



# Newsline

California Association for Medical Laboratory Technology  
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## CAML House of Delegates Approves Revised Mission Statement

2015-16 CAMLT House of Delegates recently voted in favor of revising CAMLT’s mission statement to read, “The California Association for Medical Laboratory Technology enhances clinical laboratory professions through public policy advocacy, education, and member services.” This action is the first of many more activities that will move CAMLT forward.

Members of the Long Range Planning Committee held a Strategic Planning session on December 5 and 6. Six goals relevant to the viability of CAMLT were identified - see box below. On January 16<sup>th</sup>, the Board of Directors approved the strategic plan and began the process of forming key committees for implementation. February 1 the Ad Hoc Technology and Ad Hoc Marketing Committee members were appointed and Membership Committee reactivated. These newly formed committees were charged with implementation of goals one through three respectively. To date, members of the Marketing and Membership Committees have held their first meetings. Members of the Technology Committee plan to meet in March.

### CAML Strategic Goals

1. Upgrade technology and communication tools.
2. Develop and implement a comprehensive marketing plan.
3. Implement an aggressive membership recruitment and retention plan to grow the association and foster new leaders.
4. Implement and utilize best business practices.
5. Enhance and expand education programs and delivery methods.
6. Build on its public policy advocacy to grow the membership and increase public and professional awareness.

Members of the Long Range Planning Committee that includes Board Members and key organization leaders thank our current and future members in advance for stepping up to the challenge to help CAMLT fulfill its mission for years to come. Other laboratory professionals throughout the state that reap the benefits of CAMLT’s willingness to promote and protect the future of the profession could play a huge role as well by simply adding their membership to the CAMLT ranks.

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# Message From the President



With the Super Bowl taking place in Silicon Valley this month, you can't help but notice all of the promotional paraphernalia at the airports and in the city. The Carolina Panthers and the Denver Broncos have proven that they are the best football **teams** in the USA this year. Both teams have undeniable strengths and superstars.

CAMLT, your state professional organization, is full of undeniable stars of the clinical laboratory. It's time for laboratorians to shine. When National Medical Laboratory Professionals week comes this year on April 24-30th, make sure your community knows how important CLSs are and the role they play on the health care **team**.

Now is the time to start planning for this. Here are some ideas:

1. Have your town mayor visit your lab and get a photo and an article in the local newspaper.
2. Make poster boards to show what happens to patient samples after they are collected and include the educational requirements of all of those involved in the process.
3. Make a career ladder and post it in the lab and hospital.
4. Have games that require people to learn something when they are played.
5. Invite local high school science clubs to visit the lab and give tours.
6. Create awards in your laboratory that recognize a dedicated CLS, MLT, and Lab Assistant and post the certificates awarded.

Your CAMLT Board of Directors met on January 16<sup>th</sup> in Hayward.

Included in the business meeting were updates on the selection and appointments to the Strategic Planning Subcommittees of Technology and Marketing. Also, we are revitalizing the Membership committee.

Our Spring Seminars across the state are now open for registration....see the enclosed articles for information.

Please consider volunteering in your local chapter....we have plenty of wonderful mentors. Take on a small task with others, something out of your comfort zone, and you will surprise yourself. Every day is a new day to try something new.

Sincerely,

*Ilene Dickman*

President, CAMLT

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Ilene Dickman, President

Editorial correspondence should be addressed to CAMLT/ *Newsline*, 39656 Mission Blvd., Fremont, CA 94539-3000.

Scientific articles submitted for publication in the CAMLT/ *Newsline* should be approximately 1,000 words in length or about three pages, double spaced, typed materials. Please include references when appropriate. Since the articles are relatively short, the editors do not feel that an abstract is necessary. All articles should be accompanied by a picture of the author.

Articles describing procedures should include materials and methods as well as results. All graphs and charts should be reducible. Abbreviation (except for those in common scientific usage) should be defined and introduced parenthetically when first used in text.

Advertising correspondence should be addressed to 39656 Mission Blvd., Fremont, CA 94539-3000, (510) 792-4441, FAX (510) 792-3045, e-mail: office@camlt.org.

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## Nancy Gutilla to Retire from CAMLT Executive Office Staff



Nancy Gutilla, longest serving member of the CAMLT Executive Office Staff, plans to retire at the end of March. Nancy has been a member of the CAMLT family since May of 1988. With each passing year she took on more duties and met new challenges as the office moved from typewriters and phones to computers and the Internet . Among many other responsibilities, Nancy serves as Exhibits Manager. Each new Board of Directors has meant adjusting to a new set of personalities and management styles.

Nancy has developed a great rapport with the representatives of laboratory vendors, which has been crucial to gaining their support as Convention Exhibitors and Sponsors. She has overseen the financial dealings of CAMLT for many years with scrupulous care and efficiency. At Conventions she is everywhere at once, welcoming vendors, helping with registration, and generally being one of the smiling faces our members and friends are happy to greet. Her instant recall of faces and stories makes her the CAMLT historian, the person who can put a name to a face and remember the details of events.

Nancy is a native San Franciscan. Nancy has three children and two grandchildren. Her husband Sal passed away in 2012. Sal attended many conventions and seminars and was a great supporter of CAMLT. She has three siblings, including Gail DePinna, wife of CAMLT's long-time director, Manuel DePinna. She helps to care for her father, Jack, spending her Sundays with him. Nancy is a Eucharistic minister for her church. Other interests include running, which she took up after Sal passed away (she now runs half-marathons), hiking and quilting.

Nancy lived in Fremont when she first joined CAMLT, but her commute got tougher when she moved to Antioch, giving her a 100 mile plus drive to and from work each day, one of things we are sure she will not miss upon retirement. She looks forward to spending memorable time with her grandsons Matthew and Andrew. She plans to become involved in volunteer activities, including being a "cuddler" for hospitalized babies. Nancy is a lifelong fan of Disney, so we expect she will devote some of her new-found free time to visiting Disney parks. Music – Rod Stewart. Travel – loves covered bridges.

