# Specimen Collection Manual

**Facility / Client:** _____

_____

_____

**Medical Director:** K. Che Prasad, M.D.

**Medical Director's Signature:** K Che Prasad MD

**Date:** 6/30/17

**Please Note:** This manual is updated annually and available on-line at: ***www.marinmedicallabs.com***.

If your specimen collection manual is more than a year old, please reference our current version on-line at the above website or you may also call and request a current copy at (415) 898-7649.

P.W. WASSERSTEIN, MD • F.J. KRETZSCHMAR, MD • K.C. PRASAD, MD • I. CHA, MD
1615 HILL ROAD SUITE B NOVATO, CA 94947
PHONE (415) 898-7649 FAX (415) 898-0870

Marin Medical Laboratories

An Affiliate of PathGroup

# GENERAL INFORMATION

# SPECIMEN COLLECTION MANUAL

## I. GENERAL INFORMATION

**Key Telephone Numbers**
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**Specimen Requisition Form**
**Advance Beneficiary Notice Form (ABN)**
**Mailing Requirement for Specimens**
**Supply Requisition Form**
**CLIA Certificate of Accreditation**
**CAP Certificate of Accreditation**

## II. TISSUE / BIOPSY SPECIMEN COLLECTION

## III. CYTOLOGY SPECIMEN COLLECTION

## IV. BILLING

## V. SAFETY DATA SHEETS

## VI. MEMOS / UPDATES

# KEY TELEPHONE NUMBERS

**BILLING:**

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

**COURIER:**

**AM-TRAN COURIER SERVICE** (877) 243-8733

**CYTOLOGY:**

**PAP TEST / DNA RESULTS** (415) 209-6042 fax: (415) 209-6053
Cytology Department
1615 Hill Road Suite # C, Novato, Ca 94947
Supervisor: Alla Shalagin, CT

**HISTOLOGY:**

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

**MARKETING:**

**MARKETING / CLIENT SERVICES** (415) 209-6983 fax: (415) 898-0870
Territory Manager: Nina Richardson

**PATHOLOGISTS:**

**PATHOLOGISTS / DIRECTORS** (415) 925-7174 fax: (415) 461-7228
Paul Wasserstein, MD
Frederick Kretzschmar, MD
K. Che Prasad, MD
Imok Cha, MD
Christopher Kim, MD
Wanhua Yang, MD

**PATHOLOGY:**

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

**APPOINTMENTS:** **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 two-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 / DNA –** Check mark desired test box to indicate test(s) ordered and give ICD code

☐ **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.

☐ **HPV (DNA)** – To select HPV testing, check mark appropriate box of choice:
- ☐ HPV Genotype 16 18/45 – If HPV Positive and Pap Negative
- ☐ HPV ASSAY if ASC-US (HPV will only be run if Pap is 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
☐ **Trichomonas Vaginalis** – Check mark box to request Trichomonas Vaginalis 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 2 patient identifiers (Name and Date of Birth) and Specimen Site. Lab will reject all unlabeled specimens.
- Do not use expired transport media. Check specimen container for expiration date prior to use.

**TOP COPY** • Lab Copy – Return with signed ABN on reverse (Cytology/DNA - Medicare)
**PINK COPY** • Physician / Patient Copy – ABN on reverse

Marin Medical Laboratories
An Affiliate of PathGroup
1615 HILL ROAD, SUITE C
NOVATO, CA 94947-4338

**REQUESTING PHYSICIAN OR CLINIC:** **CC:**

| **Date Specimen Collected** | Patient Name (Last) | (First) | (MI) |
|---|---|---|---|
| Date of Birth | Social Security Number | 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: ☐ Self ☐ Spouse ☐ Dependent | Responsible Party Name / Address | | |
|---|---|---|---|
| **PRIMARY** Insurance Name / Address | | **SECONDARY** Insurance Name / Address | |
| Policy Number | Group Number | Policy Number | Group Number |

