	553	471	544	453	436	3,488
2023 Reported	379	370	508	449	506	515	469	548	507	481	410	429	5571
Avg. Time to report (days)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
On Time*	2	1	0	0	3	3	0	7	1	2	2	4	25
Total On Time	442	480	561	559	691	919	1,088	781	472	546	455	440	7,434



* On Time represents pathology reports received within 2 weeks (14 days) from date of finalized pathology report.

SENDING FACILITY NAME

Quality

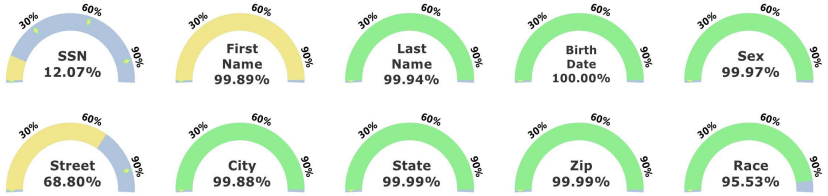
This information presented below summarizes the quality of path reports submitted to CCR. A visualization of this facility comparison is presented in the Data Quality table listed below and further detail is provided in the footnotes and Technical Notes on page five. These data items have strategically been chosen for this first review of data quality as they are critical for successful processing within CCR's data management system, successful rapid identification of cancer cases, clinical trials matching, and public health policy development. The following publications listed below document how the CCR data is being used by state and federal agencies and why this information is important:

- California Facts and Figures (https://www.ccrcal.org/retrieve-data/data-for-the-public/cancer-statistics-and-reports/)
- Cancer in North America (CINA) (https://www.naaccr.org/cancer-in-north-america-cina-volumes/)
- Report to the Nation (http://www.seer.cancer.gov/report_to_nation/)

As we assess the cancer burden, not only do we need to identify all cancer cases, we need to have complete and accurate information. All of the data items outlined below are important and without this data, underserved populations in our area may not be accurately represented.

Data Item	Known	% Known	Blank/ Unknown	% Blank/ Unknown	Invalid	% Invalid
SSN	1,861	12.07%	13,554	87.93%	0	0.00%
First Name	15,398	99.89%	0	0.00%	17	0.11%
Last Name	15,406	99.94%	0	0.00%	9	0.06%
Birth Date	15,415	100.00%	0	0.00%	0	0.00%
Sex	15,410	99.97%	5	0.03%	0	0.00%
Street Address	10,606	68.80%	870	5.64%	3,939	25.55%
City	15,396	99.88%	9	0.06%	10	0.06%
State	15,414	99.99%	1	0.01%	0	0.00%
Zip	15,414	99.99%	1	0.01%	0	0.00%
Race	14,726	95.53%	689	4.47%	0	0.00%

The gauges below illustrate percentage of **known data** on a scale from **0-100**



For each of the listed data elements, gauge indicators display individual facility data (filled gauge) compared to 90% expected known values. Green indicates data quality better than expected, whereas yellow indicates data quality lower than expected.

Any questions or feedback regarding this facility-specific data quality report or cancer reporting requirements in general should be directed to our helpdesk email cdsrbhelp@cdph.ca.gov. Additional information regarding required reporting by pathologists can be found on the CCR website https://www.ccrcal.org/submitdata/reporting-by-pathologists/. Thank you again for your continued engagement with California Department of Public Health (CDPH) and CCR.