CAMLT friends, including Board members, former Board members, newly joined members and pretty much everybody, will miss her good cheer, her positive attitude, and her efficient handling of office detail. In fact, along with Jeannie Eelen her partner in CAMLT Office life for 25 years, we consider her close to irreplaceable – a very hard act to follow indeed.

Plans for a retirement party are "in development" and will be communicated when ready.

## CAMLT Political Update Public Policy Advocates, LLC

The second year of the 2015-16 Legislative Session began on January 4. The Legislature has passed two key deadlines – the last day for any committee to hear and report to the Floor bills introduced in their house in 2015 and the last day for each house to pass bills introduced in that house in the odd-numbered year. The last day for legislation to be introduced was February 19. While the bill introductions have been very light, we do expect challenges in the form of newly introduced legislation and the possibility of movement in terms of scope of practice legislation that is still viable. Assembly Member Henry Perea, D-Fresno announced his resignation in December. Considered the unofficial leader of the body's influential moderate bloc, he was scheduled to be termed out in 2016. Governor Brown has issued a proclamation declaring a special election for Assembly District 31 on June 7, 2016. The primary for this special election will be held on April 5, 2016.

**What does this all mean for CAMLT?** CAMLT **must** be strong both financially and in membership. CAMLT is the **only** professional organization that **exclusively** protects the legislative interests of CLSs, MLTs and other laboratory personnel in the best interest of the patient and in the best interest of the laboratory profession. It is the **only** professional association representing clinical laboratory science that retains a lobbying firm in Sacramento to be **the** voice for clinical laboratory personnel in Sacramento before the legislature and state government. **If CAMLT does not grow its membership or raise the necessary revenue to support its legislative program, there will be no legislative program to protect the profession and the patients it serves.**

Organized labor has been extremely helpful in the past, and indeed, co-sponsored our CLS waived lab director bill. But labor unions also represent chiropractors, optometrists, and pharmacists in addition to CLSs. So Labor has not been in a position to take these other professions head on when they want to expand their scopes into clinical laboratory science. That has fallen to CAMLT. Other laboratory personnel professional associations may provide continuing education, certification, or fellowship—but **none** have a Sacramento presence or help to underwrite CAMLT's governmental representation on behalf of the **entire** profession. The chiropractors, optometrists, and pharmacists have strong associations, even though they number far fewer in terms of licensees state wide. They have strong and expansive political grass roots networks, and they have Political Action Committees that contribute to candidates in the hundreds of thousands of dollars. **The clinical laboratory profession must come together to unify and shore up its efforts to support CAMLT's legislative and political agenda if it wants to preserve**

**its profession—not tomorrow, but now.**

### **RECRUIT NEW CAMLT MEMBERS!** **CONTRIBUTE TO LAB-PAC!**

Recent sessions have been very rigorous and active in terms of bills legislating a frontal attack on the CLS and MLT professions, depleting CAMLT resources. Only you can ensure the growth and vibrancy of a strong, well organized CAMLT. Rise to the challenge. Recruit members to your professional organization — CAMLT. Contribute to your Lab-PAC. Meet with your legislators. Ensure the best possible patient safety in laboratory testing, and preserve your important profession.

### **LEGISLATION**

The following is a partial listing of legislation that we are tracking after the close of the bill introduction deadline. Check the CAMLT website at <http://www.camlt.org/legislation> for updates on bill status, Legislator lists, Committee assignments, and more.

#### **AB 1774 (Bonilla) Clinical Laboratories: Licensure, as introduced 2/3/16**

- ❖ Repeals the laws requiring a clinical laboratory to be licensed and inspected by Laboratory Field Services
- ❖ Repeals the laws requiring payment of laboratory facilities licensing fees

Existing federal law, CLIA, requires the federal Centers for Medicare and Medicaid Services to certify and regulate clinical laboratories. Existing law provides for the licensure, registration, and regulation of clinical laboratories and various clinical laboratory personnel by the State Department of Public Health. Under existing law the department inspects clinical laboratories and assesses a fee for licensure of those facilities. This bill would repeal the laws requiring a clinical laboratory to be licensed and inspected by the department, including the licensing fee. Location: Referred to Assembly Business, Professions and Consumer Protection Committee.

#### **SB 622 (Hernandez) Optometry, as amended 5/4/15 – OPPOSE UNLESS AMENDED**

- ❖ Amends the current language with regard to diabetes testing to allow optometrists to collect blood specimen by the finger prick method
- ❖ Expands the scope of practice for optometrists to include expanded ability to order and perform waived tests

SB 622 was initially introduced as a vocational nursing bill, and on April 9, 2015 was amended to deal with optometry and scope of practice expansion. Similar to SB 492 (Hernandez) which died on the Assembly Floor in

2014, SB 622, if passed, would expand the scope of practice for optometrists to include expanded ability to order and perform the Clinical Laboratory Improvement Amendments (CLIA) waived tests, use noninvasive, nonsurgical technology to treat a condition authorized by the Optometric Act, perform laser and minor procedures, and administer certain vaccines.

Specific provisions of the legislation are:

- Add the provision of habilitative services to the practice of optometry;
- Authorize the Board of Optometry to allow optometrists to use nonsurgical technology to treat any authorized condition under the Optometry Practice Act;
- Authorizes optometrists to perform all CLIA waived in-office testing if the optometrist becomes registered as a lab director with the Department of Public Health;
- Authorize an optometrist certified to use therapeutic pharmaceutical agents to collect a blood specimen, perform skin tests, and to use mechanical lipid extraction of certain glands;
- Require the Board to grant an optometrist certified to treat glaucoma a certificate for the use of specified immunizations;
- Amends the current language with regard to diabetes testing to allow optometrists to collect blood specimen by the finger prick method;
- Authorize an optometrist to be certified to use anterior segment lasers and to be certified to perform minor procedures;
- Would establish three new post-graduate certifications;
- Require the Board to charge specified fees to cover its costs;
- State legislative intent that the Office of Statewide Health Planning and Development authorize a health workforce pilot project relating to expanded roles for optometrists with respect to diabetes, hypertension, and hypercholesterolemia.

Location: SB 622 was not brought up for hearing in the Assembly Business and Professions Committee making it a two year bill eligible to be heard in January 2016. While we were told of the Author's intention to amend the bill to existing law with regard to clinical laboratory testing, that has not occurred.