## GYN CYTOLOGY DATA

*This information is necessary for accurate interpretation*

**Date of LMP (required):** _____ ☐ Abnormal Bleeding

**Date of Last Pap:** _____ **Results:** _____

On Hormones: ☐ Yes ☐ No If Yes, Type: _____

☐ Pregnant ☐ Post Partum ☐ Post / Perimenopausal

Pertinent Clinical Data: _____

History of Surgery: ☐ Yes ☐ No If Yes, Type: _____

Contraception: ☐ BCP ☐ IUD ☐ BTL

Other: _____

## TYPE OF PAP TEST

**Check one (required):** ☐ **NON-MEDICARE** ☐ **MEDICARE** **Specimen Source:** ☐ **Vaginal** ☐ **Cervical** ☐ **Endocervical** ☐ **Other** _____

☐ **Routine Gyn** - Abn Findings (Z01.411) ☐ **Routine Gyn** - No Abn Findings (Z01.419) ☐ **Routine Screen** - Cervix (Z12.4) ☐ **Routine Screen** - Vaginal (Z12.72)

☐ **High Risk** - Exposure to Bodily Fluids (Z77.21) ☐ **Diagnostic** *(ICD code **required**)* _____

☐ **High Risk** - History of Treatment (Z92.89) ☐ **Non-Covered Services** *(Signed ABN **required**)*

**Pap Test:** ☐ **ThinPrep Pap Test** ☐ **ThinPrep Pap Test** *without* Reflex Chlamydia if under Age 26 ☐ **No Pap**

Medicare will only pay for reasonable and necessary tests and for a screening test every two (2) years. In the event the patient has more than one screening in two years, the patient is required to sign an ABN. The ABN form is on the reverse side of the top copy of this requisition. A diagnostic test may be ordered once every 12 months if the test is associated with one of the risk factors. An appropriate diagnosis code must be specified for a diagnostic test. Please indicate the risk factor and diagnosis code.

## GYN CYTOLOGY

**HPV DNA Assay** (ThinPrep)
☐ HPV Assay
☐ HPV Assay IF Pap is ASCUS
☐ HPV Genotype 16 18/45
*ICD Code* _____

☐ **Chlamydia trachomatis**
ThinPrep/Urine/Aptima
*ICD Code* _____

☐ **Neisseria gonorrhoeae**
ThinPrep/Urine/Aptima
*ICD Code* _____

☐ **Trichomonas vaginalis**
ThinPrep/Urine/Aptima
*ICD Code* _____

## NON-GYN CYTOLOGY

☐ **Urine** ☐ Voided ☐ Catheterized ☐ Bladder Washing

☐ **Nipple Discharge** ☐ Left ☐ Right

☐ **Rectal / Anal**

☐ **Sputum**

☐ **Other** _____ *ICD Code* _____

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

## SURGICAL PATHOLOGY / HISTOLOGY / FNA

Clinical Data / Diagnosis: _____

Operative Procedure: _____ *ICD Code(s)* _____

Specimen Sites: _____ _____ _____ _____

_____ _____ _____ _____

***NOTE:*** *Additional space for notes and/or drawing is available at the bottom of the reverse side of this form.* ☐ FAX RESULTS TO _____

MARIN MEDICAL LABORATORIES ▪ 1615 HILL ROAD, SUITE C, NOVATO, CA 94947-4338 ▪ (415) 209-6042

**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 |
|---|---|---|
| ☐ Routine Screening Pap Test | Medicare only pays for this test once every 2 years. | $ 36.34 |
| ☐ HPV High Risk Screening Test – (to include HPV 16 18/45 if needed) | Medicare may not pay for this test for your condition. | $ 48.14 (+ $ 48.14) |

**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:** |
|---|---|
| | |

**CMS does not discriminate in its programs and activities. To request this publication in an alternative format, please call: 1-800-MEDICARE or email: AltFormatRequest@cms.hhs.gov.**

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.

