

Ordering, Accessioning, Reporting and Supplemental/Revised Reporting

For all Laboratory Information System Procedures please refer to the Softpath Manual located on the laboratory binder shelf in Room 2S238. Included in this Manual are ordering, accessioning, reporting, supplementary/revised reporting, and follow up letter procedures, for both in house and outside consult cytology specimens.

Practitioner Notification

Supplemental reports are issued when additional information is obtained that doesn't alter patient care. Notification of the practitioner is determined on a case by case basis. Revised reports are issued when any information is altered in the final report. If a change in results will affect patient care (i.e. a change in diagnosis, a change in the presence/absence of an infectious organism), a practitioner directly involved in the patient's care must be notified as expediently as possible. The notification of the practitioner along with date and time should be included in the revised report.

The practitioner should also be notified in cases with significant/unexpected findings in which action is needed to avert significant patient morbidity or mortality (e.g. HSIL or invasive carcinoma in a cervicovaginal smear, first diagnosis of malignancy or metastatic malignancy, unexpected pathogenic infectious agent).

Report Results

Report results are only given to physicians, nurses, physician assistants or other patient care representatives involved in the patient's care.

Report Filing/Retrieval

Finalized reports may be accessed through the Softpath and CRIS systems. See the SoftPath Manual located in Bldg 10, Rm 2S238 for specific directions in accessing signed and unsigned reports.

In the past, preliminary reports were attached to CRIS orders and kept in files for two years before being discarded. Since April 14, 2018, hard copies are no longer retained. Instead, the preliminary reports located on the LIS (currently CRIS) worksheets are scanned into the SoftPath report and kept permanently.

Slide Filing

Approximately 3 years of slides and cell blocks are kept in the Cytology office. Older slides from 1994 forward are stored in Rm B2A20. Slides and cell blocks older than this are archived in an outside storage facility. (See Appendix E Outside Slide Storage).

SUBMITTED CASES

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Receiving Submitted Cases

- 1-** Submitted cases must contain all of the following items to be acceptable:
 - properly labeled cytology material in the form of stained or unstained slides, or cell block cassettes
 - a copy of the finalized diagnosis from the original institution

- 2-** If the patient is enrolled at NIH and has an NIH Medical Record Number, an attending physician, nurse or physician's assistant must submit a CRIS order for cytology before the case is accessioned. (See the Medical Accessioning Section of the SoftPath Manual located in the Cytology Lab Rm 2S238).

- 3-** If the case is submitted as an outside consult and the patient has no NIH Medical Record Number, accession the specimen through SoftPath without obtaining a CRIS order. (See Submitted Medicals Section of the SoftPath Manual).

- 4-** After the case is accessioned, the cytotechnologist in the cytolaboratory should enter the total number of slides received, then break down the numbers of stained and unstained slides. Cell block cassettes and numbers of recuts should also be recorded. (See One Case Processing - Gross Description Section in the SoftPath Manual).

- 5-** NIH slide labels should never cover submitting institution slide labels. Place NIH labels on the back of the stained submitted slides. Unstained submitted slides should have their submitted accession numbers handwritten in pencil. NIH labels may be placed over these accession numbers.

Sending a Finalized Report

A finalized report is sent back to the submitting institution. All slides are retained, unless a faxed or emailed request for their return is sent. (Please see Submitted Slide Send Back Procedure on page 3).

SLIDE SEND OUTS

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Submitted Material sent back to the Original Institution

1- Submitted slides may be sent back to the submitting institution when we receive either a faxed (301-480-8054) or emailed (tangihoward@mail.nih.gov) request. If help is needed, please call Surgical Pathology Accessioning (301-480-8470).

2- Print a finalized copy of the medical report and all the slides involved in the case. Make sure the number of the slides matches the number of stained slides submitted in the report. **Note: No slides are to be sent out before the report is finalized.**

3- If unstained slides or cell block sections from the case were processed at NIH, they will have only our label. The diagnoses made from these slides originates at NIH, hence they are our property. We must retain these and store them in our files.

4- Make a xerox copy of the slides being sent.