**Have You Met with Your Legislators? If Not, Why Not?**

For the last twenty years, CAMLT has continued to successfully weather advertent or inadvertent legislative assaults on clinical laboratory testing that would jeopardize patient safety, but these assaults continue. **It is critical that CAMLT build its membership and engage with**

**and educate California's elected officials.** Legislators are eligible to serve up to 12 years under our new term limit law. It is imperative to build "legislative champions" for clinical laboratory science and the patients who rely on educated, qualified laboratory personnel for accurate and reliable testing results.

Have you met with your legislators? Make sure to educate your elected officials about clinical laboratory issues! Meet with your legislators in your district, send letters explaining CAMLT's philosophy, invite legislators and their staff to tour your laboratories, and introduce yourself as a constituent. The sponsors of legislation, such as optometrists and chiropractors, to expand their scope of practice into areas of clinical laboratory testing are well heeled and well organized. It is imperative that laboratory professionals engage in the process that affects the laboratory profession.

- **Which Legislator represents your home or laboratory?** Visit the CAMLT website for a current roster of Legislators and the cities they represent.
- **Visit their offices.** Make an appointment with your Legislators' District offices.
- **EDUCATE!** Explain to Legislators and their consultants what it takes to be a CLS; what you do; why it is important to maintain the integrity of the Laboratory Director when other personnel are doing laboratory tests, even if they are waived; why other allied health providers shouldn't be Laboratory Directors; the CLS shortage and what it takes to eliminate it.

**Make it a priority to meet with your Legislators.** Remember, these interactions are integral components of **your** grassroots program. For tips, please refer to the CAMLT Grassroots Guide, Brochure for Legislators and Legislative Update posted on CAMLT website at <http://www.camlt.org/legislation> and Talking Points with Legislators section.

**Talking Points with Legislators**

**Purpose:** It is imperative to educate legislators about clinical laboratory science and the patients who rely on educated, qualified laboratory personnel for accurate and reliable testing results before bills effecting laboratory science are heard in committee or voted on. We want legislators to come to CAMLT first to assess the impact of bills to the quality of patient test results before bills are introduced or amended.

- **Who is CAMLT?**
  - The **California Association for Medical Laboratory Technology** is a voluntary, not-for-profit professional association of dedicated laboratory professionals throughout the State

of California.

- **Our mission**
  - Part of CAMLT's mission is to maintain and improve high quality in laboratory testing by fostering education and working to ensure that legislators understand the impact of new bills in maintaining high quality laboratory results.
- **What is a clinical laboratory test?**
  - Laboratory tests take human biological samples such as whole blood, urine, spinal fluid and other body fluids and perform various analytical tests ranging from urine pregnancy through DNA analysis requested by physicians.
- **Why is it important to maintain high quality laboratory tests?**
  - Over 80% of clinical and diagnostic decisions are based on the results of laboratory testing.
  - Accurate and timely laboratory test results directly correlates with better patient outcomes.
  - Maintaining the integrity of the lab personnel standards is essential for accurate and timely laboratory test results.
- **Who works in the laboratory?**
  - Laboratory Tests are classified as waived, moderate, or high complexity based on the necessary skill and educational level of the testing personnel needed to perform a particular test.
  - Most testing personnel are Clinical Laboratory Scientists (CLS) who have at the minimum, a bachelor's degree and have completed a post-graduate training program in a DPH (Dept of Public Health) approved laboratory. After passing a licensure examination, they perform waived, moderate and high complexity laboratory testing, including analyzing body fluids, cells, and tissue samples. A CLS must maintain instruments to assure the highest level of accuracy. They supervise unlicensed staff, phlebotomists and Medical Laboratory Technicians (MLT). The CLS manages daily activities, direct quality assurance, finances, and technological improvements in the laboratory. In addition, the CLS may direct waived laboratories.
- **Who represents CAMLT in Sacramento?**
  - Public Policy Advocates (PPA) engage in the legislature on CAMLT's behalf.



**Senator Steve Glazer and Dora Goto, Lafayette Town Hall Meeting**

**Strengthen Your Voice: Contribute Today!**

Please donate to the CAMLT Lab-PAC fund. Lab-PAC is a critical means of supporting and electing Legislators to the California Legislature who share a like-minded philosophy with CAMLT and who are open-minded to learning the issues and challenges facing your profession. Encourage the colleagues you work with. Get your chapters and chapter members to contribute. Talk to your vendors. Get involved! Your voice in the political process is much louder as CAMLT than as an individual. Contribute to the collective resources of CAMLT to grow your political clout. Visit the Lab-PAC page at <http://www.camlt.org/labpac> for a donation form. Your gift in any amount will help your profession. Contribute now!

**Please mail donations made payable to:**

CAMLT LAB-PAC  
39656 Mission Blvd., Fremont, CA 94539-3000

**Please write a check to LAB-PAC now!**

# PROTECT WHAT MATTERS TO YOU —JOIN CAMLT TODAY!

Laboratory professionals share a commitment to providing the highest quality of care to patients and produce the most accurate test results. Our mission is to advance professional growth and development of laboratory professionals through quality educational programs, legislative representation and member services. At CAMLT, we understand your commitment to your profession, which is why we are dedicated to helping you:

- **STAY INFORMED** about the latest news with regular publications of our journal, *Newsline*, electronic communications and website postings.
- **CONNECT** with peers and colleagues by attending continuing education seminars, our Annual Meeting and Exhibits, and other networking events, or by becoming a local representative.
- **LEARN** via our affordable continuing education programs or distance learning courses.
- **GET INVOLVED** by serving on a committee or running for local chapter or state office.
- **WITH UNSURPASSED LEGISLATIVE REPRESENTATION.**
  - ⇒ Better patient care and safety
  - ⇒ Better medical outcomes
  - ⇒ Work scope expansion, professional status, higher salaries and benefits
- **SAVE** with the lowest rates in the industry.