GEN.40511
GEN.40512
GEN.71000

# 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 and Client Services

P.W. WASSERSTEIN, MD • F.J. KRETZSCHMAR, MD • K.C. PRASAD, MD • I. CHA, MD
1615 HILL ROAD SUITE C • NOVATO, CA 94947
PHONE (415) 898-7649 FAX (415) 898-0870

Marin Medical Laboratories
An Affiliate of PathGroup

**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) 925-7174 | Fax (415) 461-7228 |

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

# SUPPLY REQUEST FORM

## FAX TO 415-209-6053

### HISTOLOGY CLIENTS: FAX TO 415-898-3765

***THIS FORM CAN ALSO BE FOUND ONLINE AT MARINMEDICALLABS.COM***

***Please order at least <u>one week</u> before intended use.***

Contact Name: _____ Date: _____

Office Name: _____ Phone: _____

Address: _____

_____

| QTY | GYN CYTOLOGY | QTY | PATHOLOGY / HISTOLOGY |
|---|---|---|---|
| PK | ThinPrep PreservCyt Vials (25/pack) | CS | Formalin Bottles, 40ml (96/case) |
| PK | Brushes with Spatulas (25/pack) | EA | Formalin Bottles, 90ml (each) |
| PK | Brooms (25/pack) | BG | Formalin Vials, 7ml (100/bag) |
| EA | APTIMA Urine Collection Kit (each) | RL | Derm Bottle Labels (1000/roll) |
| EA | APTIMA Unisex Swab Kit (each) | RL | Small Derm Vial Labels (500/roll) |
| EA | APTIMA Vaginal Swab Kit (each) | _____ | Other: _____ |

| QTY | NON-GYN / FNA CYTOLOGY | QTY | GENERAL SUPPLIES |
|---|---|---|---|
| EA | Non-Gyn CytoLyt Cups (each) | PK | Specimen Bags (50/pack) |
| PK | FNA Formalin Bottles, 40ml (24/pack) | PK | Specimen Requisitions (100/pack) |
| BX | FNA Slides, Label-End (72/box) | PD | Supply Request Forms (25/pad) |
| EA | FNA Plastic Slide Holders (each) | _____ | Other: _____ |

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

| | OUTSTANDING | SATISFACTORY | NEEDS IMPROVEMENT | COMMENTS |
|---|---|---|---|---|
| Quality of Service | ❑ | ❑ | ❑ | _____ |
| Patient Billing | ❑ | ❑ | ❑ | _____ |
| Courier Service | ❑ | ❑ | ❑ | _____ |
| Report Turnaround Time | ❑ | ❑ | ❑ | _____ |

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
02/28/2017

LABORATORY DIRECTOR
IMOK CHA, MD

EXPIRATION DATE
02/27/2019

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.

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Karen W. Dyer, Acting Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

1267 Certs2_013117

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:

| LAB CERTIFICATION (CODE) | EFFECTIVE DATE | LAB CERTIFICATION (CODE) | EFFECTIVE DATE |
|---|---|---|---|
| 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.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
01/18/2017

LABORATORY DIRECTOR
PAUL W WASSERSTEIN MD

EXPIRATION DATE
01/17/2019

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.

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CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Karen W. Dyer, Acting Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

268 Certs2_122016

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:

| LAB CERTIFICATION (CODE) | EFFECTIVE DATE |
|---|---|
| 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 |

| LAB CERTIFICATION (CODE) | EFFECTIVE DATE |
|---|---|

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OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR
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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 GENERAL HOSPITAL LABORATORY
250 BON AIR RD
2ND FL
GREENBRAE, CA 94904-1702

CLIA ID NUMBER
05D0604317

EFFECTIVE DATE
02/28/2017

LABORATORY DIRECTOR
KEDAR C PRASAD

EXPIRATION DATE
02/27/2019

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.