5- Generate a standard letter on official letterhead (**See Letter #2**) containing the send out date, the original institution's name and address, along with a contact person's name, the case's NIH and submitted accession numbers, and the number of slides being sent.

6- Scan the above paperwork (our send out letter, any other correspondence and a xerox copy of slides sent out) to be saved along with the original case report to SoftPath using the SoftMedia program (see SoftPath Procedure Manual in the Cytology Lab Rm 2S238) before attaching it to the hard copy of the finalized report.

7- Send out the letter, slides* and a copy of our finalized report(s) via USPS (Item #1). USPS drop off is located in Rm 2S262. If it is necessary to expedite the send out, send it via Fedex (see Item #2). Fedex drop off is also located in Rm 2S262.

*Place slide(s) in slide holder(s) with tissue between top of slides and lid. Secure lid with tape. Place in small padded jiffylite mail envelope. Wrap tissue around cell block cassette(s). Place in small sealed plastic bag. Place plastic bag in small padded jiffylite mail envelope.

SLIDE SEND OUTS

Submitted Material having No NIH Medical Record Number Requested by Third Party:

1- Slide send outs for submitted material having no NIH Medical Record Number may only be sent to the original institution. In the event we receive a verbal or written medical legal request from patients, practitioners (from NIH or outside institutions) or other third parties for the release of such cytology materials, inform them of this, then have them submit an NCI/CCR/LP Record Authorization for the Release of Medical Information/Materials Form (See Form #1) from the Cytology Office (Bldg 10, Rm 2S242) or from the Medical Records Department (Bldg 10, Rm 1N208) and forward it to the address listed below:

National Institutes of Health
National Cancer Institute
Laboratory of Pathology
Cytopathology Section
10 Center Drive, MSC 1500
Bldg 10, Room 2S242
Bethesda, MD 20892-1500
301-480-7430 (phone)
301-480-8054 (fax)

2- Once the request has been returned to the cytology office, give the cytopathologist the completed medical release form, a finalized copy of the medical report(s), and the case slides to examine. **Note: No slides are to be sent out before the case is finalized.**

3- Make a xerox copy of the slides being sent.

4- Generate a standard letter on official letterhead (**See Letter #3**) to the original institution containing the send out date, the original institution's name and address, along with a contact person's name, the case's NIH and submitted accession numbers, and the number of slides being sent.

5- Scan the above paperwork (completed medical release form and all attached correspondence, our send out letter, and xerox copy of slides sent out) to be saved along with original report to SoftPath using the SoftMedia program (see Softpath Procedure Manual in Cytology Lab) before attaching it to the hard copy of the finalized report.

6- Send out the letter, slides* and a copy of our finalized report(s) to the original institution via USPS (Item #1). USPS drop off is located in Rm 2S262. If it is necessary to expedite the send out, send it via Fedex (see Item #2). Fedex drop off is also located in Rm 2S262.

*Place slide(s) in slide holder(s) with tissue between top of slides and lid. Secure lid with tape. Place in small padded jiffy lite mail envelope. Wrap tissue around cell block cassette(s). Place in small sealed plastic bag. Place plastic bag in small padded jiffy lite mail envelope.

Submitted Material having an NIH Medical Record Number Requested by Third Party:

1-In the event we receive a verbal and/or written medical legal request from patients, practitioners (from NIH or outside institutions), or other third parties for the release of submitted cytology materials that were issued an NIH Medical Record Number, we must direct them to the Medical Record Department:

National Institutes of Health
Warren Grant Magnuson Clinical Center
Medical Record Department
Bldg 10, Room 1N208
Bethesda, MD 20892
301-496-4433

The Medical Record Dept will have them complete the National Institutes of Health Medical Record Authorization for the Release of Medical Information Form (NIH-527). **(See Form #2).**

2- Next, we will receive a letter from the Medical Legal Dept. approving the request, along with other information regarding the specimen(s) to be released. **(See Form #3).**

3- Give the cytopathologist the Medical Legal Dept letter and paperwork, a finalized copy of the medical report(s), and the case slides to examine. **Note: No slides are to be sent out before the case is finalized.**

4- Make a xerox copy of the slides being sent.