CALIFORNIA  
ASSOCIATION FOR  
MEDICAL LABORATORY  
TECHNOLOGY

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#### Professional Association

Professional Association	Annual Membership Dues	Annual Meeting and Exhibits Fee per 6 CEUs
California Association for Medical Technology	\$120	\$100
American Society for Clinical Pathology	\$ 99	\$159
American Society for Clinical Laboratory Science	\$124	\$140
American Association of Clinical Chemists	\$215	\$180
Clinical Laboratory Managers Association	\$205	\$299

- **JOB OPPORTUNITIES** posted on our website: [camlt.org](http://camlt.org)

Please Post

## CAMLT 2016 SPRING SEMINAR SOUTH GENERAL INFORMATION

\* CAMLT wishes to thank Kaiser Regional Laboratory as venue sponsor for this seminar.

Visit <http://www.camlt.org/calendar> for complete abstracts/objectives

**Advance Registration:** You have the best opportunity of securing a seat in your “first choice” sessions if you register early. Registration fees may be paid by check, VISA, MasterCard or money order. Sorry, American Express and Discover cards are not accepted.

**Pre-registration Deadline: Thursday, March 10, 2016 at Noon.** Registrations received after above date/time will not be processed. To register on-site, arrive at least 40 minutes prior to the beginning of your first class. On-site registrations will be accepted subject to space availability.

**Registration Fees: Note ... No CE price increase from 2015 rates!**

A standard \$10 registration fee applies to all individuals.

### **Additional fees:**

**CAMLT Members: \$45 per workshop**

**Non-Members: \$75 per workshop**

**Students: Free workshops!**

**Non-Members:** Become a CAMLT member and save! If you join CAMLT at the time of registration, you may apply the difference between member and non-member fees toward your annual membership dues. For further details, contact CAMLT at 510-792-4441. You may also go to <http://www.camlt.org/membership> to download a membership application.

### **Payment:**

**Make checks payable to CAMLT and mail to:**

CAMLT  
39656 Mission Boulevard  
Fremont, CA 94539-3000

**Or fax credit card registrations to:**

510-792-3045

**Lunch:** Lunch is not included with the seminar. You may purchase lunch at nearby restaurants or bring your own.

**Hotel Room Block: Not negotiated for this seminar**

**Disclaimer:** CAMLT hereby disclaims any liability for, or endorsement of, any products, services or information presented.

**Attendance Policy:** Choice of workshops may NOT be changed on-site. In compliance with state accreditation requirements, participants must attend the entire workshop to receive credit. Partial credit cannot be awarded for late arrivals or early departures. Excessive absences from a workshop for any circumstance may result in forfeiture of CE credit. NO EXCEPTIONS.

**Accreditation:** CAMLT is approved by the California Department of Public Health as a CA CLS/MLT/CPT Accrediting Agency (#21) for Continuing Education and by the State of Nevada, Bureau of Licensing and Certification.

**Refund Policy:** CAMLT reserves the right to cancel any program with insufficient registration. Registrants will be immediately notified and will receive a complete refund for programs cancelled by CAMLT. There may be changes in program content or faculty due to circumstances beyond our control. CAMLT is not responsible for penalties incurred as a result of cancellation, including non-refundable transportation fees and hotel room deposits.

**Cancellation Policy:** For a full refund (less \$10 fee) written notice must be postmarked or faxed by February 26, 2016. Written cancellations postmarked or faxed after this date will be issued a full CREDIT (less a \$25 cancellation fee) toward a future CAMLT state seminar or convention. No refunds or credits after March 10, 2016.

### **Location Information:**

**Winter Seminar South:**

**Kaiser Permanente Regional Reference Laboratory  
11668 Sherman Way  
North Hollywood, CA 91605**

**Parking:** free in Kaiser parking lot. Access to the parking lot is gate controlled. Press the button to have the gate opened. Park closest to the “East” Building – 66. The classrooms are in the first building on the left as you enter the gate.

**Note:** No part of the seminar handouts or presentation (no tape, video or digital recorders please) may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, recorded, or otherwise, without prior written permission from CAMLT.



## REGISTER NOW for CAMLT's 2016 Spring Seminar South

Location: Kaiser Permanente Regional Reference Laboratory

11668 Sherman Way, North Hollywood, CA 91605

\* Venue proudly sponsored by Kaiser Regional Laboratory \*

We are pleased to have the following speakers join us:

### 2016 SPRING SEMINAR SOUTH – SCHEDULE-AT-A-GLANCE

(Complete abstracts/objectives online: [www.caml.org/calendar](http://www.caml.org/calendar))

Saturday, March 19, 2016 ~ Registration – 7:30 – 8:30 a.m.

**161-100 (3.0 CE) - Morning: 8:30 – 11:30 a.m. - (Note: you must attend both parts to receive credit)**

**Rhonda Hensley, MS, SM(ASCP)<sup>CMC</sup>** | AVP Group Manager, Classic Infectious Disease | ARUP Laboratories | Salt Lake City, UT

**Part I) T&C's of C&T's: Terms and Conditions of Competency and Training**

**Part II) Assays: To Make or Buy?**

**Level (Part I):** Intermediate; **Level (Part II):** Basic | **Sponsor:** ARUP Laboratories

**Abstract (Part I):** Documentation of training and competency continues to take a larger role in the laboratory. This interactive session will briefly review current regulatory requirements, share ideas on designing checklists, discuss different approaches to competency assessment, and teach how to design well-written questions to reduce test-wise employee's guessing the right answers. Please email or bring examples of your lab's checklists and competency assessments to share. [rhonda.hensley@aruplab.com](mailto:rhonda.hensley@aruplab.com). **Objectives (Part I):** Upon completion of this course, the participant will be able to: 1) define Competency and Training; 2) review current regulations on competency and training; 3) design a well-written training/competency checklist; 4) discuss different approaches to competency assessment; and 5) design well-written test questions.

**Abstract (Part II):** This session offers a brief overview of using test cost and breakeven analysis to compare cost effectiveness of different methodologies or determining whether to bring an assay in-house. Please bring a calculator or smart phone to work on examples. **Objectives (Part II):** Upon completion of this course, the participant will be able to: 1) define terms associated with test cost analysis; 2) determine the break-even point of a new assay/instrument; and 3) strategize whether to make or buy a test.