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Karen W. Dyer, Acting Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

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1268 Certs2 013117

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:

| LAB CERTIFICATION (CODE) | EFFECTIVE DATE |
|---|---|
| BACTERIOLOGY (110) | 07/25/1995 |
| MYCOBACTERIOLOGY (115) | 11/17/2015 |
| MYCOLOGY (120) | 07/25/1995 |
| PARASITOLOGY (130) | 07/25/1995 |
| VIROLOGY (140) | 07/25/1995 |
| SYPHILIS SEROLOGY (210) | 03/17/2011 |
| GENERAL IMMUNOLOGY (220) | 07/25/1995 |
| ROUTINE CHEMISTRY (310) | 07/25/1995 |
| URINALYSIS (320) | 07/25/1995 |
| ENDOCRINOLOGY (330) | 07/25/1995 |
| TOXICOLOGY (340) | 03/29/2003 |
| HEMATOLOGY (400) | 07/25/1995 |
| ABO & RH GROUP (510) | 07/25/1995 |

| LAB CERTIFICATION (CODE) | EFFECTIVE DATE |
|---|---|
| ANTIBODY TRANSFUSION (520) | 07/25/1995 |
| ANTIBODY NON-TRANSFUSION (530) | 07/25/1995 |
| ANTIBODY IDENTIFICATION (540) | 07/25/1995 |
| COMPATIBILITY TESTING (550) | 07/25/1995 |

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.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 REGISTRATION*

**LABORATORY NAME AND ADDRESS**

SONOMA VALLEY HOSPITAL DISTRICT
MAIN LABORATORY
347 ANDRIEUX ST
SONOMA, CA 95476-0600

**CLIA ID NUMBER**

05D0612446

**EFFECTIVE DATE**

10/20/2015

**EXPIRATION DATE**

10/19/2017

**LABORATORY DIRECTOR**

FREDERICK KRETZSCHMAR M.D.

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.

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Karen W. Dyer, Acting Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

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:

| LAB CERTIFICATION (CODE) | EFFECTIVE DATE |
|---|---|
| BACTERIOLOGY (110) | 04/16/2004 |
| MYCOLOGY (120) | 11/10/2011 |
| VIROLOGY (140) | 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 |
| COMPATIBILITY TESTING (550) | 04/16/2004 |
| HISTOPATHOLOGY (610) | 04/16/2004 |
| CYTOLOGY (630) | 04/16/2004 |

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.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**
SANTA ROSA MEMORIAL HOSPITAL LAB
1165 MONTGOMERY DRIVE
SANTA ROSA, CA 95405-4801

**CLIA ID NUMBER**
05D0706122

**EFFECTIVE DATE**
07/27/2017

**LABORATORY DIRECTOR**
PAUL W WASSERSTEIN M.D.

**EXPIRATION DATE**
07/26/2019

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.

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Karen W. Dyer, Acting Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

266 Certs2_080117

**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:**

| LAB CERTIFICATION (CODE) | EFFECTIVE DATE |
|---|---|
| BACTERIOLOGY (110) | 07/27/1995 |
| MYCOLOGY (120) | 07/27/1995 |
| PARASITOLOGY (130) | 02/04/2000 |
| VIROLOGY (140) | 07/16/1996 |
| SYPHILIS SEROLOGY (210) | 07/27/1995 |
| GENERAL IMMUNOLOGY (220) | 07/27/1995 |
| ROUTINE CHEMISTRY (310) | 07/27/1995 |
| URINALYSIS (320) | 07/27/1995 |
| ENDOCRINOLOGY (330) | 03/29/2003 |
| TOXICOLOGY (340) | 03/29/2003 |
| HEMATOLOGY (400) | 07/27/1995 |
| ABO & RH GROUP (510) | 07/27/1995 |
| ANTIBODY TRANSFUSION (520) | 07/27/1995 |
| ANTIBODY NON-TRANSFUSION (530) | 07/27/1995 |
| ANTIBODY IDENTIFICATION (540) | 07/27/1995 |
| COMPATIBILITY TESTING (550) | 07/27/1995 |
| HISTOPATHOLOGY (610) | 02/04/2000 |
| ORAL PATHOLOGY (620) | 02/04/2000 |
| CYTOLOGY (630) | 07/16/1996 |

**FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.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.**

COLLEGE of AMERICAN PATHOLOGISTS

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS

# The College of American Pathologists certifies that the laboratory named below

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

CAP Number: 2394501
AU-ID: 1188148
CLIA Number: 05D0663150

has met all applicable standards for accreditation and is hereby accredited by the College of American Pathologists' Laboratory Accreditation Program. Reinspection should occur prior to September 2, 2019 to maintain accreditation.

