



GENERAL INFORMATION



SPECIMEN COLLECTION MANUAL

I. GENERAL INFORMATION

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KEY TELEPHONE NUMBERS

BILLING:

BILLING INQUIRIES

Patient Calls (877) 239-6536 (toll free number)
Physician Offices (415) 898-7649

COURIER:

COURIER SERVICE

Supervisor: Karen Herrera (415) 209-6017

CYTOLOGY:

PAP TEST / DNA RESULTS

Cytology Department (415) 209-6042 fax: (415) 209-6053
1615 Hill Road Suite # C, Novato, Ca 94947
Supervisor: Kenric Silva, CT

HISTOLOGY:

DERMATOLOGY SPECIMENS

Histology Department (415) 209-6076 fax: (415) 898-3765
1615 Hill Road Suite # C, Novato, Ca 94947
Supervisor: Bruce Gapinski, HT

MARKETING:

MARKETING/CLIENT SVCS

Territory Manager: Nina Richardson (415) 209-6983 fax: (415) 898-0870

PATHOLOGISTS:

PATHOLOGISTS / DIRECTORS

Paul Wasserstein, MD (415) 925-7174 fax: (415) 461-7228
Frederick Kretzschmar, MD
Christopher Jacques, MD
K. Che Prasad, MD
Imok Cha, MD

PATHOLOGY:

TISSUE/BIOPSY/FNA RESULTS

Pathology Department at Marin General Hospital (MGH) (415) 925-7174 fax: (415) 461-7228
250 Bon Air Road, Greenbrae, Ca 94904
Supervisor: Kim Fochetti

APPOINTMENTS:

BONE DENSITY / BODY MASS

(415) 925-6967

FINE NEEDLE ASPIRATION

(415) 925-7171

SUPPLIES:

SUPPLIES (Fax in order or call numbers below)

ThinPrep / FNA = Cytology (415) 209-6042 fax: (415) 209-6053
Tissue / Biopsy = Histology (415) 209-6076 fax: (415) 898-3765



REQUISITION COMPLETION INSTRUCTIONS

Marin Medical Laboratories requisition is a three-part form. The following information is **required** on the requisition in order to process the specimen and bill for the services rendered:

PATIENT INFORMATION

- Patient name, date of birth, sex, address, phone number, and social security number.

INSURANCE INFORMATION – Copy of Insurance Card (front and back) is required.

- Insured's Name (ie: patient, spouse, or parent, etc)
- Insurance Company Name *and* Claim Mailing Address
- Member/Insurance Identification Number *and* Group Identification Number
- Medicare or Medi-Cal billing -. Complete ID number is required.

CYTOLOGY – You must check mark desired test box to indicate test(s) being requested

ThinPrep Pap Test – Box must be check marked in order for Pap test to be performed.

Reflex Chlamydia included IF UNDER AGE 26

- Type of ThinPrep test must be checked.
- A signed ABN is required for Medicare patients receiving “Non-Covered Services V76.2”.
- An ABN form is provided on the reverse side of the Top Copy.
- High Risk Criteria and an Explanation of Covered Services for Medicare is provided on the requisition; located on reverse side of Yellow Copy.
- HPV** – Indicate the type of HPV testing, if any, by checking appropriate box of choice:
 - HPV ASSAY if ASC-US (HPV will only be run if ASC-US)
 - HPV ASSAY (HPV test will be performed regardless of results).*Note: Automatic reflex for HPV Assay testing preference is available at client request. Please contact our Cytology department @ 415-209-6042 for further information.*
- Chlamydia (DNA)** – Check mark box to request Chlamydia (DNA) test
- N. gonorrhoeae (DNA)** – Check mark box to request N. gonorrhoeae (DNA) test
- ThinPrep Pap Test **without Reflex Chlamydia IF UNDER AGE 26***
**Note: Only check mark this box to opt-out of Reflex Chlamydia UNDER AGE 26 for patient.*

SURGICAL PATHOLOGY / HISTOLOGY / FNA

- Provide clinical data and clinical diagnosis.
- State operative procedure.
- Specify specimen site(s).
- Additional comments/drawing space is available on lower reverse side of the Top Copy.

ADDITIONAL REQUIREMENTS

- Date Specimen Collected is Required.
- Requesting Physician or Clinic Name is Required.
- Cc: Requests need to state Physician Name and Address.
- All Slides and Containers must be labeled with Patient's Full Name and Specimen Site. Lab will reject all unlabeled specimens.

TOP COPY • Lab Copy – Return with signed ABN on reverse (if applicable)

YELLOW COPY • Physician Copy – High Risk Criteria printed on reverse

PINK COPY • Patient Copy – ABN on reverse for patient notification



Marin Medical
Laboratories

1615 HILL ROAD, SUITE C
NOVATO, CA 94947-4338

REQUESTING PHYSICIAN OR CLINIC:	CC:
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PATIENT INFORMATION (Please Print)

Date Specimen Collected	Patient Name (Last)	(First)	(MI)
Social Security Number	Date of Birth / /	Sex	Phone Number
Address		City	State Zip Code

COMPLETE BILLING INFORMATION MUST BE BELOW OR ATTACHED - PATIENT IS BILLED WHEN NOT PROVIDED!

Relationship to Insured: <input type="checkbox"/> Self <input type="checkbox"/> Spouse <input type="checkbox"/> Dependent	Responsible Party Name / Address		
PRIMARY Insurance Name / Address	SECONDARY Insurance Name / Address		
Policy Number	Group Number	Policy Number	Group Number

CYTOLOGY

ThinPrep Pap Test HPV if ASC-US HPV Assay Chlamydia (DNA) N. gonorrhoeae (DNA)
Reflex Chlamydia included IF UNDER AGE 26

TYPE OF THINPREP PAP TEST (Check one of the following - REQUIRED)

NON-MEDICARE PATIENT:

- Routine Screening **V76.2**
- High Risk Screening **V15.89**
- Diagnostic - ICD-9 Code _____

MEDICARE PATIENT:

- Routine Screening **V76.2**
- High Risk Screening **V15.89**
- Diagnostic - ICD-9 Code _____
- Non-Covered Services **V76.2**
(Signed ABN **REQUIRED**)

MEDICARE will only pay for reasonable and necessary tests. **Medicare will only pay for a screening Pap Test every two years.** In the event the patient has more than one screening Pap in two years, **the patient is required to sign an ABN, which is on the reverse side. Medicare does not cover HPV for primary screening.**

A High Risk Pap may be ordered once every twelve months if the Pap is associated with one of the risk factors. A Diagnostic Pap must have an appropriate ICD-9 code specified. Please indicate the risk factor and ICD-9 code.

ThinPrep Pap Test **without**
Reflex Chlamydia IF UNDER AGE 26

GYN SOURCE: Endocervical Cervical Vaginal Other: _____

LMP: _____ Clinical Data / Diagnosis: _____

- Post / Perimenopausal Hysterectomy Abnormal Bleeding Oral Contraceptive IUD
- Post Partum / Nursing Hormonal RX Pregnant ____ # Weeks

NON-GYN SOURCE:

ICD-9 Code: _____

- Urine: Nipple Discharge: Rectal / Anal
- Voided Left Right Sputum
- Catheterized
- Bladder Washing Other: _____

***** LAB USE ONLY *****

NOTE: All slides and containers must be labeled with patient's full name and specimen site. Lab will reject all unlabeled specimens.

SURGICAL PATHOLOGY HISTOLOGY / FNA

Clinical Data / Diagnosis: _____

Operative Procedure: _____ FAX RESULTS TO: _____

Specimen Sites: _____

NOTE: Additional space for notes and/or drawing is available at the bottom of the reverse side of this form.

R. COHEN, MD ■ P.W. WASSERSTEIN, MD ■ F.J. KRETZSCHMAR, MD ■ C.J. JACQUES, MD ■ K.C. PRASAD, MD ■ I. CHA, MD

CYTOLOGY 415-209-6042 FAX 415-209-6053 ■ HISTOLOGY 415-209-6076 FAX 415-898-3765 ■ PATHOLOGY 415-925-7170 FAX 415-461-7228 ■ BILLING 877-239-6536



CYTOLOGY

Cytology Dept (415) 209-6042 ☎ Billing Questions (877) 239-6536
 1615 Hill Road, Suite C, Novato, California 94947

Patient Name: _____

Identification Number: _____

ADVANCE BENEFICIARY NOTICE OF NONCOVERAGE (ABN)

NOTE: If Medicare doesn't pay for the checked items below, you may have to pay.

Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the checked items below.

Checked Items Only:	Reason Medicare May Not Pay:	Estimated Cost:
<input type="checkbox"/> Routine Screening Pap Test	Medicare only pays for this test once every two (2) years.	\$ 37.52
<input type="checkbox"/> High Risk Screening Pap Test	Medicare only pays for this test once yearly.	\$ 37.52
<input type="checkbox"/> HPV Screening Test	Medicare does not pay for this test for your condition.	\$ 49.71

WHAT YOU NEED TO DO NOW:

- Read this notice, so you can make an informed decision about your care.
- Ask us any questions that you may have after you finish reading.
- Choose an option below about whether to receive the checked items listed above.

Note: If you choose Option 1 or 2, we may help you to use any other insurance that you might have, but Medicare cannot require us to do this.

OPTIONS: Check only one box. We cannot choose a box for you.

OPTION 1. I want the checked items listed above. You may ask to be paid now, but I also want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn't pay, I am responsible for payment, but **I can appeal to Medicare** by following the directions on the MSN. If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.

OPTION 2. I want the checked items listed above, but do not bill Medicare. You may ask to be paid now as I am responsible for payment. **I cannot appeal if Medicare is not billed.**

OPTION 3. I don't want the checked items listed above. I understand with this choice I am **not** responsible for payment, and **I cannot appeal to see if Medicare would pay.**

Additional Information:

This notice gives our opinion, not an official Medicare decision. If you have other questions on this notice or Medicare billing, call **1-800-MEDICARE** (1-800-633-4227/TTY: 1-877-486-2048).

Signing below means that you have received and understand this notice. You also receive a copy.

Signature: _____

Date: _____

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0566. The time required to complete this information collection is estimated to average 7 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

HIGH RISK SCREENING PAP TEST CRITERIA FOR MEDICARE COVERAGE

- A. Cervical/ Vaginal High Risk Factors:
 - i. Early onset of sexual activity (under 16 years of age)
 - ii. Multiple sexual partners (five or more in a lifetime)
 - iii. History of sexually transmitted disease (including HIV)
 - iv. Fewer than three negative Pap tests within the previous 7 years
 - v. DES exposed daughters of women who took DES during pregnancy
- B. Childbearing age women with examination indicating the presence of cervical or vaginal cancer or other abnormality during the preceding 3 years.