**161-200 (3.0 CE) - Afternoon: 1:00 - 4:00 p.m.**

**Jim DeMase, BS** | Senior Account Manager – Los Angeles Hemostasis Territory | Instrumentation Laboratory, Inc. | Bedford, MA

**Implementation of the Anti-Xa Assay for Monitoring Heparin**

**Level:** Intermediate | **Sponsor:** Instrumentation Laboratory, Inc.

**Abstract:** This lecture will review the origins of Heparin and its anticoagulation action as the initial anticoagulant of choice in the hospital setting. We will review the different options for the laboratory monitoring of heparin, comparing the Activated Partial Thromboplastin Time (APTT) vs. the Anti-Xa assay. The benefits of monitoring with the Anti-Xa chromogenic assay will be explored, highlighting the benefits to patient care and increased laboratory efficiency. The successful implementation of the Anti-Xa assay in the lab, as well as hospital-wide, will be discussed.

**Objectives:** Upon completion of this course, the participant will be able to: 1) review the anticoagulation action of Heparin; 2) compare heparin monitoring with APTT vs. Anti-Xa assay; 3) summarize the benefits of monitoring with Anti-Xa; and 4) discuss steps for successful implementation in the lab and hospital-wide.

Sunday, March 20, 2016 ~ Registration - 7:30 - 8:30 a.m.

**161-300 (3.0 CE) - Morning: 8:30 – 11:30 a.m.**

**Matthew C. Wagner, PhD** | Technical Product Specialist | Sebia Inc. | Norcross, GA

**Hemoglobins and Hb A1c: What They Are and How to Catch Them**

**Level:** Intermediate | **Sponsor:** Sebia Inc.

**Abstract:** Qualitative and quantitative hemoglobin disorders – hemoglobinopathies and thalassemias – will be reviewed. Principles behind various methodologies used in hemoglobin variant screening will be discussed. The most common hemoglobin variants, their presentation on various methodologies and effect of alpha- and beta-thalassemias on hemoglobin variant concentration and Hb A2 will be presented. Hb A1c concentration is used to diagnose/monitor diabetes. The principles behind immunoassays, ion-exchange chromatography and boronate affinity chromatography and capillary electrophoresis will be described and compared to the International Federation of Clinical Chemistry (IFCC) reference methods. Factors affecting Hb A1c concentration measurement on various systems will be reviewed. The role of precision and accuracy in determining sigma values will be discussed in detail. **Objectives:** Upon completion of this course, the participant will be able to: 1) describe hemoglobinopathies and thalassemias; 2) differentiate alpha-, beta-, and delta-chain variants; 3) compare various methods commonly used to identify hemoglobinopathies and thalassemias; 4) discuss different techniques commonly used to measure Hb A1c; 5) define the reference methods for measuring Hb A1c; 6) recognize interferences affecting Hb A1c results; and 7) identify factors that determine Hb A1c technique sigma values.

**161-400 (3.0 CE) – Afternoon – 1:00 – 4:00 p.m. - (Note: you must attend both parts to receive credit)**

**Theresa Joseph, RN, BSN** | Medical Scientific Liaison | Roche Diagnostics Corporation | Indianapolis, IN

**James M. Harris, BA** | Director, Scientific Affairs | Roche Diagnostics Corporation | Indianapolis, IN

**Part I) Natriuretic Peptides and Troponin: Testing Today**

**Part II) Hormone Feedback Loops – Special Focus with Thyroid Disease**

**Level (Part I):** Intermediate | **(Part II):** Basic | **Sponsor:** Roche Diagnostics Corporation

**Abstract (Part I):** This program is intended to familiarize health professionals and laboratorians with data supporting evidence-based practice guidelines related to care of the patient with Acute Coronary Syndrome and/or Heart Failure. The focus will be on diagnostic and prognostic value of troponin and natriuretic peptides. Analytical and clinical considerations will be discussed, as will pathophysiology of the heart in Acute Coronary Syndrome and Heart Failure. **Objectives (Part I):** Upon completion of this course, the participant will be able to: 1) describe the biochemical and physiological effects of the cardiac natriuretic peptide and troponin system; 2) identify biological and physiological factors for consideration in the clinical application of natriuretic peptide and troponin measurements in acute and chronic disease settings; and 3) analyze evidence-based clinical outcome data related to the diagnostic and prognostic impact of natriuretic peptide and troponin use in primary and acute care settings.

**Outline (Part II):** 1. Physiology of the Thyroid; 2. Pathology of Thyroid Disease; 3. Diagnosis of Thyroid Disease; and 4. Treatment of Thyroid Disease. **Objectives (Part II):** Upon completion of this course, the participant will be able to: 1) describe the physiology of the Thyroid; 2) verify and validate various Thyroid diseases; 3) evaluate the clinical utility for testing used to diagnose Thyroid disease; and 4) recognize the different Thyroid diseases and appropriate therapeutic approaches.

## 2016 Spring Seminar South – Schedule-at-a-Glance

March 19 & 20, 2016

Location: Kaiser Permanente SCPMG Regional Reference Laboratory

11668 Sherman Way

North Hollywood, CA 91605

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# CAMLT 2016 SPRING SEMINAR NORTH GENERAL INFORMATION

Proudly sponsored by the

UCDMC Department of Pathology and Laboratory Medicine's Partners in Education (PIE).

**Advance Registration:** You have the best opportunity of securing a seat in your "first choice" sessions if you register early. Registration fees may be paid by check, VISA, MasterCard or money order. Sorry, American Express and Discover cards are not accepted.

**Pre-registration Deadline:** **Thursday, April 7, 2016 at Noon.** Registrations received after above date/time will not be processed. To register on-site, arrive at least 40 minutes prior to the beginning of your first class. On-site registrations will be accepted subject to space availability.

**Registration Fees:** **Note ... No price increase from 2015 rates!**

A standard \$10.00 registration fee applies to all individuals.