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

Chair, Commission on Laboratory Accreditation

President, College of American Pathologists

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COLLEGE of AMERICAN PATHOLOGISTS

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The College of American Pathologists certifies that the laboratory named below

**Marin General Hospital**
**Marin Medical Laboratories**
**Greenbrae, California**
**Kedar C. Prasad, MD**

CAP Number: 2394904
AU-ID: 1188152
CLIA Number: 05D0706572

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Chair, Commission on Laboratory Accreditation

President, College of American Pathologists

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***Main Laboratory***
***Greenbrae, California***
***Kedar C. Prasad, MD***

CAP Number: 2394901
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CLIA Number: 05D0604317

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COLLEGE of AMERICAN PATHOLOGISTS

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certifies that the laboratory named below

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**Main Laboratory**
**Santa Rosa, California**
**Paul W. Wasserstein, MD**

CAP Number: 2410501
AU-ID: 1188198
CLIA Number: 05D0706122

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Chair, Commission on Laboratory Accreditation

President, College of American Pathologists

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# TISSUE / BIOPSY

# SPECIMEN COLLECTION

# TISSUE / BIOPSY SPECIMEN COLLECTION PROTOCOLS
# SECTION INDEX

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Bone Marrow Specimens 5

Pathology Specimen Submission Requirements 5


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Tissue/Biopsy Supplies 5


**HISTOLOGY SERVICES:**


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Medicare Derm Specimen Requirements 6

Special Stains and Antibodies - Immunohistochemistry 7

Medicare Derm Billing Form

# 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 Safety Data Sheet*]. 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 2 patient identifiers (name and date of birth). CAP requirement, including physician 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 cytogentics, 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

Do not use expired transport media. Check specimen container for expiration date prior to use.

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 must be submitted with Medicare Slide Prep Derm Billing Form and requires the following information be provided:

- Patient First and Last Name
- Date of Birth
- Gender
- Patient Mailing Address, City, State, Zip Code
- Medicare Number and Secondary Insurance Information (Attach Copy of Cards)
- Specimen Date
- Specimen Site and Number of Pieces
- ICD-10 Code
- Physician Name

# Marin Medical Laboratories
# Immunohistochemistry Antibodies and Special Stains

***Antibodies***

AMACR (P504S)
Ber-EP4 (Ep-CAM)
Calponin
Calretinin
CD3
CD20
CD34
CD45, LCA
CD79α
CD138
CDX-2
CEA
Chromogranin A
c-KIT (CD117)
Cytokeratin 7
Cytokeratin 8 & 18
Cytokeratin 20
Cytokeratin, High Molecular Weight (34βE12)
Cytokeratin, Pan (PAN-K)
Cytomegalovirus (CMV)
D2-40 (Podoplanin)
Desmin
E-Cadherin
Estrogen Receptor (ER)
GATA3
Helicobacter pylori
PATHWAY HER-2/neu
Ki-67
MART-1
Melanosome (HMB45)
MOC-31 (Epithelial Related Antigen)
MSI PANEL:
- MLH-1
- MSH2
- MSH6
- PMS2

p16
p53
p63
PAX-8

***Antibodies***

Progesterone Receptor (PR)
S100
Smooth Muscle Actin (SMA)
Synaptophysin
Thyroid Transcription Factor-1 (TTF-1)
Triple PIN Stain:
- p63
- AMACR
- HMW Cytokeratin

WT-1

***Special Stains***

AFB
Alcian Blue pH2.5
Amyloid
Gram Stain
Trichrome
GMS
PAS
PAS-D
Fe
Mucin
Reticulum
VVG