COVERED SERVICES FOR MEDICARE PAP TESTS

- A. Medicare will pay for Diagnostic Pap Tests for Medicare patients at any interval in the appropriate clinical setting.
- B. Medicare will pay for High Risk Screening Pap Tests for Medicare patients only once yearly.
- C. Medicare will pay for Routine Screening Pap Tests for Medicare patients only once every two years.
- D. Under all other circumstances, Pap Tests for Medicare patients are not currently a covered service by Medicare. An Advance Beneficiary Notice (ABN) must be submitted with this type of cytopathology requisition. Please explain to your patients that this is not a covered service. They will be billed separately by our offices.

HPV SCREENING FOR MEDICARE AND MEDI-CAL

- A. Medicare and Medi-Cal do not cover HPV testing for primary screening.
- B. A Medicare ABN is required for screening HPV.
- C. ASC-US reflex is covered by Medicare and Medi-Cal.



BONE DENSITY CENTER

Scheduling (415) 925-6967 📞 Billing Questions (877) 239-6536
 1300 South Eliseo Drive, Suite 102, Greenbrae, California 94904

Patient Name: _____

Identification Number: _____

ADVANCE BENEFICIARY NOTICE OF NONCOVERAGE (ABN)

NOTE: If Medicare doesn't pay for the checked items below, you may have to pay.

Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the checked items below.

Checked Items Only:	Reason Medicare May Not Pay:	Est. Cost:
<input type="checkbox"/> Bone Density Study (DXA)	Medicare only pays for this test once every two (2) years.	\$ 69.06
<input type="checkbox"/> Bone Density Study, Forearm	Medicare does not recognize this test as medically necessary.	\$ 34.09
<input type="checkbox"/> Vertebral Fracture Assessment	Medicare does not recognize this test as medically necessary.	\$ 34.43
<input type="checkbox"/> Body Mass Composition (DXA)	Medicare does not recognize this test as medically necessary.	\$ 198.92

WHAT YOU NEED TO DO NOW:

- Read this notice, so you can make an informed decision about your care.
- Ask us any questions that you may have after you finish reading.
- Choose an option below about whether to receive the checked items listed above.

Note: If you choose Option 1 or 2, we may help you to use any other insurance that you might have, but Medicare cannot require us to do this.

OPTIONS:	Check only one box. We cannot choose a box for you.
<input type="checkbox"/> OPTION 1.	I want the checked items listed above. You may ask to be paid now, but I also want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn't pay, I am responsible for payment, but I can appeal to Medicare by following the directions on the MSN. If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.
<input type="checkbox"/> OPTION 2.	I want the checked items listed above, but do not bill Medicare. You may ask to be paid now as I am responsible for payment. I cannot appeal if Medicare is not billed.
<input type="checkbox"/> OPTION 3.	I don't want the checked items listed above. I understand with this choice I am not responsible for payment, and I cannot appeal to see if Medicare would pay.

Additional Information:

This notice gives our opinion, not an official Medicare decision. If you have other questions on this notice or Medicare billing, call **1-800-MEDICARE** (1-800-633-4227/TTY: 1-877-486-2048).

Signing below means that you have received and understand this notice. You also receive a copy.

Signature: _____	Date: _____
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According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0566. The time required to complete this information collection is estimated to average 7 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.



BONE DENSITY

Scheduling (415) 925-6967 ☎ Billing Questions (877) 239-6536
 1300 South Eliseo Drive, Suite 102, Greenbrae, California 94904

FINANCIAL OBLIGATION, BENEFITS ASSIGNMENT AND INTEREST CHARGE NOTICE Regarding Bone Densitometry and Body Mass Composition Scans:

Marin Medical Laboratories (MML) will bill your insurance for services you receive from MML.

Some insurance limits the frequency or requires authorization prior to your having a Bone Densitometry scan. It is unlikely that Body Mass Composition services will be covered by insurance. In the event that your insurance does not cover MML’s billed services, you/the patient will receive an invoice for payment from Marin Medical Laboratories.

HMO, PPO, POS & FEE-FOR-SERVICES INSURANCES: If my/the patient’s health plan does not cover all charges, I understand that I am fully responsible to pay directly to Marin Medical Laboratories any charges that are not covered by the plan’s policy, as well as the required co-pay or deductible (as defined within my health plan policy). All accounts, after 60 days from date of service, may be subject to interest at the prevailing legal rate. Should the account be referred to an attorney or collection agency for collection, I may also be billed actual attorneys’ fees and collection expenses.

SELF-PAY: I understand that I am legally obligated to pay the full charges for any and all services rendered to me/the patient by Marin Medical Laboratories. I also understand that I can establish a reasonable payment plan should I desire to do so. All accounts, after 60 days from date of service, may be subject to interest at the legal rate. Should the account be referred to any attorney or collection agency for collection, I may also be billed actual attorneys’ fees and collection expenses.

2012 DEXA STUDY BILLING CHARGE:

- Bone Densitometry DXA (CPT # 77080) Billed Charge Amount is \$352.20
- Wrist/Forearm Bone Densitometry (CPT # 77081) Billed Charge Amount is \$113.59
- Vertebral Fracture Assessment (CPT # 77082) Billed Charge Amount is \$98.73
- Body Mass Composition DXA (CPT # 76499) Billed Charge Amount is \$198.92

RELEASE OF INFORMATION:

The undersigned agrees that, to the extent necessary to determine liability for payment and to obtain reimbursement, Marin Medical Laboratories may disclose portions of the patient’s record, including his/her medical records, to any person or corporation which is or may be liable, for all or any portion of Marin Medical Laboratories’ charge, including but not limited to insurance companies, health care service plans, or workers’ compensation carriers. To ensure coordination of my medical care with my primary care physician, and/or referral source, I authorize release of my medical information.

AUTHORIZATION:

The undersigned certifies that he/she has read the foregoing, received a copy thereof, and is the patient, the patient’s legal representative, or is duly authorized by the patient as the patient’s general agent to execute the above and accept its terms.

 Patient Signature Date

 Witness Signature Date

 Guardian/Representative Signature Date

 Relationship



ORDER FORM

MARIN MEDICAL LABORATORIES

Bone Density Clinic
 1300 So. Eliseo Dr., Suite 102
 Greenbrae, CA 94904
 Phone # 415 925-6967
 Fax # 415 461-4913

PATIENT INFORMATION (Please Print)

PATIENT NAME (LAST)		(FIRST)	M.I.
SOCIAL SECURITY NUMBER		BIRTHDATE (REQUIRED)	SEX
ADDRESS	CITY	ZIP CODE	PHONE # HM: WK:
INSURANCE INFORMATION, required. Patient is billed when not provided.			
Relationship to Insured: <input type="checkbox"/> Self <input type="checkbox"/> Spouse <input type="checkbox"/> Dependent			
Primary Insurance Company / Responsible Party Name		MEDICARE NO.	MEDI-CAL NO.
ORDERING PHYSICIAN	CC:		
Clinical Information (REQUIRED)	ORDERING DATE	<u>ICD-9 CODE</u>	

MEDICATIONS:

CHECK TEST ORDERED	PERFORMED AT:	INSTRUCTIONS TO PATIENT	PROCEDURE TIME
<input type="checkbox"/> Bone Density Hip & Spine * <input type="checkbox"/> BMD of Forearm <input type="checkbox"/> Body Mass Composition	1300 So. Eliseo Suite #102 Greenbrae	Suggest wearing pants, preferably without a zipper (no metal to be worn from the waist to the knees). No Calcium supplements or Multi Vitamins are to be taken 24 hours prior to your appointment. Patient must be under 450 lbs. Arrive 15 minutes prior to scheduled appointment time. **	30 Minutes

*Routinely a Hip/Spine Bone density will be performed; if the hip or spine cannot be evaluated a fracture risk assessment of the forearm will be performed. There is an additional charge for fracture risk assessment of the forearm. On patients with known or suspected hyperparathyroidism a Bone Density of the hip, spine and forearm will be performed.

 ORDERING PHYSICIAN'S SIGNATURE

You have my permission to mail a copy of this report to my patient. _____ (Physician must initial)

**Please call us at least 24 hours prior to your appointment if you need to cancel. Failure to do so will result in a "NO SHOW" charge of \$50.00. Thank You.

R. COHEN, MD • P.W. WASSERSTEIN, MD • F.J. KRETZSCHMAR, MD • C.J. JACQUES, MD • K.C. PRASAD, MD • I. CHA, MD



Mailing Requirement for Specimens

Date:

Client Name
Mailing Address
City / State / Zip Code

Dear Client,

Marin Medical Laboratories has implemented new and specific requirements for specimens mailed to us via U.S. Postal Service in compliance with federal regulations.

To ensure the safety of the specimen and general public, we now require specimens be mailed as follows:

1. Place prepared specimen vial into cardboard cylinder container with two cotton balls on bottom and two cotton balls on top of specimen container
2. Next place cardboard cylinder into specimen baggie and zip baggie closed removing excess air from bag
3. Put folded completed patient specimen requisition in bottom of the final outer cardboard box-- which is self-addressed and pre-stamped for your convenience
4. Insert bagged cardboard cylinder on top of requisition in box and close lid
5. Tape box closed with a piece of clear packing tape to secure closure and mail

Note: You will find the cardboard cylinders have already been prepared for you with cotton balls, bagged, and placed inside the enclosed labeled cardboard boxes.

Please discard the old business reply envelopes and be sure to only use the enclosed supplies and above shipping instructions when mailing specimens.

To order additional shipping supplies, please contact Jennifer directly at (415) 209-6068.

If you have any questions or require further assistance, please call me at (415) 209-6983.

Sincerely,

Nina Richardson
Marketing / Client Services



1615 Hill Road, Suite C • Novato, CA 94947-4338

Cytology Phone (415) 209-6042 Fax (415) 209-6053
Histology Phone (415) 209-6076 Fax (415) 209-6053
Pathology Phone (415) 925-7170 Fax (415) 461-7228

R. COHEN, MD
 P.W. WASSERSTEIN, MD
 F.J. KRETZSCHMAR, MD
 C.J. JACQUES, MD
 K.C. PRASAD, MD
 I. CHA, MD

SUPPLY REQUEST FORM

Please use this form to notify us of your supply requirements.

NOTE: Order at least one week before intended use.