## **Additional fees:**

**CAMLT Members: \$45.00 per workshop**

**Non-Members: \$75.00 per workshop**

**Students: Free workshops!**

**Non-Members:** Become a CAMLT member and save! If you join CAMLT at the time of registration, you may apply the difference between member and non-member fees toward your annual membership dues. For further details, contact CAMLT at 510-792-4441. You may also go to <http://www.camlt.org/membership> to download a membership application.

## **Payment:**

### **Make checks payable to CAMLT and mail to:**

CAMLT  
39656 Mission Boulevard  
Fremont, CA 94539-3000

### **Or fax credit card registrations to:**

510-792-3045

**Accreditation:** CAMLT is approved by the California Department of Public Health as a CA CLS/MLT/CPT Accrediting Agency (#21) for Continuing Education, and by the State of Nevada.

**Refund Policy:** CAMLT reserves the right to cancel any program with insufficient registration. Registrants will be immediately notified and will receive a complete refund for programs cancelled by CAMLT. There may be changes in program content or faculty due to circumstances beyond our

control. CAMLT is not responsible for penalties incurred as a result of cancellation, including non-refundable transportation fees and hotel room deposits.

**Cancellation Policy:** For a full refund (less \$10.00 fee) written notice must be postmarked or faxed by March 25, 2016. Written cancellations postmarked or faxed after this date will be issued a full CREDIT (less a \$25.00 cancellation fee) toward a future CAMLT state seminar or convention. No refunds or credits after April 7, 2016.

## **Location Information:**

**Spring Seminar North:**  
**UC Davis Medical Center Campus**  
**School of Medicine Building**  
**Rooms 2205 & 2206**  
**4610 X St., Sacramento, CA 95817**

**Daily Parking:** Park in Lot # 14, one-day permits can be purchased at dispensing machine via cash or credit card. Lot 14 entrance at 45<sup>th</sup> Street and 2<sup>nd</sup> Avenue.

**Hotel Room Block:** Not negotiated for this seminar

**Lunch:** A cafeteria is located on the first floor of the Surgical and Emergency Services Pavilion across the street from the Med Center. There are fast food restaurants a few blocks away but for convenience and safety, the cafeteria is suggested ... or, bring your own lunch.

**Note:** No part of the seminar handouts or presentation (no tape, video or digital recorders please) may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, recorded, or otherwise, without prior written permission from CAMLT.

**Disclaimer:** CAMLT hereby disclaims any liability for, or endorsement of, any products, services or information presented.

**Attendance Policy:** Choice of workshops may NOT be changed on-site. In compliance with state accreditation requirements, participants must attend the entire workshop to receive credit. Partial credit cannot be awarded for late arrivals or early departures. Excessive absences from a workshop for any circumstance may result in forfeiture of CE credit. **NO EXCEPTIONS.**

## REGISTER NOW for CAMLT's 2016 Spring Seminar North

Location: UC Davis Medical Center Campus (School of Medicine Building)

4610 X Street, Sacramento, CA 95817

### SCHEDULE-AT-A-GLANCE

Complete abstracts/objectives available online: [www.camlt.org/calendar](http://www.camlt.org/calendar)

We are pleased to have the following speakers join us:

**SATURDAY, APRIL 16, 2016 – REGISTRATION: 7:45 – 8:30 AM**

**162-100 (3.0 CE) - Morning: 8:30 – 11:30 AM (note: you must attend both parts to receive credit)**

**Elizabeth L. Frank, PhD, MT(ASCP), DABCC**, Medical Director – ARUP Laboratories | Associate Professor – University of Utah  
ARUP Laboratories, Salt Lake City, UT

**Sponsor: ARUP Laboratories**

**Part I: Porphyrins and Porphyrins**

**Part II: Diagnosing Porphyrin**

Level of Difficulty (both parts): Intermediate

**Abstract (Part I):** The porphyrias are a group of rare diseases associated with defects in the biosynthetic pathways of heme. Heme biosynthesis and the porphyrias will be discussed in this session. Porphyrins are intermediates in the heme biosynthetic pathway that may be produced in excess, accumulated in body tissues, and excreted in body fluids. Characteristics of porphyrins and other pathway intermediates present in the body fluids of patients with disease will be described. Laboratory tests and methods used to detect porphyrins and precursor compounds for diagnosis of porphyria will be reviewed. **Abstract (Part II):** The acute and non-acute porphyrias - including signs and symptoms of the diseases, enzyme deficiencies, inheritance patterns, prevalence, and precipitating factors - will be described. The properties of porphyrins and other intermediates of heme biosynthesis will be discussed. These features contribute to toxicity and produce characteristic symptoms of diseases, and allow for their detection in body fluids. An algorithm for laboratory testing used for evaluation of suspected porphyria will be presented. Participants will assess typical laboratory test results in the context of characteristic patient presentation to differentiate the individual porphyrias.

**162-200 (3.0 CE) - Afternoon: 1:00 – 4:00 PM**

**Jim DeMase, BS** | Senior Account Manager – Los Angeles Hemostasis Territory | Instrumentation Laboratory, Inc. | Bedford, MA

**Implementation of the Anti-Xa Assay for Monitoring Heparin**

Level: Intermediate | **Sponsor: Instrumentation Laboratory, Inc.**

**Abstract:** This lecture will review the origins of Heparin and its anticoagulation action as the initial anticoagulant of choice in the hospital setting. We will review the different options for the laboratory monitoring of heparin, comparing the Activated Partial Thromboplastin Time (APTT) vs. the Anti-Xa assay. The benefits of monitoring with the Anti-Xa chromogenic assay will be explored, highlighting the benefits to patient care and increased laboratory efficiency. The successful implementation of the Anti-Xa assay in the lab, as well as hospital-wide, will be discussed.