5- Generate a standard letter on official letterhead containing the send out date, the receiver's name and address, the case's NIH and submitted accession numbers, and the number of slides being sent. Process the materials as stated in the Medical Legal Request.

6- Scan the above paperwork (medical legal request form and all attached correspondence, our send out letter, and xerox copy of slides sent out) to be saved along with original report to SoftPath using the SoftMedia program (see Softpath Procedure Manual in Cytology Lab) before attaching it to the hard copy of the finalized report.

7- Send out the letter, slides* and a copy of our finalized report(s) via USPS (Item #9). USPS drop off is located in Rm 2S262 . If it is necessary to expedite the send out, send it via Fedex (see Item #10). Fedex drop off is also located in Rm 2S262.

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*Place slide(s) in slide holder(s) with tissue between top of slides and lid. Secure lid with tape. Place in small padded jiffylite mail envelope. Wrap tissue around cell block cassette(s). Place in small sealed

plastic bag. Place plastic bag in small padded jiffyite mail envelope.

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Slide Send Outs for Original NIH Material (Outside Consultation Requests):

1- In the event we receive a verbal and/or written medical legal request from patients, practitioners (from NIH or outside institutions), or other third parties for the release of cytology materials that originated from the NIH, we must direct them to the Medical Record Department:

National Institutes of Health
Warren Grant Magnuson Clinical Center
Medical Record Department
Bldg 10, Room 1N208
Bethesda, MD 20892
301-496-4433

The Medical Record Dept will have them complete the National Institutes of Health Medical Record Authorization for the Release of Medical Information Form (NIH-527). **(See Form #2).**

2- Next, we will receive a letter from the Medical Legal Dept. approving the request, along with other information regarding the specimen(s) to be released. **(See Form #3).**

3- Give the cytopathologist the Medical Legal Dept letter and paperwork, a finalized copy of the medical report(s), and the case slides to examine. Cytopathologist selects slides to be sent out. **Note: No slides are to be sent out before the case is finalized.**

4- Make a xerox copy of the slides being sent.

5- Using official letterhead, a letter is issued requesting the return of our material along with a copy of the outside consultation report **(Letter #4)**. Also contained in this letter is the send out date, the receiver's name/institution and address, and our accession number(s).

6- Data on the material being sent out is recorded in the In House Medical Legal Request Tracking Log located in the NIH Slide Send Out Binder. **(See Form #4).**

7- Scan the above paperwork (medical legal request form and all attached correspondence, our send out letter, and xerox copy of slides sent out) to be saved along with original report to SoftPath using the SoftMedia program (see Softpath Procedure Manual in Cytology Lab) before attaching it to the hard copy of the finalized report.

8- Send out the letter, slides* and a copy of our finalized report(s) via USPS (Item #9). USPS drop off is located in Rm 2S262. If it is necessary to expedite the send out, send it via Fedex (see Item #10). Fedex drop off is also located in Rm 2S262.

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9- Once the original slides are sent back to our institution, the numbers of slides/cassettes are logged in the In House Medical Legal Request Tracking Log along with the date returned. The reviewing institution's diagnosis is scanned to SoftPath using the SoftMedia program (see SoftPath Procedure Manual in the Cytology Lab Rm 2S238).

*Place slide(s) in slide holder(s) with tissue between top of slides and lid. Secure lid with tape. Place in small padded jiffylite mail envelope. Wrap tissue around cell block cassette(s). Place in small sealed plastic bag. Place plastic bag in small padded jiffylite mail envelope.

Slide Send Outs for NIH Material (Subpoenas):

1- In the event we receive a subpoena for cytology material, we must direct the party to the Medical Records Coordinator, Attorneys at Law Offices:

National Institutes of Health
Warren Grant Magnuson Clinical Center
Medical Record Department
Bldg 10, Room 1N208
Bethesda, MD 20892
301-496-4433

The Medical Record Dept will have them complete the National Institutes of Health Medical Record Authorization for the Release of Medical Information Form (NIH-527). **(Form #2)** if the case contains an NIH Medical Record Number, or an NCI/CCR/LP Record Authorization for the Release of Medical Information/Materials Form (Form #1) if the case has no NIH Medical Record Number.