FAX TO 415-209-6053

Contact Name: _____ Date: _____

Office Name: _____ Phone: _____

Mailing Address: _____

QTY	GYN CYTOLOGY	QTY	PATHOLOGY / HISTOLOGY
_____	ThinPrep PreservCyt Vials (25/pack)	_____	Formalin-Filled Bottles, 40mL
_____	Brushes with Spatulas (25/pack)	_____	Formalin-Filled Bottles, 90mL
_____	Brooms (25/pack)	_____	Derm Labels

QTY	NON-GYN / FNA CYTOLOGY	QTY	GENERAL SUPPLIES
_____	Non-Gyn CytoLyt Cups	_____	Specimen Bags
_____	FNA CytoLyt Cups	_____	Mailing Envelopes
_____	Slides, Label-End	_____	Requisition Forms (100/pack)
_____	Plastic Slide Holders	_____	Supply Request Forms (100/pad)

So we may serve you better, please check the box that best describes the services we provide.

	OUTSTANDING	NEEDS IMPROVEMENT	COMMENTS
Quality of Service	<input type="checkbox"/>	<input type="checkbox"/>	_____
Patient Billing	<input type="checkbox"/>	<input type="checkbox"/>	_____
Courier Service	<input type="checkbox"/>	<input type="checkbox"/>	_____
Report Turnaround Time	<input type="checkbox"/>	<input type="checkbox"/>	_____

CENTERS FOR MEDICARE & MEDICAID SERVICES
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS
CERTIFICATE OF ACCREDITATION

LABORATORY NAME AND ADDRESS
MARIN MEDICAL LABORATORIES
1615 HILL ROAD, SUITE B/C/D
NOVATO, CA 94947

CLIA ID NUMBER
05D0663150

EFFECTIVE DATE
02/28/2011

LABORATORY DIRECTOR
IMOK CHA, MD

EXPIRATION DATE
02/27/2013

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.



Judith A. Yost

Judith A. Yost, Director
Division of Laboratory Services
Survey and Certification Group
Center for Medicaid and State Operations

1391 cert52_012911A

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>	<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>
BACTERIOLOGY (110)	08/25/2006		
VIROLOGY (140)	08/25/2006		
HISTOPATHOLOGY (610)	07/28/1995		
CYTOLOGY (630)	09/09/2003		

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.HHS.GOV/CLIA
OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR
YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.

**CENTERS FOR MEDICARE & MEDICAID SERVICES
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS
CERTIFICATE OF ACCREDITATION**

LABORATORY NAME AND ADDRESS
MARIN MEDICAL LABORATORIES
250 BON AIR ROAD
GREENBRAE, CA 94904

CLIA ID NUMBER
05D0706572

EFFECTIVE DATE
01/18/2011

LABORATORY DIRECTOR
PAUL W WASSERSTEIN MD

EXPIRATION DATE
01/17/2013

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.



Judith A. Yost

Judith A. Yost, Director
Division of Laboratory Services
Survey and Certification Group
Center for Medicaid and State Operations

245 certs2_122510

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>	<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>
PARASITOLOGY (130)	03/05/2009		
HEMATOLOGY (400)	03/05/2009		
HISTOPATHOLOGY (610)	11/19/1997		
ORAL PATHOLOGY (620)	11/19/1997		
CYTOLOGY (630)	11/19/1997		

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.HHS.GOV/CLIA OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.

**CENTERS FOR MEDICARE & MEDICAID SERVICES
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS
CERTIFICATE OF ACCREDITATION**

LABORATORY NAME AND ADDRESS
NOVATO COMMUNITY HOSPITAL / LAB
180 ROWLAND WAY
NOVATO, CA 94945

CLIA ID NUMBER
05D0663151

EFFECTIVE DATE
02/28/2011

LABORATORY DIRECTOR
PAUL W WASSERSTEIN

EXPIRATION DATE
02/27/2013

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.



Judith A. Yost

Judith A. Yost, Director
Division of Laboratory Services
Survey and Certification Group
Center for Medicaid and State Operations

1390 cert52_012911A

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>	<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>
BACTERIOLOGY (110)	10/13/1995	ANTIBODY IDENTIFICATION (540)	10/13/1995
MYCOLOGY (120)	11/12/2007	COMPATIBILITY TESTING (550)	10/13/1995
PARASITOLOGY (130)	03/31/2000	HISTOPATHOLOGY (610)	08/15/2003
VIROLOGY (140)	02/10/2006		
GENERAL IMMUNOLOGY (220)	10/13/1995		
ROUTINE CHEMISTRY (310)	10/13/1995		
URINALYSIS (320)	10/13/1995		
ENDOCRINOLOGY (330)	10/13/1995		
TOXICOLOGY (340)	10/13/1995		
HEMATOLOGY (400)	10/13/1995		
ABO & RH GROUP (510)	10/13/1995		
ANTIBODY TRANSFUSION (520)	10/13/1995		
ANTIBODY NON-TRANSFUSION (530)	10/13/1995		

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.HHS.GOV/CLIA
OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR
YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.

**CENTERS FOR MEDICARE & MEDICAID SERVICES
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS
CERTIFICATE OF ACCREDITATION**

LABORATORY NAME AND ADDRESS
SONOMA VALLEY HOSPITAL DISTRICT
MAIN LABORATORY
347 ANDRIEUX ST PO BOX 600
SONOMA, CA 95476-0600

CLIA ID NUMBER
05D0612446

EFFECTIVE DATE
04/16/2012

EXPIRATION DATE
04/15/2014

LABORATORY DIRECTOR
PAUL T WASSERSTEIN MD

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown herein (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.
This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.



Judith A. Yost

Judith A. Yost, Director
Division of Laboratory Services
Survey and Certification Group
Center for Medicaid and State Operations

283 cms2_031712

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>	<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>
BACTERIOLOGY (110)	04/16/2004	COMPATIBILITY TESTING (550)	04/16/2004
MYCOLOGY (120)	11/10/2011	HISTOPATHOLOGY (610)	04/16/2004
VIROLOGY (140)	04/16/2004	CYTOLOGY (630)	04/16/2004
SYPHILIS SEROLOGY (210)	04/16/2004		
GENERAL IMMUNOLOGY (220)	04/16/2004		
ROUTINE CHEMISTRY (310)	04/16/2004		
URINALYSIS (320)	04/16/2004		
ENDOCRINOLOGY (330)	04/16/2004		
TOXICOLOGY (340)	04/16/2004		
HEMATOLOGY (400)	04/16/2004		
ABO & RH GROUP (510)	04/16/2004		
ANTIBODY TRANSFUSION (520)	04/16/2004		
ANTIBODY NON-TRANSFUSION (530)	04/16/2004		

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.HHS.GOV/CLIA
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YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.



Advancing Excellence

**Accredited
Laboratory**



The College of American Pathologists

certifies that the laboratory named below

***Marin General Hospital
Marin Medical Laboratories
Greenbrae, California
Paul W. Wasserstein, MD***

LAP Number: 2394904

AU-ID: 1188152

CLIA Number: 05D0706572

has met all applicable standards for accreditation and is hereby fully accredited by the College of American Pathologists' Laboratory Accreditation Program. Reinspection should occur prior to September 2, 2013 to maintain accreditation.

Accreditation does not automatically survive a change in director, ownership, or location and assumes that all interim requirements are met.

Frank R. Rudy

Chair, Commission on Laboratory Accreditation

John A. Baum MD FCAP

President, College of American Pathologists



Advancing Excellence

**Accredited
Laboratory**



The College of American Pathologists

certifies that the laboratory named below

***Marin Medical Laboratories
Novato, California
Imok Cha, MD***

LAP Number: 2394501

AU-ID: 1188148

CLIA Number: 05D06663150

has met all applicable standards for accreditation and is hereby fully accredited by the College of American Pathologists' Laboratory Accreditation Program. Reinspection should occur prior to September 2, 2013 to maintain accreditation.

Accreditation does not automatically survive a change in director, ownership, or location and assumes that all interim requirements are met.

Frank R Rudy

Chair, Commission on Laboratory Accreditation

John H Baum MD FACP

President, College of American Pathologists



Advancing Excellence

**Accredited
Laboratory**



The College of American Pathologists

certifies that the laboratory named below

Marin General Hospital

Main Laboratory

Greenbrae, California

Paul W. Wasserstein, MD

LAP Number: 2394901

AU-ID: 1188150

CLIA Number: 05D0604317

has met all applicable standards for accreditation and is hereby fully accredited by the College of American Pathologists' Laboratory Accreditation Program. Reinspection should occur prior to September 2, 2013 to maintain accreditation.

Accreditation does not automatically survive a change in director, ownership, or location and assumes that all interim requirements are met.

Frank R Rudy

Chair, Commission on Laboratory Accreditation

Stephen A. Baum MD FCCP

President, College of American Pathologists



TISSUE / BIOPSY

SPECIMEN COLLECTION

TISSUE / BIOPSY SPECIMEN COLLECTION PROTOCOLS

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PATHOLOGY SPECIMEN SUBMISSION REQUIREMENTS

Marin Medical Laboratories requisition form must accompany all pathology/histology specimens. Patient data should be filled out as completely as possible, including the patient name, date of birth, sex, address, insurance information, physician name and address, specimen identification (tissue type and site), operative procedure, collection date, clinical diagnosis, and any applicable history. Please attach a copy of patient's insurance card. Any special requests, (e.g., fax requests, extra copies of reports to additional physicians, special stain requests, etc.), should be stated on the Request form.

For routine specimens each separately identified specimen should be submitted in a plastic screw top container filled with 10% neutral buffered formalin [*reference MSDS*]. Containers filled with 10% neutral buffered formalin are available on request from our Histology Laboratory. Please fill out and fax in a supply request form, or call our lab at (415) 209-6076 for urgent supply requests.

The container must be labeled with the patient's name and physician's name. Smaller specimens should be put in formalin contained in the small plastic screw top containers and placed in the sealable plastic bag provided by Marin Medical Laboratories. The folded Request form should be placed in the pocket on the back of the plastic bag, separated from the specimen container to avoid contamination from unexpected leaking of the specimen container.

Larger specimens may require the use of large containers with enough 10% neutral buffered formalin to completely cover the specimen. Inadequate fixation of larger specimens may result in a delay of specimen processing.

For Bone Marrow specimens, submit a copy of the patient's most recent CBC, peripheral smear and aspirate smears in plastic slide containers or aspirate in purple top tube, and aspirate in green top tube for flow cytometry and cytogenetics.

Once the specimen has been placed in the proper specimen container and the Request form completed properly, your designated courier will retrieve the specimen at a scheduled time. The specimen will then be promptly processed and submitted to the pathologist for diagnosis.

For procedures and requirements for handling of non-routine specimens, (e.g., frozen section, kidney biopsies, immunofluorescence studies, muscle biopsies, products of conception for cytogenetics, etc.), please contact the Pathology laboratory at (415) 925-7174.