**SUNDAY, APRIL 17, 2016 – REGISTRATION: 7:45 – 8:30 AM**

**162-300 (3.0 CE) - Morning: 8:30 – 11:30 AM (note: you must attend both parts to receive credit)**

**Carmen L. Wiley, PhD, DABCC, FACB** | Regional Manager of Scientific Affairs - Cardiac | Roche Diagnostics Corporation | Indianapolis, IN

**Jingzi L. Sherman, MD, MS** | Senior Scientific Affairs Manager | Roche Diagnostics Corporation | Indianapolis, IN

**Part I) Natriuretic Peptides and Troponin: Testing Today (Wiley)**

**Part II) Personalized Healthcare (PHC) – Fitting the Treatment to the Patients (Sherman)**

Level: Basic | **Sponsor: Roche Diagnostics Corporation**

**Abstract (Part I):** This program is intended to familiarize health professionals and laboratorians with data supporting evidence-based practice guidelines related to care of the patient with Acute Coronary Syndrome and/or Heart Failure. The focus will be on diagnostic and prognostic value of troponin and natriuretic peptides. Analytical and clinical considerations will be discussed, as will pathophysiology of the heart in Acute Coronary Syndrome and Heart Failure.

**Outline (Part II):** 1) Why Personalized Healthcare; 2) Benefits for patients, physicians, and payers; 3) Role of Biomarkers; and 4) Personalized Healthcare in practice.

**162-400 (3.0 CE) - Afternoon: 1:00 – 4:00 PM**

**Aigars Brants, PhD** | Scientific Affairs Officer | Sebia, Inc. | Norcross, GA

**Sponsor: Sebia, Inc**

**Screening for Multiple Myeloma and Diabetes by Capillary Electrophoresis**

Level of Difficulty: Intermediate

**Abstract: Serum Electrophoresis** – The most common electrophoresis technique routinely used in clinical laboratories is gel electrophoresis. The most current approach to electrophoresis, capillary electrophoresis (CE), allows fast separation of protein molecules in electrical field based on the charge and size using free buffer system and direct fraction measurement using absorbance at 200 nm. Gel and capillary electrophoresis methods will be discussed and some differences identified. Serum protein electrophoresis is used to detect various disorders, including multiple myeloma and amyloidosis. Various serum protein profiles will be reviewed. Profiles covering different conditions (inflammatory profiles, nephrotic patterns, oligoclonal patterns, monoclonal gammopathy) will be discussed and differences between the various patterns identified. Monoclonal gammopathies (MG) are characterized by chromosomal aberration of B-cells or plasma cells resulting in benign or malignant proliferation of the affected clone. The product of such clone, a monoclonal protein, is an essential laboratory marker for the detection, identification and classification of MG and aid in diagnosing the associated conditions. The lecture will provide the background for understanding monoclonal gammopathies and the guidelines for interpretation of immunotyping results from serum samples. **Hb A1c** – Hb A1c concentration is used to diagnose/monitor diabetes. The principles behind immunoassays, ion-exchange chromatography and boronate affinity chromatography and capillary electrophoresis will be described and compared to the IFCC reference methods. Factors affecting Hb A1c concentration measurement on various systems will be reviewed. The role of precision and accuracy in determining sigma values will be discussed in detail. **Objectives:** Upon completion of this course, the participant will be able to: 1) explain the principles of capillary electrophoresis; 2) define the concepts of monoclonal gammopathy and explain the formation of monoclonal proteins; 3) discuss multiple myeloma stages; 4) recognize the importance of early detection of monoclonal proteins in patients and the role of electrophoresis in the process; 5) distinguish between normal and abnormal serum electrophoresis patterns; 6) describe the principles of immunotyping and interpret basic immunotyping patterns; 7) discuss different techniques commonly used to measure Hb A1c; 8) define the reference methods for measuring Hb A1c; and 9) recognize interferences affecting Hb A1c results.

**2016 Spring Seminar North – Registration Form  
April 16 & 17, 2016**

**Location: UC Davis Medical Center Campus  
School of Medicine Building  
4610 X Street, Sacramento, CA 95817**

<p>Name:</p> <p>CLS/MLT License / CPT Cert. #:</p> <p>Address:</p> <p>City: State: Zip:</p> <p>Daytime Phone:</p> <p>Preferred Email:</p> <p>Employer:</p> <p>Work Address:</p> <p>City: State: Zip:</p> <p>Work Phone:</p> <p>CAMLT Member? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Member # / Chapter:</p> <p>If member, do you have 20/20 Option? <input type="checkbox"/> Y <input type="checkbox"/> N</p> <p>ATTENTION STUDENTS: Your program coordinator/school counselor must sign/provide email/telephone contact here for acceptance:</p> <p>_____</p> <p>(Email / phone)</p> <p>_____</p> <p>(Signature of program coordinator/school counselor)</p> <p>_____</p> <p>(Accredited program/school)</p>	<p align="center"><b>Check Your Selected Courses – 3.0 CE Each</b> (Note: if a session is in two parts, you must attend both to receive credit)</p> <p><b>Saturday, AM – 4/16/2016 (8:30 – 11:30 AM)</b>  <input type="checkbox"/> 162-100 – Part I) Porphyrins and Porphyrrias   Part II) Diagnosing Porphyria</p> <p><b>Saturday, PM – 4/16/2016 (1:00 – 4:00 PM)</b>  <input type="checkbox"/> 162-200 – Implementation of the Anti-Xa Assay for Monitoring Heparin</p> <p><b>Sunday, AM – 4/17/2016 (8:30 – 11:30 AM)</b>  <input type="checkbox"/> 162-300 – Part I) Natriuretic Peptides and Troponin: Testing Today   Part II) Personalized Healthcare (PHC) – Fitting the Treatment to the Patients</p> <p><b>Sunday, PM – 4/17/2016 (1:00 – 4:00 PM)</b>  <input type="checkbox"/> 162-400 – Screening for Multiple Myeloma and Diabetes by Capillary Electrophoresis</p> <p><b>Method of Payment:</b>            Credit card, check, or money order</p> <p><input type="checkbox"/> VISA  <input type="checkbox"/> MasterCard</p> <p>Expiration date: _____            Three digit security code: _____            Card #: _____ - _____ - _____ - _____</p> <p>_____            Signature (required for cc processing)</p>
<p>FEE SCHEDULE: Course fees are based upon a base registration fee of \$10.00, plus a fee based upon the number of continuing education units.</p> <p><b>FEE SCHEDULE: Course fees are based upon a base registration fee of \$10.00, plus a fee based upon the number of continuing education units.</b></p> <p><b>Registration Fee: \$10.00</b>            +  <b>Number of workshops</b> _____ x \$ _____            (example: 2 x \$45.00 = \$90.00)</p> <p>Members: \$45.00 per workshop (\$15.00 per unit)            Non-Members: \$75.00 per workshop (\$25.00 per unit)            Student Member: Free workshops (does not include CEUs)</p> <p><b>Less 20/20 Option Discount: \$ - _____</b>  <b>(If applicable) (Applies only to course fees at this seminar)</b></p> <p><b>Total Due: \$ _____</b></p>	<p align="center"><b>Make check payable and mail to:</b></p> <p align="center"><b>CAMLT</b>  <b>39656 Mission Boulevard</b>  <b>Fremont, CA 94539-3000</b></p> <p align="center"><b>FAX: 510.792.3045</b></p> <p align="center"><b>Questions? Contact CAMLT Executive Office:</b>  <b>510.792.4441 / office@camlt.org</b></p> <p align="center"><b>Returned checks subject to a \$20.00 fee</b></p> <p align="center"><b>Pre-Registration Deadline:</b>  <b>Thursday, April 7, 2016 at Noon</b></p> <p align="center"><b>(Registrations received after this date will not be processed and certificates will be mailed post-seminar)</b></p>

