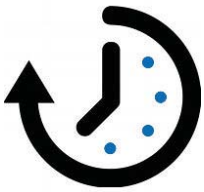
Pathology Laboratory Quick Facts for Cancer Reporting to the California Cancer Registry

Reporting Requirements

It is the responsibility of the original pathologist to report all cancer diagnoses. 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 CCR by the original pathologist within two weeks of finalizing the revised pathology documentation.



Timeline

- Now Open: Electronic Pathology Registration Portal (https://pathreporting.ccr.ca.gov/registration/).
- Now Open: Vendor Self-Initiated Testing Portal.
- July 1, 2018: Pathology Laboratory Registration Deadline.
- July 31, 2018: Pathology Direct Data Entry Web Portal.
- January 1, 2019: Data submission to CCR must be established by pathology labs on behalf of represented pathologists before the January 1, 2019 deadline.

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 CCR Electronic Pathology Reporting Standards Implementation Guide 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 AB2325Help@cdph.ca.gov or go to our website to submit your question: *www.ccrcal.org/AB2325.shtml*

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CCR Electronic Pathology Reporting

Please go to the CCR website (www.ccrcal.org/AB2325.shtml) for more information on Pathology cancer reporting and to download a copy of the CCR Electronic Pathology Reporting Standard Implementation Guide.

Reportable Diagnoses

1. Invasive malignancies
2. In Situ malignancies
   To see the tems within a pathology reports that indicate in situ behavior and are reportable please go to page 5 of the CCR Electronic Pathology Reporting Standard Implementation Guide.
3. Benign and borderline intracranial and/or Central Nervous System (CNS) tumors
4. All Hematopoietic and lymphoid neoplasms as outlined in the following link: http://seer.cancer.gov/seertools/hemelymph are reportable.
5. Carcinoid Tumors, NOS of the Appendix.
6. Severe or high-grade dysplasia, documented as being synonymous with carcinoma.
7. Neuroendorine tumor when the diagnosis is insulinoma.
8. Cystic Pancreatic Endocrine Neoplasm (CPEN).
9. Cystic pancreatic endocrine specified as neourendorcrine tumor, grades 1 and 2
10. Solid pseudopapillary neoplasm of pancreas.
11. Non-Invasive Mucinous Cystic Neoplasm (MCN) of pancreas with high grade dysplasia.
12. Mature teratoma of the testes in adult.

Non-Reportable Diagnoses

1. Basal and squamous cell carcinoma of the skin, unless it occurs on the genital organs (vulva, scrotum and penis). Specifically, do not report the following histologies occurring in the skin:
   - 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
2. Carcinoma in situ (CIS) or intraepithelial neoplasia grade III (CIN III) of the cervix.
3. Benign and borderline neoplasms that are not primary intracranial and/or CNS neoplasms.

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
- Cytology Reports:
  - Biopsy (fine needle aspiration)
  - Brushings (e.g., endoscopic evaluation of pancreas, PAP smear)
  - Fluids (Urine, Peritoneal, Pleural, Cerebrospinal
  - Fluid, Broncheoalveolar lavage)
  - Hematologic Specific Reports:
  - Immunohistochemistry (IHC)
  - Peripheral Blood Count Flow Cytometry
  - Molecular Reports:
    - Molecular Diagnosis PCR
    - RT-PCR
    - Sequencing (NGS, Pyrosequencing, etc)
    - ISH
    - FISH
    - Gene Array
- Consults
- Slide Reviews
- Biomarker results
- Pathology Report Addenda

What are the Required Data Elements?

All data elements listed in the California Cancer Registry NAACCR Volume 5 Version 4.0 – HL7 2.5.1 Constraints Document are required or required if accessible. These data elements include:

- Facilities Information
- Ordering Provider Information
- Patient Demographics
- Tumor Specific Information

Facilities and ordering provider information is required in order to successfully match pathology information to existing records in CCR's database and/or to match to the criteria for research studies/ clinical trials.

Patient demographic items are essential for epidemiological incidence and mortality research.

CCR recognizes that not all facility/patient information may be available to all pathologists. However, 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.

Vendor Self-Initiated Testing

A vendor self-initiated test portal is available to upload test files for automatic evaluation and feedback on pathology reports. The self-testing tool validates test messages for structure and format. The file is checked to determine that it is parsable, and that the required fields are completed. Edits are run against the submitted file. Multiple record types from pathology laboratory vendors may be needed. If the files pass, the service will update the user account allowing user 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 conducts outreach to entities registered to initiate organization and laboratory specific testing. Organization and laboratory specific testing requires 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 labs submitting data on behalf of pathologists are required to participate in a testing and validation process with CCR. CCR works with pathology labs, 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 CCR Electronic Pathology Reporting Standards Implementation Guide (http://www.ccrcal.org/pdf/AB2325/EPathReportingStds_IG_Final_V1.0_2017.docx).*
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 CCR Electronic Pathology Reporting Standards Implementation Guide: http://www.ccrcal.org/pdf/AB2325/EPathReportingStds_IG_Final_V1.0_2017.docx and review the reporting requirements to ensure the required data is being transmitted.*