HISTOLOGY TISSUE / BIOPSY SUPPLIES:

- Formalin-filled Bottles, Large 90 ml.
- Formalin-filled Bottles, Small 40 ml.
- Formalin-filled Vials, 7ml.
- Plastic Transport Bags
- Facsimile Supply Order Forms
- Requisition Forms

Order from MML Histology Department at (415) 209-6076 one week in advance of intended use.

DERMATOLOGIC SPECIMEN SUBMISSION REQUIREMENTS

Marin Medical Laboratories has an in-house histology department with a wealth of stains and antibodies available offering quality slide preparation.

For dermatologic slide preparation we require the following information:

- Patient First and Last Name
- Date of Birth
- Gender
- Specimen Date
- Specimen Site and Number of Pieces
- Internal Dermatologists Accession #
- Physician Name

MEDICARE DERMATOLOGIC SPECIMEN SUBMISSION REQUIREMENTS

Medicare derm specimens require the following information in addition to the above:

- Patient Address, City, State, Zip Code
- Medicare Number
- ICD-9 Code

Marin Medical Laboratories

Immunohistochemistry Antibodies and Special Stains

Antibodies:

ER
PR
HER-2/neu
ki-67
AE-1/AE-3
Cam 5.2
Cytokeratin 7
Cytokeratin 20
High Molecular weight cytokeratin (CK901)
HMB-45
H- Pylori
S-100
p63
B72.3
Calret (calretinin)
CD-3
CD-20
CD-45 (LCA)
CD79a
AMACR
SMA
CEA
Chromogranin A
E-Cadherin
TTF-1
Triple PIN Stain
 p63
 AMACR
 HMW Cytokeratin
Synaptophysin
MART-1/melan A

Special Stains:

AFB
Alcian Blue pH 2.5
Amyloid
Gram Stain
Trichrome
GMS
PAS
PAS-D
Fe
Mucin
Reticulum



1615 Hill Road, Suite C • Novato, CA 94947-4338

Cytology Phone (415) 209-6042 Fax (415) 209-6053

Histology Phone (415) 209-6076 Fax (415) 898-3765

Pathology Phone (415) 925-7170 Fax (415) 461-7228

P.W. WASSERSTEIN, MD

F.J. KRETZSCHMAR, MD

C.J. JACQUES, MD

K.C. PRASAD, MD

I. CHA, MD

A.R. DOHERTY, MD

MEDICARE SLIDE PREP DERM BILLING

PATIENT INFORMATION

LAST NAME		FIRST NAME		M.I.
ADDRESS		CITY	STATE	ZIP CODE
SOCIAL SECURITY NUMBER		PHONE NUMBER	SEX	DATE OF BIRTH

INSURANCE INFORMATION

RELATIONSHIP TO INSURED <input type="checkbox"/> Self <input type="checkbox"/> Spouse <input type="checkbox"/> Dependent	SECONDARY INSURANCE COMPANY		
MEDICARE IDENTIFICATION NUMBER	SECONDARY INSURANCE ADDRESS		
<i>Please attach copies of patient's Medicare and Insurance cards</i>	SECONDARY INSURANCE IDENTIFICATION NUMBER	GROUP NUMBER	

SPECIMEN INFORMATION

ICD-9 CODE	CPT: 88305-TC	NUMBER OF SPECIMENS SUBMITTED:
DATE SPECIMEN COLLECTED	REQUESTING PHYSICIAN OR CLINIC NAME	

✓ **Please print all information.**

✓ **Entire form must be complete.**

✓ **All sections are required for dermatological slide preparation.**



CYTOLOGY

SPECIMEN COLLECTION

CYTOLOGY SPECIMEN COLLECTION PROTOCOLS

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THINPREP PAP TEST QUICK REFERENCE GUIDE

CYTOLOGY SPECIMEN COLLECTION PROTOCOLS

GENERAL INFORMATION

CRITERIA FOR ACCEPTABLE SPECIMENS:

1. All specimens accepted by the laboratory must be labeled with the patient's name or unique identifying information.
2. Specimens submitted on glass slides should have the patient's name written directly on the slide. Unlabeled glass slides can be accepted only if they arrive in a sealed container or folder clearly labeled with the patient's name.
3. **Fluid specimens must be in a secure leak-proof labeled container and placed in MML specimen baggie. Lab will reject improperly packaged specimens.**
4. THINPREP vials & screw-cap cups must be labeled with patient name and cap securely tightened so that torque line on cap passes the torque line on the vial or cup.
5. Specimens can be received only from licensed, authorized sources, such as physicians, nurse practitioners/midwives, physicians' assistants, authorized medical clinics and hospitals.
6. All specimens must be accompanied by the mandatory patient information on the request form. Form to be placed in the exterior pocket of specimen baggie.
7. Conventional pap smears are no longer accepted.

REQUEST FORM: Use outpatient, MML request form for all cytology specimens.

REQUEST FORM INFORMATION INCLUDES:

- Patient Name
- Birth Date
- Requesting Physician
- Specimen Source
- Date Specimen Collected
- Pertinent Clinical Information/History

IN ADDITION, FOR GYNECOLOGIC SPECIMENS:

- Date of patient's last menstrual period
- Previous history of abnormal report, treatment, or biopsy

BILLING INFORMATION:

- Patient address
- Insurance – attach copy (front and back) of card, make sure it is legible
- Signed ABN form for Medicare patients when appropriate (See "Requisition Completion Instructions" for more information).

Label container and/or slides with patient identification. Place specimen into specimen baggie along with requisition for transport. Submit to cytology promptly.

NOTE: Specimens improperly identified will not be accepted for processing until information is provided.

CYTOLOGIC PROCEDURES PERFORMED BY MML: (Dependent upon specimen)

1. **THINPREP:** Thin layer slide is prepared by THIN PREP 2000 processor, then stained by Papanicolaou technique. Used for GYN (pap) specimens. FNA's, and various non-gynecologic specimens.
- 1a. **THINPREP IMAGING:** GYN specimens are analyzed by the ThinPrep Imaging System, an interactive computer system which assists the lab in the screening of ThinPrep Pap Test slides.
2. **DNA TESTING FROM THE THINPREP VIAL:** A small amount of fluid is removed from the ThinPrep vial for DNA testing. The Digene Hybrid Capture II method is used to detect the presence of High Risk HPV, Chlamydia (CT) or N. gonorrhoeae (GC).
3. **AIR-DRIED SMEARS:** Smears are prepared on label-end slides and quickly air-dried (no fixation). Slides are stained using May Grunwald-Giemsa (MGG) stain technique. Used for Fine Needle Aspirates (FNAs) and certain body cavity fluid specimens.
4. **BUTTON (Cell Block):** Samples are mixed with a formaldehyde-based fixative and are centrifuged to pack the cellular material into a "button". The button is then processed like a surgical tissue specimen by Histology Department. Slides made from button are stained using H&E Histology technique. Used in conjunction with other preparatory procedures for FNAs and Non-gynecologic specimens.

TURN-AROUND TIMES FOR SPECIMEN RESULTS:

1. Gynecologic Pap Results – Approximately one to four working days
2. DNA (HPV, CT & GC) – One to four working days
3. Non-Gynecologic Results – One to two working days
4. FNA Results – One to two working days

TRANSPORTATION OF CYTOLOGY SPECIMENS:

Specimens are delivered to Cytology via MML courier, or patient drop off.

Patient drop off of specimens should be done as soon as possible after collection. Department hours are 8:30am to 5:00pm, Monday through Friday, located at 1615 Hill Road Suite C, Novato.

Special requests or questions regarding specimen pick-up and delivery should be directed to the Pathology Supervisor at MGH at (415) 925-7178.

REQUESTS FOR DNA TESTING (Hybrid Capture II)

For DNA testing from the ThinPrep vial, please indicate on the Cytology Request Form by checking the appropriate test box as follows:

- Check test box: **HPV Assay if Pap is ASC-US** to perform HPV testing on paps with a diagnosis of Atypical Squamous Cells of Undetermined Significance.
- Check test box: **HPV Assay** to perform HPV testing regardless of diagnosis.
- Check test box: **Chlamydia (DNA)** to perform Chlamydia test.
- Check test box: **N. gonorrhoeae (DNA)** to perform N. gonorrhoeae test.
- Check test box: **ThinPrep Pap Test without Reflex Chlamydia under age 26** to opt-out of Reflex Chlamydia UNDER AGE 26 for patient.

LIMITATIONS OF THE PAP TEST:

The Pap Test is a screening test with inherent false positive and false negative rates. Because the Pap Test is an interpretive test which relies on the ability of the clinician to obtain well-preserved representative cells, the accuracy of this test varies from 70 - 90% in the literature. A single Pap Test should not be relied upon to rule out cancerous and pre-cancerous lesions of the uterine cervix. Diagnostic follow-up studies are needed whenever suspicious signs or symptoms are evident, regardless of the Pap Test screening interpretation/result findings. Repeat Pap testing, preferably on an annual basis, is recommended to detect cervical lesions.

LIMITATIONS OF DNA TESTING FROM THE THINPREP VIAL:

Digene's Hybrid Capture II (HC II) DNA tests (HPV, CT & GC) require a minimum of 4 ml of PreservCyt solution remaining in the ThinPrep vial after the ThinPrep slide has been processed (6 ml if two or more tests are requested).

If there is less than 4 ml of PreservCyt solution left, this indicates that an insufficient number of cells was collected from the cervix and transferred to the vial. If the 20 ml of PreservCyt has little cellular material, the ThinPrep 2000 processor will evacuate as much of the solution as is required to adequately populate the ThinPrep slide with cells and leave insufficient solution for DNA testing.

To achieve adequate cellularity, we recommend following the Cytoc specimen collection protocols. Remember to scrape the cervix with the plastic spatula first, then collect the endocervical sample with the brush device second. Vigorous swirling of the spatula in the ThinPrep vial and swirling of the endocervical brush while pushing it against the vial wall also helps to further release cellular material.

If there is not enough PreservCyt solution left in the ThinPrep vial, the following comment will be attached to the DNA report:

“COMMENT: The specimen volume remaining in the PreservCyt vial was insufficient for DNA testing after the ThinPrep slide was prepared.”

For volumes less than 4 ml, Marin Medical Laboratories has performed an in-house validation study that indicates a 2 ml solution volume may be adequate for HPV testing. If this is done, the following disclaimer will appear on that specimens DNA report:

** The amount of specimen received is less than the recommended volume for HPV (High Risk) DNA testing. Correlation with clinical findings is required and it is suggested that the sample be recollected and tested prior to performance of surgical treatment and/or diagnosis of patient.