2- Next, we will receive a letter from the Medical Legal Dept. approving the request, along with other information regarding the specimen(s) to be released. **(Form #3)**.

3- Give the Department Director the Medical Legal Dept letter and paperwork, a finalized copy of the medical report(s), and the case slides to examine.

4- Make a xerox copy of the slides being sent.

5- We must supply the Medical Legal Office with a copy of any and all cytology slides* and accompanying reports pertaining to the patient. Along with this we will send a cover letter on official letterhead, containing a compilation of report accession numbers and number of slides being sent, signed by the Cytopathology Director.

6- If the case originates from NIH, data on the material being sent out is recorded in the In House Medical Legal Request Tracking Log located in the NIH Slide Send Out Binder. **(Form #4)**.

7- Scan the above paperwork (medical legal request form, subpoena, our cover letter, all other relevant paperwork, and xerox copy of slides sent out) to be saved along with original report(s) to SoftPath using the SoftMedia program (see Softpath Procedure Manual in Cytology Lab) before attaching it to the hard copy of the finalized report.

8- The Department Director will need a copy of the cover letter, report and subpoena for his/her record keeping.

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9- Once the original slides are sent back to our institution, the numbers of slides/cassettes are logged in the In House Medical Legal Request Tracking Log along with the date returned. All associated paperwork including any reviewing institution's diagnosis is scanned to SoftPath using the SoftMedia program (see SoftPath Procedure Manual in the Cytology Lab Rm 2S238).

*Place slide(s) in slide holder(s) with tissue between top of slides and lid. Secure lid with tape. Place in small padded jiffylite mail envelope. Wrap tissue around cell block cassette(s). Place in small sealed plastic bag. Place plastic bag in small padded jiffylite mail envelope.

Policy for Slide and Block Removal from Cytopathology Section

The College of American Pathologists dictates that all diagnostic slides must be secured, thus under no conditions can any slides or cell blocks be removed from the Cytopathology files by any individual other than a member of the Cytopathology staff for any reason. The policy for slide/block removal is as follows:

1. Please present a list of desired slides/blocks to a member of the cytopathology section (technologists or secretary).
2. Member of Cytopathology staff will place request in "Borrowed Slide Book".
3. Member of Cytopathology staff will process request as rapidly as possible.
4. Requesting physicians, nurses, physician's assistants, or their assisting technologists sign and date the borrowed slide book.
5. Upon returning the cytology material, they sign and date the book again.

Under no circumstances are slides or blocks to be removed without following this procedure. Slides and blocks are stored in locked file cabinets and in the locked cytology room. Only cytopathology staff have access to these areas.

Policy for Releasing Material for FISH and Molecular Studies

The College of American Pathologists dictates that there is a policy to ensure defined handling and documentation of the use, circulation referral, transfer and receipt of original slides/blocks to ensure availability of materials for consultation and legal proceedings. Thus, under no conditions can any slides or cell blocks be removed from the Cytopathology files by any individual other than a member of the Cytopathology staff for any reason. The policy for releasing material for FISH/molecular studies intradepartmentally is as follows:

1. Please present a list of accession numbers for desired cases along with the number of unstained cell block sections needed for each case.
2. A member of the Cytopathology staff will place the request in the "FISH and Molecular Log".
3. A member of the Cytopathology staff will process the request as rapidly as possible. An H&E section will be processed along with the unstained sections to ensure there is still adequate material on the cell block.
4. Once the request has been processed, a cytology staff member will record the date and the name of the receiving department in the log before releasing the slides.
5. Upon returning the cytology H&E section, a Cytopathology staff member or the requesting party will sign and date the log again. The special stains slides will be kept in the FISH/Molecular department.

Procedure for Accepting Specimens during CRIS Down Time

In the event the computer system for ordering specimens (CRIS) is down, practitioners involved in patient care may use CRIS Downtime Requisition Forms which are located both in the Cytopathology Laboratory in Rm 2S238 and the Secretarial Handbook in Rm 2S242.

(See Form #5).

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Approved: _____ Date: _____
Revised: _____ Date: _____