Marin Medical Laboratories
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**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
K.C. PRASAD, MD
I. CHA, MD

# MEDICARE 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<br>❑ Self ❑ Spouse ❑ Dependent | SECONDARY INSURANCE COMPANY | |
|---|---|---|
| MEDICARE IDENTIFICATION NUMBER | SECONDARY INSURANCE ADDRESS | |
| ***Please attach copies of patient's Medicare and Insurance cards*** | SECONDARY INSURANCE IDENTIFICATION NUMBER | GROUP NUMBER |

## SPECIMEN INFORMATION

| ICD-10 CODE | NUMBER OF SPECIMENS SUBMITTED |
|---|---|
| | |

| DATE SPECIMEN COLLECTED | REQUESTING PHYSICIAN OR CLINIC NAME |
|---|---|
| | |

✓ Please print all information.

✓ Entire form must be complete.

✓ All sections are <u>required</u> for dermatological slide preparation.

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# CYTOLOGY

# SPECIMEN COLLECTION

# CYTOLOGY/DNA SPECIMEN COLLECTION PROTOCOLS
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**HPV TESTING PREFERENCE ORDERS:**

HPV TESTING PREFERENCE REFLEX FORM

**SPECIMEN COLLECTION REFERENCE GUIDES:**

Urine Cytology Specimen Collection Instructions for Patient
Aptima Urine Collection Guide for Male & Female Urine Specimens
Aptima Unisex Swab Female Collection Guide for Endocervical Specimens
Aptima Unisex Swab Male Collection Guide for Male Urethral Swab Specimens
Aptima Vaginal Swab Clinician Collection Guide for Vaginal Swab Specimens
ThinPrep Pap Test Quick Reference Guide

# CYTOLOGY / DNA SPECIMEN COLLECTION PROTOCOLS
# GENERAL INFORMATION

## CRITERIA FOR ACCEPTABLE SPECIMENS:

1. All specimens accepted by the laboratory must be labeled with the patient's name and unique identifying information.

2. Specimens submitted on glass slides should have the patient's name and date of birth 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 and date of birth.

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 date of birth (or other identifier) cap securely tightened so that torque line on cap passes the torque line on 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.

8. Check specimen container for expiration date prior to use. Collection supplies, ie. Transport tubes, Swabs, ThinPrep, CytoLyt, etc must be checked for Expiration before use. Do not use expired transport media.

**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 at least 2 patient identifiers. 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. **STD BY NAAT TESTING FROM THE THINPREP VIAL:** A small amount of fluid is removed from the ThinPrep vial for NAAT testing. The APTIMA ASSAY is used to detect the presence of High Risk HPV, Chlamydia (CT), N. gonorrhoeae (GC), and Trichomonas.

3. **STD BY NAAT TESTING BY APTIMA:** In addition to ThinPrep vial specimens, Urine, Endocervical and Vaginal specimens can be tested by the APTIMA method for the presence of CT, GC and Trichomonas. Urines can be collected with the APTIMA Urine Specimen Transport kit, while Endocervical and Vaginal specimens can be collected with the Unisex Swab kit, or Vaginal with the Vaginal Swab kit (preferred).

4. **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.

5. **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.

**REQUESTS FOR NAAT TESTING (APTIMA ASSAYS)**

For NAAT 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 (NAAT)** to perform Chlamydia (CT) test.

Check test box: □ **N. gonorrhoeae (NAAT)** to perform N. gonorrhoeae (GC) test.

Check test box: □ **ThinPrep Pap Test without Reflex Chlamydia under age 26** to opt-out of Reflex Chlamydia UNDER AGE 26 for patient.

Check test box: □ **Trichomonas (NAAT)** to perform Trichomonas vaginalis (TV) test.