Lastly, the following comment will appear on DNA reports where the HC II results are close to positive cut-off values for HPV, but are not sufficient to be reportable: **EQUIVOCAL RESULTS:** Results are near cut-off, suggest recollection of a new sample: The established cut-off value for this assay is 1.0. It has been shown that samples with values ranging from 1.0 to 2.5 should be retested. Due to insufficient quantity of specimen it was unable to be retested. Thus it is suggested that a new sample be collected.

REFLEX CHLAMYDIA SCREENING:

Reflex Chlamydia screening is performed on all samples submitted for Pap tests on women under the age of 26. This is based on ACOC, the CDC and the US Preventive Services Task Force Guidelines.

To opt-out of the Chlamydia reflex for a specific patient, check the option “ThinPrep Pap Test without Reflex Chlamydia UNDER AGE 26” on the Cytology Request Form.

SUPPLIES FOR CYTOLOGY SPECIMENS

A. GYNECOLOGIC (THINPREP PAP) SUPPLIES:

Requisition Forms
Gyn Preserv Cyt Vials (25/pk)
Cytobrushes (25/pk)
Plastic Spatulas (25/pk)
Cytobrooms (25/pk)
Specimen Baggies
Facsimile Supply Order Forms

Order from Cytology Department at (415) 209-6042 or fax request at (415) 209-6053.
(Order supplies at least one week before intended usage).

NOTE: PreservCyt solution is methanol based, buffered preservative designed to support cells during transport and slide preparation of the THINPREP Processor. It cannot be substituted with any other reagents.

A Material Safety Data Sheet is included in the MSDS section of this manual.

Store vials at 15-30 degrees Celsius (59-86 degrees Fahrenheit).

Once vials contain specimen, cells are preserved for 2 weeks.

Do not use PreservCyt vials after the expiration date on the vial label.

INTERFERING SUBSTANCES – The use of lubricants (Aquagel, KY-Jelly) should not be used prior to specimen collection.

B. FINE NEEDLE ASPIRATE SUPPLIES:

Requisition Forms
Label-end Slides
Plastic Slide Holders (For Air-Dried Smears)
Formalin (40 ml)
Specimen Baggies
Facsimile Supply Order Forms
Order from Cytology Department (415) 209-6042 or fax to (415) 209-6053.

C. NON-GYNECOLOGIC SPECIMEN SUPPLIES:

THINPREP CYTOLYT SCREW-CAP CUPS:

For Breast Cyst FNA's
For Small Volume (Less than 30ml) Fluids and
For Endoscopic Brushing Specimens-
(Bronchial, Esophageal, Gastric, etc.)
For Anal/rectal brushing specimens and nipple discharges

NOTE: Cytolyt Screw-Cap solution is a methanol-based, buffered, preservative solution designed to lyse red blood cells, prevent protein precipitation, dissolve mucus, and preserve morphology of Non-gynecologic specimens. It is intended as a transportation medium used in specimen preparation prior to processing. Do not add or substitute any other reagents to cup.

NON-GYNECOLOGIC SPECIMEN SUPPLIES – Continued

Store cups at 15-30 degrees Celsius (59-86 degrees Fahrenheit).

Do not use CytoLyt cups after expiration date.

Transport specimen to Cytology immediately for processing, though CytoLyt preserves up to 8 days. Preservation period pertains to samples in a minimum CytoLyt solution to sample ratio of one part CytoLyt to 3 parts sample.

A Material Safety Data Sheet is included in the MSDS section of this manual.

GYNECOLOGIC SPECIMENS (THINPREP PAP) COLLECTION

A. THINPREP Broom-like Device Protocol:

1. Complete request form as previously described.
2. Follow protocol exactly- DO NOT OVERLOAD VIAL!
3. Obtain an adequate sampling from the cervix using a broom-like device. Insert the central bristles of the broom into the endocervical canal deep enough to allow the sorter bristles to fully contact the ectocervix. Push gently, and rotate the broom in a clockwise direction three times.
5. Rinse the broom into the PreservCyt Solution vial by pushing the broom into the bottom of the vial 10 times, forcing the bristles apart. As a final step, swirl the broom vigorously to further release material. Discard the collection device.
6. Tighten the cap so that the torque line on the cap passes the torque line on the vial.
7. Record the patient's name on the vial.
8. Place the vial and requisition in specimen bag for transport.

B. THINPREP Endocervical Brush/Spatula Protocol:

1. Complete request form as previously described.
2. Follow protocol exactly- DO NOT OVERLOAD VIAL!
3. Obtain an adequate sampling from the ectocervix using a plastic spatula.
4. Rinse the spatula into the PreservCyt Solution vial by swirling the spatula vigorously in the vial 10 times. Discard the spatula.
5. Obtain an adequate sampling from the endocervix using an endocervical brush device. Insert the brush into the cervix until only the bottommost fibers are exposed. Slowly rotate $\frac{1}{4}$ or $\frac{1}{2}$ turn in one direction. DO NOT OVER-ROTATE.
6. Rinse the brush in the PreservCyt Solution by rotating the device in the solution 10 times while pushing against the PreservCyt vial wall. Swirl the brush vigorously to further release material. Discard the brush.
7. Tighten the cap so that the torque line on the cap passes the torque line on the vial.
8. Record the patient's name on the vial.
9. Place the vial and requisition in a specimen bag for transport to the laboratory.
(SEE THINPREP PAP TEST QUICK REFERRAL GUIDE AT END OF SECTION)

CONCURRENT BIOPSY AND PAP PROTOCOL:

1. Collect specimen as per routine protocols.
2. Complete Cytology request form and add notation: "CONCURRENT BIOPSY TAKEN".
3. Complete Pathology request form and add notation: "CONCURRENT PAP TAKEN".
4. Send both specimens to Laboratory as soon as possible.

NON-GYNECOLOGIC SPECIMEN COLLECTION BY SOURCE

1. BREAST/NIPPLE DISCHARGE:

- A. NIPPLE SECRETIONS** – Express secretion by gently compressing the areolar area between the thumb and index finger, first vertically, then in a clockwise direction to include the total area. When a mass is palpable, gently milk the space between the mass and the areolar area before expressing the secretion. Collect sample directly into Cytolyt cup or PreservCyt vial.

If secretion is thick, use a plastic spatula to facilitate transfer of sample to cup/vial.

If secretion is scanty, lightly scrape spatula against the nipple, then rinse spatula in Cytolyt cup or PreservCyt vial.

BREAST CYST ASPIRATES – Express fluid obtained directly into a THINPREP Cytolyt screw-cap cup. Tighten cap past torque line. Label container and submit with request form to Lab as soon as possible.

DO NOT SUBMIT NEEDLES.

- B. FINE NEEDLE ASPIRATES OF SOLID BREAST TUMORS** – Prepare air-dried Smears (2-4 slides), then expel remainder of aspirate directly into a small, 40ml formalin-filled bottle. Submit to Lab with request form as soon as possible.

2. ENDOSCOPIC BRUSHINGS: (Bile Duct, Esophageal, Gastric, Hepatic)

Deposit specimen from brush directly into THINPREP Cytolyt screw-cap cup by swirling the brush in the solution while pushing brush against the cup wall to release material. If desired, brush tip can be cut off and left in cup.

Tighten cap past cup torque line. Label cup and submit with request form, both Properly labeled as to specific site of brushing, to Cytology as soon as possible.

3. FINE NEEDLE ASPIRATIONS: (ALL SITES)

Prepare 2-4 air-dried slides, then expel remainder of aspirate directly into a small, 40ml formalin-filled bottle.

Label slides and bottle. Submit with requisition to Lab as soon as possible.

4. FLUIDS: (Less than 30 ml)

Abdominal / Peritoneal fluids and aspirates of cysts, joints and bursae should be submitted as soon as possible for processing. Observe sterile technique in handling sample if cultures are also desired.

Collect specimen and express directly into a THINPREP Cytolyt screw-cap cup.

Tighten cap. Label cup and send to Cytology as soon as possible with completed request form.

5. ORAL LESIONS:

Use a plastic spatula and scrape off as much of the surface of the lesion that can be exfoliated. Rinse material in a Cytolyt cup or PreservCyt vial. Label cup/vial and submit specimen with request to Lab as soon as possible.

6. **RECTAL/ANAL SPECIMENS:**

Rinse collection device into Cytolyt cup or PreservCyt vial. Label cup/vial and submit specimen with request to Lab as soon as possible.

7. **SPUTUM:**

Patient Instructions:

1. Upon awakening, clear throat of any material which may have accumulated overnight and discard.
2. Rinse mouth out with water several times.
3. Cough deeply several times during the next hour.
4. Spit whatever you raise from your lungs into the specimen cup provided. The material Needed for the test is the material coughed up from deep in the lungs, **not** saliva from the mouth.
5. After collection, secure the lid tightly.
6. Label container with patient identification and complete request form.
7. Deliver sample to the doctor or Laboratory as soon as possible.

8. **URINE, BLADDER WASHINGS, URETERAL SAMPLE, RENAL CYST FLUID:**

Submit specimen fresh for immediate processing. Refrigerate specimen prior to transport to Lab. Label container, complete request form and send to Lab as soon as possible.

VOIDED URINE COLLECTION:

24 hour collections are unsatisfactory and first morning voiding may not be optimal. Therefore, the following procedure is recommended (early a.m. collection with hydration).

1. Void and discard first morning urine.
2. Drink 6-8 ounces of fluid.
3. Collect all of first subsequent voided urine.
4. Label container with patient identification and submit with request to Lab as soon as possible.

Random spontaneously voided specimens are next in preference. Send to Lab immediately.

RENAL BRUSHINGS –

See Endoscopic Brushing instructions on page 11.

9. **ALL OTHER SPECIMENS:**

Call Cytology Department for instructions, (415) 209-6042.



URINE CYTOLOGY SPECIMEN COLLECTION INSTRUCTIONS FOR THE PATIENT

1. Void and discard the first morning urine.
2. Drink 6-8 ounces of fluid.
3. Label specimen cup with patient's name and today's (specimen collection) date.
4. Fill specimen cup $\frac{3}{4}$ full with second voided urine.
5. Screw on specimen cup lid tightly.
6. Complete Cytology Request Form. The completed form must include the patient's name, birthdate, address, insurance information (copy of insurance card, front and back), clinical data and clinical diagnosis (or ICD-9 code), date specimen collected, and name of physician ordering test.
7. Put specimen cup and request form in an MML plastic baggie.
8. Refrigerate specimen if delivery is delayed for more than one hour.
9. Take specimen to laboratory **as soon as possible** the same day, or place out for courier pickup.

MARIN MEDICAL LABORATORIES Cytology Department is located at:

1615 Hill Road, Suite C in Novato.

Phone number: (415) 209-6042

Fax number: (415) 209-6053



HPV TESTING PREFERENCE ORDERS

Now available, reflex Digene High Risk HPV Assay testing in conjunction with ThinPrep Pap tests. To request automatic and/or reflex testing, please complete this enrollment form including your signature and the date. Patients with persistent or recurrent disease should be treated according to ACOG guidelines.

PLEASE FAX COMPLETED ORDERS TO 415-209-6053

Client/Physician Name: _____ **Date:** _____

Address: _____ **Phone Number:** _____

City / State / Zip: _____ **Fax Number:** _____

Clinician Name

Clinician Name

Clinician Name

Clinician Name

Clinician Name

Clinician Name

PLEASE CHECK ONE OF THE FOLLOWING:

Reflex High Risk HPV If **ASCUS** only.

OR

(HPV Screening)

Reflex High Risk HPV If ASCUS **and** Reflex High Risk HPV **Regardless of Results for patients age 30 and above.**

I request that Marin Medical Laboratories perform the Digene HPV Assay according to the selections above. The test will be performed on the ThinPrep solution vial containing PreservCyt. By signing below, the above selected automatic reflex will remain in effect for one year and will automatically renew annually thereafter until written notification for change and/or to terminate is received.

Signature: _____ **Date:** _____

(Physician or Medical Director)



BILLING



BILLING POLICY

DIRECT PATIENT BILLING

Marin Medical Laboratories will directly bill patients for services when incomplete or no insurance information is provided, or upon request. To request direct patient billing, the necessary box should be checked and the appropriate billing information recorded on the requisition. Each test requisition will result in a separate bill from Marin Medical Laboratories. We utilize CPT coding procedures as prescribed by the American Medical Association and recognized by most third-party payors. Patient billing is due upon receipt and Marin Medical Laboratories will seek payment for any unpaid bills with subsequent monthly statements, letters and normal collection activity.

THIRD PARTY BILLING

Marin Medical Laboratories will directly file insurance to third party agencies. The patient will be responsible for payment of total charges which may include denied claims, co-payments deductibles and amounts above the insurance company's usual customary and reasonable (UCR) fee schedule.

Please note that when a non-covered service is ordered on Medicare patients (such as routine pap tests, exceeding one test every 2 years) the specimen and requisition **must** be accompanied by a **signed Advance Beneficiary Notice (ABN)**. The patient will be billed for these denied non-covered services at Marin Medical Laboratories rates.

To ensure proper submission and payment of your patient's insurance claims, please make certain that all necessary billing information is recorded, current and correct.

Submission of a copy of the patient's current insurance card (front and back) is the optimal method for assuring proper billing of your patient's claim(s).

MONTHLY PHYSICIAN BILLING

If a Physician client prefers to be billed directly for our laboratory services, an itemized monthly statement will be provided each month detailing the services provided. The itemization will include the date of service, patient name, procedure code and charged amount. Please contact our Marketing / Client Services Representative at (415) 209-6983 if you would like to discuss this billing option.



MATERIAL SAFETY DATA SHEETS

TABLE OF CONTENTS:

CYTOLYT SOLUTION
FORMALDEHYDE SOLUTION
PRESERVCYT SOLUTION

1. CHEMICAL AND COMPANY IDENTIFICATION

Product Identification: ThinPrep® CytoLyt® Solution

Trade Name/Chemical Family/Synonyms: Methanol-water solution

Product Description: A methanol based, buffered preservative solution.

Product Use: A preservative solution to support cells during transport and slide preparation.

Manufacturer: Hologic Inc.
250 Campus Drive
Marlborough, Massachusetts 01752
USA
Telephone: 800-442-9892

EMERGENCY TELEPHONE NUMBERS: **For Health/Transportation/Chemical Spills**
(24 hours a day and 7 days a week) **(Multilingual capabilities and free calls accepted)**
Continental United States: (800) 424-9300
Outside of continental United States: +(703) 527-3887

2. COMPOSITION/ INFORMATION ON INGREDIENTS

Chemical	CAS Registry #	Wt. %
Methanol	67-56-1	20 - 50
Water	7732-18-5	40 - 70

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW: **Warning! Material is a clear flammable liquid. Inhalation of vapors may cause nonspecific discomfort (nausea, weakness), drowsiness with anesthetic effects and possible blindness. Swallowing as little as 10 ounces (296 ml) may cause blindness and in extreme cases death.**

Potential Health Effects:

Inhalation: May cause depression of central nervous system resulting in nausea, weakness, drowsiness and possibly blindness.

Eye Contact: May cause transient irritation.

Skin Contact: May cause irritation and/or dermatitis. Material may be absorbed through the skin resulting in effects similar to ingestion or inhalation.

Ingestion: May cause intoxication, Central nervous system depression, nausea, and dizziness. May damage liver, kidneys and nervous system. May cause blindness and/or death.

Target Organs: Liver, kidneys, and central nervous system.

Medical Conditions Aggravated by Exposure: Individuals with preexisting diseases of the retina (eyes) or liver may have increased susceptibility to toxicity at lower levels of successive exposure (repeated exposures).

Chronic: Liquid and vapor can penetrate skin and mucous membranes. May cause chronic liver, kidney or nervous system disorders.

4. FIRST AID MEASURES

Inhalation: Remove patient to fresh air. If symptoms of intoxication or vision problems are apparent, get immediate medical aid.

Eye Contact: Immediately flush with clean water for at least 15 minutes. Get medical aid.

Skin Contact: Remove contaminated clothing and shoes. Flush affected area with copious amounts of water. If irritation or other symptoms are present, get immediate medical assistance.

Ingestion: **Do not induce vomiting unless directed to do so by medical personnel.** Give one or two glasses of water and get immediate medical assistance.

Notes to Physician: Treat for CNS depression and possible renal failure.

5. FIRE FIGHTING MEASURES

Flammability: Flash point: 109°F (42.7°C) (closed cup)
 Auto ignition temperature: 725°F (385°C)
 Flammable limits: LEL = 6.7 UEL = 36 (based on methanol component)
 Flammable liquid and vapor.

Explosion Data: Above flash point, vapor air mixtures are explosive within flammable limits noted above. Moderate explosion hazard and dangerous fire hazard when exposed to heat, sparks or flames. Sensitive to static discharge.

General Hazard: Flammable material. Heated material may form toxic and/or explosive vapors.

Fire Fighting Instructions: Wear full turnout gear with NIOSH approved self-contained breathing apparatus with full face piece operated in the pressure demand or other positive pressure mode. If material is not involved in fire, attempt to cool with water or remove from area. **FLAME INVISIBLE IN DAYLIGHT**

Fire Fighting Equipment: Wear full turnout gear with NIOSH approved self-contained breathing apparatus with full face piece operated in the pressure demand or other positive pressure mode.

Extinguishing Media: Use dry chemical, alcohol foam or carbon dioxide (water may be ineffective).

Hazardous Combustion Products: Carbon Monoxide and Carbon Dioxide

NFPA Hazard Rating: Health – 1
 (National Fire Protection Association) Flammability – 2
 Reactivity – 0
 Special Information – None

0=Insignificant
 1=Slight
 2=Moderate
 3=High
 4=Extreme
 U=Unknown *=No Information

Special Information: None

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions: Immediately contact emergency personnel. Keep unnecessary personnel away. Ventilate area of leak or spill. Remove all sources of ignition. Use suitable protective equipment (Section 8). Isolate hazard area.

Environmental Precautions: Avoid dispersal of spilled material, runoff and contact with soil, waterways, drains and sewers. Dyke large spills with absorbent with an inert material (e.g., vermiculite, dry sand, earth). Absorb small spills with clay or kitty litter. For spills in excess of 50 gallons, contact licensed HAZWOPER responders.

Methods for Containment: Contain and recover liquid when possible. Use non-sparking tools and equipment. Collect liquid in an appropriate container or absorb with an inert material (e.g., vermiculite, dry sand, earth).

Methods for Clean-Up: Scoop up with non-sparking tools and equipment then place into a suitable container for disposal.

Other Information: Follow local, state, provincial and federal guidelines for all spills.

7. HANDLING AND STORAGE

Handling: KEEP OUT OF THE REACH OF CHILDREN. Avoid contact with eyes, skin and clothing. Keep container closed. Wear recommended personal protective equipment. Avoid contact with heat, sparks and flame. Do not ingest or inhale. Wash thoroughly after handling.

Storage: Store away from excessive heat and sources of ignition. Keep container closed and protect from damage.
Storage temperature: Without cytologic sample: 59 – 86°F (15 – 30°C)

8. EXPOSURE CONTROLS / PERSONAL PROTECTIVE EQUIPMENT

Engineering Controls: Supply exhaust and/or ventilation to keep vapor levels below threshold limit value.

Personal Protective Equipment:
Eye/Face Protection: Wear safety glasses with side shields.
Hand Protection: Wear chemical resistant gloves.
Skin and Body Protection: Wear suitable protective clothing.
Respiratory Protection: Where engineering controls are not adequate, use approved NIOSH respirators or supplied air respirators.

Exposure limit values:

Ingredient	OSHA PEL	ACGIH TLV®	
Methanol	200 ppm – TWA	200 ppm – TWA 250 ppm – STEL	
	Canada – Alberta, British Columbia, New Brunswick, Manitoba, Ontario, Quebec, and Yukon		Canada – Saskatchewan
TWA – 8 hr STEL – 15 minute	200 ppm – TWA 250 ppm – STEL		262 mg/m ³ TWA 328 mg/m ³ STEL

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear, colorless liquid
Odor: Alcohol type odor
Specific Gravity (Water=1): 0.97
Solubility in Water: Complete
Freezing Point (°F/°C): Not available
Evaporation Rate (BuAc=1): >1
Viscosity: Not available
Lower Flammability Limit: Not available
Coefficient of Water/Oil Distribution: Not available

Color: Colorless
Physical State: Liquid
VOC Content, wt. %: Not available
Vapor Density (Air=1): 1.1
Vapor Pressure mm/Hg: 127
pH: 7
Boiling Point (°F/°C): 148°F (64.4°C)
Upper Flammability Limit: Not available
Auto-ignition Temperature: 725°F (385°C)

10. STABILITY AND REACTIVITY

General Stability:	Stable under normal temperatures and pressures.
Conditions To Avoid:	High temperatures, incompatible materials, ignition sources, oxidizers.
Incompatible Materials:	Strong oxidizers (may ignite product).
Hazardous Decomposition Products:	May form carbon dioxide, carbon monoxide, and formaldehyde when heated to decomposition.
Hazardous Polymerization:	Will not occur.