## TURN-AROUND TIMES FOR SPECIMEN RESULTS:

| | |
|---|---|
| **Gynecologic Pap Results** | Approximately one to five working days |
| **NAAT (HPV, CT, GC, TV)** | One to five working days |
| **Non-Gynecologic Results** | One to two working days |
| **FNA Results** | One to two working days |

## TRANSPORTATION OF CYTOLOGY SPECIMENS:

Specimens are delivered to Cytology via AM-TRAN 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.

## 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 NAAT TESTING FROM THE THINPREP VIAL:

APTIMA ASSAYS (HPV, CT, GC, & TV) require only 1 ml of PreservCyt solution remaining in the ThinPrep vial after the ThinPrep slide has been processed.

If there is less than 1 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 NAAT testing.

**To achieve adequate cellularity,** we recommend following the Cytyc 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 NAAT report:

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

Lastly, the following comment will appear on NAAT reports where the results are close to positive cut-off values for HPVH, but are not sufficient to be reportable: EQUIVOCAL RESULTS: Results are near cut-off, suggest recollection of a new sample.

## 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 ACOG, 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.

**REFLEX HPV GENOTYPING (16 18/45):** HPV Genotyping, if the PAP diagnosis is Negative and the HPV High Risk is DETECTED for patients age 30 and above, can be set up to run reflexively by submitting an “HPV TESTING PREFERENCE ORDERS” form.

# SUPPLIES FOR CYTOLOGY / NAAT 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.

Safety Data Sheet is located for reference on our website http://www.marinmedicallabs.com under Helpful Materials.

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 on cups.

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.

Safety Data Sheet is located for reference on our website http://www.marinmedicallabs.com under Helpful Materials.

## D. APTIMA HPV, CT/GC, & TRICHOMONAS SUPPLIES:

APTIMA Unisex Swab – White Label – Purple Lettering
APTIMA Vaginal Swab – Orange Label
APTIMA Urine Specimen Transport Tube – Yellow Label
Hologic ThinPrep Vial
Requisition Forms
Specimen Baggies

Do not use Transport Tubes or Swabs after expiration date.

Safety Data Sheet is located for reference on our website http://www.marinmedicallabs.com under Helpful Materials.

# 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.
6. 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.
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 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 ¼ or ½ 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 FOR CYTOLOGY:**

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.

# DNA SPECIMEN COLLECTION FOR STD'S (Other than ThinPrep)

## APTIMA ASSAY CT/GC & TRICHOMONAS SPECIMEN COLLECTION:

1. Urine: Patient should not have urinated for at least 1 hour prior to specimen collection. Direct patient to provide **first-catch** urine (approximately 20-30 ml of initial urine stream) into urine collection cup free of any preservatives. Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity. Female patients should not cleanse labial area prior to providing specimen.
2. Vaginal: Submit specimen in orange labeled APTIMA Vaginal Swab Transport Tube.
3. Endocervical: Submit endocervical specimen in APTIMA Unisex Swab Transport Tube.
4. Male Urethral: Patient should not have urinated for at least 1 hour prior to specimen collection. Submit male urethral specimen in APTIMA Unisex Swab Transport Tube.

(SEE APTIMA SPECIMEN COLLECTION REFERENCE GUIDES AT END OF SECTION)

## ALL OTHER SPECIMENS:

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

# HPV TESTING PREFERENCE ORDERS

Preferences for reflex 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 NAME | ADDRESS | PHONE | FAX |
|---|---|---|---|
| | | | |

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**.

***AND***

☐ **(HPV 16 18/45 GENOTYPING)**

Reflex HPV 16 18/45 GENOTYPING if **PAP is Negative and HPV High Risk is DETECTED for patients age 30 and above**.

I request that Marin Medical Laboratories perform the HPV Assay(s) 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.

# SAFETY DATA SHEETS

## TABLE OF CONTENTS:

10% Neutral Buffered Formalin
ThinPrep® Cytolyt Solution
ThinPrep® PreservCyt Solution
Aptima Specimen Transport Media Collection Devices
Aptima Urine Specimen Collection

Marin Medical Laboratories

An Affiliate of PathGroup

# MEMOS / UPDATES