11. TOXICOLOGICAL INFORMATION

For Methanol: Product not tested as a mixture

Inhalation:	LC50 Rat: 64000 ppm/4H
Oral:	LD50 Rat: 5628 mg/kg LD50 Mouse: 7300 mg/kg
Dermal:	LD50 Rabbit: 15800 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity:	This material is expected to be slightly toxic to aquatic life. Fish: LC ₅₀ Pimephales promelas (fathead minnows) 29.4 g/l/96 hr, (28-29 days old) EC50 (30 min) Photo bacterium phosphoreum: 51,000 – 320,000 mg/L
Persistence/ Degradability:	No data available.
Bioaccumulation/ Accumulation:	No data available.
Mobility in Environment:	No data available.

13. DISPOSAL CONSIDERATION

Disposal Instructions:	Dispose of container and unused contents in accordance with local, state, provincial, and federal laws.
RCRA Hazardous Waste if Discarded?	Yes
RCRA ID number:	D001, Ignitable waste.

14. TRANSPORTATION INFORMATION

Regulatory Information	UN number	Proper shipping name	Class	Packing group
US DOT Classification	1993	Flammable liquids, n.o.s. (Methanol)	3	III

15. REGULATORY INFORMATION

USA:	The MSDS was prepared pursuant to the Hazardous Communication Standard (29 CFR 1910.1200).
Toxic Substances Control Act (TSCA):	All ingredients listed on TSCA inventory.
CERCLA:	RQ for methanol = 5,000 lbs (2270 kg).
SARA 311 Status:	Immediate, fire hazard
SARA 313:	Methanol is listed on the 313 Toxic Pollutant reporting list.
State Issues:	Not listed for California Proposition 65
WHMIS Status (Canada):	A controlled product. Classification: B2;D1B;D2A This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all the information required by the CPR.
Foreign Chemical Inventories:	All ingredients are listed on the chemical inventories of the following countries: Canada (DSL) Japan European Union Australia

16. OTHER INFORMATION

Current Issue Date:	February, 2010
Previous Issue Date:	Initial Hologic
Other Information:	None

Information Note: Where no corresponding data was contained in manufacturer's MSDS, additional research is required and available upon request. THE INFORMATION RELATES TO THIS SPECIFIC MATERIAL. IT MAY NOT BE VALID FOR THIS MATERIAL IF USED IN COMBINATION WITH ANY OTHER MATERIALS OR IN ANY PROCESS. IT IS THE USER'S RESPONSIBILITY TO SATISFY ONESELF AS TO THE SUITABILITY AND COMPLETENESS OF THIS INFORMATION FOR HIS OR HER OWN PARTICULAR USE.

Material Safety Data Sheet



Section 1. Chemical Product and Company Identification

Product Name	Product Code
Formalin Solution 10% Neutral Buff. pH 7.0	28600
Manufacturer's Name	Emergency Telephone Number
StatLab Medical Products, Inc.	800-424-9300
Address (Number, Street, City, State, and ZIP Code)	Telephone Number for Informator
407 Interchange st.	800-442-3573 x 2
McKinney Tx 75071	Date Prepared
	10/14/2003 (rev 10/20/05)
	Signature of Preparer (optional)

Section 2. Composition/Information on Ingredients

Component	CAS #	OSHA PEL	ACGIH TLV	Other Limits Recommended	Percent
Formaldehyde	50-00-0	0.75 ppm	C 0.3 mg/m ³		3-4
Methyl Alcohol	67-56-1	200 ppm	250 ppm		1-1.5
Sodium Phosphate Monobasic Monohydrate	10049-21-5	N/A	N/A		<1
Sodium Phosphate Dibasic	7558-79-4	N/A	N/A		<1
Water, Deionized	7732-18-5	N/A	N/A		Balance

Section 3. Hazards Identification

Emergency Overview

Contains Formaldehyde, a suspected carcinogen. Irritating to the eyes, respiratory system and skin. May cause sensitization by inhalation or skin contact. May be fatal if swallowed. If ingested, dilute with water, induce vomiting then call a physician. Wash areas of contact with water. If inhaled, remove to fresh air.

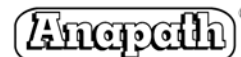
Potential Health Effects

Target Organs	Eyes, skin, respiratory system.
Eye	Causes irritation, redness and pain.
Skin	May cause irritation, redness and pain. Frequent or prolonged exposure may cause hypersensitivity leading to contact dermatitis.
Ingestion	May cause severe abdominal pain, vomiting, headache and diarrhea.
Inhalation	Causes irritation of respiratory tract. Symptoms may include sore throat, coughing and shortness of breath.
Chronic/Carcinogenicity	IARC-Formaldehyde is probably carcinogenic. NTP-Formaldehyde is reasonably anticipated to be a carcinogen. OSHA-Yes (Formaldehyde)
Teratology	Mutation data cited in "Registry of Toxic Effects of Chemical Substances" on Formaldehyde.
Reproduction	Reproductive effects cited in "Registry of Toxic Effects of Chemical Substances" on Formaldehyde.
Mutagenicity	

Material Safety Data Sheet

Product Name Formalin Solution 10% Neutral Buff. pH 7.0

28600



Section 4. First Aid Measures

Eye Irrigate immediately with large quantity of water for at least 15 minutes.

Skin Flush with water for at least 15 minutes.

Ingestion Dilute immediately with water or milk. Induce vomiting. Call a physician.

Inhalation Remove to fresh air. Give artificial respiration if necessary.

All Other Means of Exposure CONTACT POISON CONTROL CENTER IMMEDIATELY. Be prepared to provide hazardous ingredient information from Section 2.

Section 5. Fire Fighting Measures

Flammable Properties	Flash Point	N/A	Method	N/A
Flammable Limits	Lower	N/A	Upper	N/A
Autoignition Temperature				
Hazardous Combustion Products				
Extinguishing Media	Use any means suitable for extinguishing the surrounding fire. (Water spray, dry chemical, alcohol foam, or carbon dioxide.)			
Fire & Explosion Hazards	Not considered to be a fire or explosion hazard.			
Fire Fighting Instructions	Use normal procedures/instructions.			
Fire Fighting Equipment	Use protective clothing and breathing equipment appropriate for the surrounding fire.			

Section 6. Accidental Release Measures

Ventilate area of leak or spill. Cover spill with 1:1:1 mixture of Sodium Carbonate, clay cat litter and sand. Scoop into container and transport to fume hood. Add the mixture to cold water (about 10 mL water for each 1 mL of Formaldehyde solution). Slowly add household bleach (2.5 mL bleach for each 1 mL of Formaldehyde solution). Allow to stand for 20 minutes. Decant liquid to drain. Flush with water. Treat solid residue as normal refuse.

Section 7. Handling and Storage

Handling/Storage As with all chemicals, wash hands thoroughly after handling. Avoid contact with eyes. Protect from freezing and physical damage. Use with adequate ventilation. Store at controlled room temperature, 15-30°C.

SAFETY STORAGE CODE: HEALTH

Material Safety Data Sheet

Product Name Formalin Solution 10% Neutral Buf; Product Code

28600



Section 8. Exposure Controls, Personal Protection

Engineering Controls Use of a fume hood is recommended.

Respiratory Protection If the exposure level is exceeded, wear a full facepiece respirator equipped with a formaldehyde cartridge.

Skin Protection Gloves

Eye Protection Safety glasses or goggles.

Permissible Exposure Levels (see also Section 2)

Component	CAS #	OSHA PEL	ACGIH TLV	Other Limits Recommended	Percent
Formaldehyde	50-00-0	0.75 ppm	C 0.3 mg/m ³		3-4
Methyl Alcohol	67-56-1	200 ppm	250 ppm		1-1.5
Sodium Phosphate Monobasic Monohydrate	10049-21-5	N/A	N/A		<1
Sodium Phosphate Dibasic	7558-79-4	N/A	N/A		<1
Water, Deionized	7732-18-5	N/A	N/A		Balance

Section 9. Physical and Chemical Properties

Boiling Point	approx. 100°C	Specific Gravity (H ₂ O = 1)	approx. 1.02
Vapor Pressure (mm Hg)	N/A	Melting Point	approx. 0°C
Vapor Density (AIR = 1)		Evaporation rate (Butyl Acetate = 1)	
Solubility in Water	Infinite	Physical State	
Appearance and Odor	Clear, colorless/pungent odor	Other	pH: 7.0

Section 10. Stability and Reactivity

Chemical Stability Stable under normal conditions of use and storage.

Incompatibility Strong oxidizers, strong alkalies, acids, phenol, urea.

Hazardous Decomposition Products May form Carbon Dioxide, Carbon Monoxide and Formaldehyde when heated to decomposition.

Hazardous Polymerization Nonhazardous polymerization may occur, forming paraformaldehyde, a white solid.

Section 11. Toxicological Information

LD₅₀, Oral, Rat: (Formaldehyde) 100 mg/kg; LD₅₀, Oral, Rat: (Sodium Phosphate Diabasic) 17,000 mg/kg; Details of toxic effects not reported other than lethal dose value.

Material Safety Data Sheet

Product Name Formalin Solution 10% Neutral Buf; Product Code

28600



Section 12. Ecological Information

Ecotoxicological Information: Formaldehyde is expected to be slightly toxic to aquatic life.

Chemical Fate Information: Formaldehyde is expected to readily biodegrade when released into water.

Section 13. Disposal Considerations

Whatever cannot be saved for recovery or recycling should be disposed of in a RCRA approved waste disposal facility. Dispose of in accordance with local, state, and federal regulations.

Section 14. Transport Information

GROUND SHIPMENTS: Not regulated

AIR SHIPMENTS: Aviation Regulated Liquid n.o.s. (formaldehyde), 9, UN3334

NOTE: It is ultimately the shippers responsibility to make hazard class determination based on their best information available.

Section 15. Regulatory Information

OSHA Status: This item meets the OSHA Hazard Communication Standard (29 CFR 1910.1200) definition of a hazardous material.

TSCA Status: All components of this solution are listed on the TSCA Inventory.

CERCLA Reportable Quantity: Formaldehyde, RQ 100 pounds.

SARA TITLE III:

Section 302 Extremely Hazardous Substances: Formaldehyde TPQ 500 pounds

Section 311/312 Hazardous Categories: No

Section 313 Toxic Chemicals: Formaldehyde, 0.1% De Minimus concentration

RCRA Status: No

California Proposition 65: No listed (Formaldehyde gas is listed)

Florida: Formaldehyde is listed on the state Toxic Substances List.

Pennsylvania: Formaldehyde is listed as an environmental and special hazard on the Hazardous Substances List.

Section 16. Other Information

NFPA Ratings: Health: 2 Flammability: 2 Reactivity: 0 Special Notice Key: None

HMIS® Ratings: Health: 4 Flammability: 2 Reactivity: 0 Protective Equipment: C

(protective eyewear and gloves)

When handled properly by qualified personnel, the product described herein does not present a significant health or safety hazard. Alteration to its characteristics by concentration, evaporation, addition of other substances, or other means may present hazards not specifically addressed herein and which must be evaluated by the user. The information furnished herein is believed to be accurate and represents the best data currently available to us. No warranty, expressed or implied, is made and STATLAB MEDICAL PRODUCTS, INC. assumes no legal responsibility or liability whatsoever resulting from its use.

1. CHEMICAL AND COMPANY IDENTIFICATION

Product Identification: ThinPrep® PreservCyt® Solution

Trade Name/Chemical Family/Synonyms: Methanol-water solution

Product Description: A methanol based, buffered preservative solution

Product Use: A preservative solution to support cells during transport and slide preparation.

Manufacturer: Hologic Inc.
250 Campus Drive
Marlborough, Massachusetts 01752
USA
Telephone: 800-442-9892

EMERGENCY TELEPHONE NUMBERS: For Health/Transportation/Chemical Spills
(24 hours a day and 7 days a week) (Multilingual capabilities and free calls accepted)
Continental United States: (800) 424-9300
Outside of continental United States: +(703) 527-3887

2. COMPOSITION/ INFORMATION ON INGREDIENTS

Chemical	CAS Registry #	Wt. %
Methanol	67-56-1	30 - 60
Water	7732-18-5	40 - 70

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW: Warning! Material is a clear flammable liquid. Inhalation of vapors may cause nonspecific discomfort (nausea, weakness), drowsiness with anesthetic effects and possible blindness. Swallowing as little as 4 ounces (118 ml) may cause blindness and in extreme cases death.

Potential Health Effects:

Inhalation: May cause depression of central nervous system resulting in nausea, weakness, drowsiness and possibly blindness.

Eye Contact: May cause transient irritation.

Skin Contact: May cause irritation and/or dermatitis. Material may be absorbed through the skin resulting in effects similar to ingestion or inhalation.

Ingestion: May cause intoxication, Central nervous system depression, nausea, and dizziness. May damage liver, kidneys and nervous system. May cause blindness and/or death.

Target Organs: Liver, kidneys, and central nervous system.

Medical Conditions Aggravated by Exposure: Individuals with preexisting diseases of the retina (eyes) or liver may have increased susceptibility to toxicity at lower levels of successive exposure (repeated exposures).

Chronic: Liquid and vapor can penetrate skin and mucous membranes. May cause chronic liver, kidney or nervous system disorders.

4. FIRST AID MEASURES

Inhalation: Remove patient to fresh air. If symptoms of intoxication or vision problems are apparent, get immediate medical aid.

Eye Contact: Immediately flush with clean water for at least 15 minutes. Get medical aid.

Skin Contact: Remove contaminated clothing and shoes. Flush affected area with copious amounts of water. If irritation or other symptoms are present, get immediate medical assistance.

Ingestion: **Do not induce vomiting unless directed to go so by medical personnel.** Give one or two glasses of water and get immediate medical assistance.

Notes to Physician: Treat for CNS depression and possible renal failure.

5. FIRE FIGHTING MEASURES

Flammability: Flash point: 80°F (26.5°C) (closed cup)
 Auto ignition temperature: 725°F (385°C)
 Flammable limits: LEL = 6.7 UEL = 36 (based on methanol component)
 Flammable liquid and vapor.

Explosion Data: Above flash point, vapor air mixtures are explosive within flammable limits noted above. Moderate explosion hazard and dangerous fire hazard when exposed to heat, sparks or flames. Sensitive to static discharge.

General Hazard: Flammable material. Heated material may form toxic and/or explosive vapors.

Fire Fighting Instructions: Wear full turnout gear with NIOSH approved self-contained breathing apparatus with full face piece operated in the pressure demand or other positive pressure mode. If material is not involved in fire, attempt to cool with water or remove from area. **FLAME INVISIBLE IN DAYLIGHT**

Fire Fighting Equipment: Wear full turnout gear with NIOSH approved self-contained breathing apparatus with full face piece operated in the pressure demand or other positive pressure mode.

Extinguishing Media: Use dry chemical, alcohol foam or carbon dioxide (water may be ineffective).

Hazardous Combustion Products: Carbon Monoxide and Carbon Dioxide

NFPA Hazard Rating: Health – 1
 (National Fire Protection Association) Flammability – 3
 Reactivity – 0
 Special Information – None

0=Insignificant
 1=Slight
 2=Moderate
 3=High
 4=Extreme
 U=Unknown *=No Information

Special Information: None

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions: Immediately contact emergency personnel. Keep unnecessary personnel away. Ventilate area of leak or spill. Remove all sources of ignition. Use suitable protective equipment (Section 8). Isolate hazard area.

Environmental Precautions: Avoid dispersal of spilled material, runoff and contact with soil, waterways, drains and sewers. Dyke large spills with absorbent with an inert material (e.g., vermiculite, dry sand, earth). Absorb small spills with clay or kitty litter. For spills in excess of 50 gallons, contact licensed HAZWOPER responders.

Methods for Containment: Contain and recover liquid when possible. Use non-sparking tools and equipment. Collect liquid in an appropriate container or absorb with an inert material (e.g., vermiculite, dry sand, earth).

Methods for Clean-Up: Scoop up with non-sparking tools and equipment then place into a suitable container for disposal.

Other Information: Follow local, state, provincial and federal guidelines for all spills.

7. HANDLING AND STORAGE

Handling: KEEP OUT OF THE REACH OF CHILDREN. Avoid contact with eyes, skin and clothing. Keep container closed. Wear recommended personal protective equipment. Avoid contact with heat, sparks and flame. Do not ingest or inhale. Wash thoroughly after handling.

Storage: Store away from excessive heat and sources of ignition. Keep container closed and protect from damage.
Storage temperature: Without cytologic sample: 59 – 86°F (15 – 30°C)
With cytologic samples, for up to three weeks: 39 – 99°F (4 – 37°C)

8. EXPOSURE CONTROLS / PERSONAL PROTECTIVE EQUIPMENT

Engineering Controls: Supply exhaust and/or ventilation to keep vapor levels below threshold limit value.

Personal Protective Equipment:
Eye/Face Protection: Wear safety glasses with side shields.
Hand Protection: Wear chemical resistant gloves.
Skin and Body Protection: Wear suitable protective clothing.
Respiratory Protection: Where engineering controls are not adequate, use approved NIOSH respirators or supplied air respirators.

Exposure limit values:

Ingredient	OSHA PEL	ACGIH TLV®	
Methanol	200 ppm – TWA	200 ppm – TWA 250 ppm – STEL	
TWA – 8 hr STEL – 15 minute	Canada – Alberta, British Columbia, New Brunswick, Manitoba, Ontario, Quebec, and Yukon 200 ppm – TWA 250 ppm – STEL	Canada – Saskatchewan 262 mg/m ³ TWA 328 mg/m ³ STEL	

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear, colorless liquid
Odor: Alcohol type odor
Specific Gravity (Water=1): 0.92
Solubility in Water: Complete
Freezing Point (°F/°C): Not available
Evaporation Rate: >1
Viscosity: Not available
Lower Flammability Limit: Not available
Coefficient of Water/Oil Distribution: Not available

Color: Colorless
Physical State: Liquid
VOC Content, wt. %: Not available
Vapor Density (Air=1): 1.1
Vapor Pressure mm/Hg: 127
pH: 5.5
Boiling Point (°F/°C): 148°F (64.5°C)
Upper Flammability Limit: Not available
Auto-ignition Temperature: 725°F (385°C)

10. STABILITY AND REACTIVITY

General Stability: Stable under normal temperatures and pressures.

Conditions To Avoid: High temperatures, incompatible materials, ignition sources, oxidizers.

Incompatible Materials: Strong oxidizers (may ignite product).

Hazardous Decomposition Products: May form carbon dioxide, carbon monoxide, and formaldehyde when heated to decomposition.

Hazardous Polymerization: Will not occur.

11. TOXICOLOGICAL INFORMATION

For Methanol: Product not tested as a mixture

Inhalation: LC50 Rat: 64000 ppm/4H

Oral: LD50 Rat: 5628 mg/kg
LD50 Mouse: 7300 mg/kg

Dermal: LD50 Rabbit: 15800 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity: This material is expected to be slightly toxic to aquatic life.
Fish: LC50 Pimephales promelas (fathead minnows) 29.4 g/l/96 hr, (28-29 days old)
EC50 (30 min) Photo bacterium phosphoreum: 51,000 – 320,000 mg/L

Persistence / Degradability: No data available.

Bioaccumulation / Accumulation: No data available.

Mobility in Environment: No data available.

13. DISPOSAL CONSIDERATION

Disposal Instructions: Dispose of container and unused contents in accordance with local, state, provincial, and federal laws.

RCRA Hazardous Waste if Discarded? Yes

RCRA ID number: D001, Ignitable waste.

14. TRANSPORTATION INFORMATION

Regulatory Information	UN number	Proper shipping name	Class	Packing group	Label
US DOT Classification	1993	Flammable liquids, n.o.s. (Methanol)	3	III	2.2

15. REGULATORY INFORMATION

USA:	The MSDS was prepared pursuant to the Hazardous Communication Standard (29 CFR 1910.1200).
Toxic Substances Control Act (TSCA):	All ingredients listed on TSCA inventory.
CERCLA:	RQ for methanol = 5,000 pounds (2270 kg).
SARA 311 Status:	Immediate, fire hazard
SARA 313:	Methanol is listed on the 313 Toxic Pollutant reporting list.
State Issues:	Not listed for California Proposition 65
WHMIS Status (Canada):	A controlled product. Classification: B2, D1B;D2A This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all the information required by the CPR.
Foreign Chemical Inventories:	All ingredients are listed on the chemical inventories of the following countries: Canada (DSL) Japan European Union Australia

16. OTHER INFORMATION

Current Issue Date:	February, 2010
Previous Issue Date:	Initial Hologic
Other Information:	None

Information Note: Where no corresponding data was contained in manufacturer's MSDS, additional research is required and available upon request. THE INFORMATION RELATES TO THIS SPECIFIC MATERIAL. IT MAY NOT BE VALID FOR THIS MATERIAL IF USED IN COMBINATION WITH ANY OTHER MATERIALS OR IN ANY PROCESS. IT IS THE USER'S RESPONSIBILITY TO SATISFY ONESELF AS TO THE SUITABILITY AND COMPLETENESS OF THIS INFORMATION FOR HIS OR HER OWN PARTICULAR USE.



MEMOS / UPDATES