# VIRAL HEPATITIS 2015: CAUSES, DIAGNOSIS, AND TREATMENT

Course # DL-004

2.0 CE

Level of Difficulty: Intermediate

Les Revier, BS, MBA, CLS, C(ASCP)

Senior Manager, UCSD Medical Center (Retired)

Helen M. Sowers, MS, CLS

Dept. of Biological Sciences (Retired)

CSU East Bay

## OBJECTIVES:

After completing this course the participant will be able to:

1. List the viral causes of hepatitis.
2. Summarize the history of the hepatitis viruses.
3. Describe the extent of the toll of the viral hepatitises world-wide and in the U.S.
4. Outline the causative agents, transmission, symptoms, sequelae, diagnosis, treatment, and prevention of the five viral hepatitises.
5. Discuss the laboratory testing for each type of hepatitis.

## INTRODUCTION:

Hepatitis has been known since ancient times. Hippocrates characterized its signs, including jaundice. It was recognized as a disease affecting the liver, causing the skin to turn yellow. By the eighth century some cases were found to be infectious. Epidemics of jaundice have been reported since the 5th century BC, with major epidemics documented in Europe during the 17th and 18th centuries. Epidemics were so frequent among armies that the disease was termed campaign jaundice. In the 19th century the cause was thought to be obstruction of the common bile duct by a mucus plug and was called acute catarrhal jaundice. However growing evidence for the infectious nature of the disease culminated in 1923 when Blumer concluded that infectious hepatitis was the epidemic form of catarrhal jaundice.

Hepatitis is inflammation of the liver, usually producing swelling and, in many cases, permanent damage to liver tissues. A number of agents can cause hepatitis, including infectious diseases, chemical poisons, drugs, and alcohol. In the 1940s doctors began to suspect that many hepatitis cases were caused by a virus that was carried in human blood. In 1965 Dr. Baruch Blumberg discovered the Australia antigen, which later would be known as the hepatitis B surface antigen or HBsAg. The hepatitis A agent was discovered about 10 years later. Around this time Harvey J. Alter, Chief of the Infectious Disease Section at the National Institute of Health, and his research team noted many hepatitis cases that were not hepatitis B virus (HBV) or hepatitis A virus (HVA). This virus was called non-A, non-B hepatitis (NANBH) and was confirmed by Alter in a panel of NANBH specimens in 1988. In 1989 the discovery of the causative virus was published in *The Journal of Science* and was renamed Hepatitis C (HCV). Hepatitis delta virus (HDV) was identified in the 1970s, but it was not until 1990 that it was found to exist only in the presence of HBV. Hepatitis E (HEV) virus was discovered in 1990 and Hepatitis G virus in 1995.

Viral hepatitis is the most common type of liver disease worldwide, including in the United States. Hepatitis A, Hepatitis B, Hepatitis C, Hepatitis D, and Hepatitis E are all found in the U.S.

The liver, which is located in the upper right quadrant of the abdomen, performs many vital functions. These functions include: purifying the blood by converting harmful chemicals into harmless ones; producing proteins such as albumin and blood clotting factors; storing sugars, fats, and vitamins until they are needed; manufacturing necessary hormones and enzymes; and forming and secreting bile. If the liver is extensively damaged and these functions are impaired, the result is liver disease that may cause the following:

- jaundice from accumulation of bilirubin in the blood
- bleeding or easy bruising from lack of clotting factors
- swelling of the legs due to decrease in serum albumin

Laboratory tests for hepatitis include routine tests CBC, albumin, alkaline phosphatase, alanine aminotransferase (ALT), aspartate aminotransferase (AST) and bilirubin. Serologic tests include immunoassays for antibodies and antigens to detect the presence of infection, the immune status, the disease status and need for treatment. Nucleic acid-based tests are used to detect viremia and measure viral load. Genotyping tests are used to determine the hepatitis genotype.

This paper will discuss each of the major types of the viral hepatic infections, with extensive discussion of hepatitis C. It will elaborate on each of the viral causes of the hepatitises including causative agent, methods of transmission, symptoms, sequelae, diagnosis, treatment, prevention, and laboratory diagnosis.

## HEPATITIS A

Hepatitis A, caused by the Hepatitis A virus (HAV), is also known as infectious hepatitis or short-incubation hepatitis. It is the most common form of viral hepatitis worldwide. It accounts for about 1,700 of the approximately 7,000 new cases of hepatitis reported in the United States each year. Hepatitis A is an acute form of hepatitis that never becomes chronic. However, 10-15% of patients may experience a relapse of symptoms during six months after acute illness.

HAV is primarily spread through the fecal-oral route. HAV is excreted in the bile and then shed in the feces from two weeks before to one week after the onset of clinical illness. It is commonly ingested through contaminated food or water, and frequently spread among

household members due to poor hand washing or by close contact. It can also be spread by sexual practices that involve oral-fecal contact. Blood-borne transmission of HAV is uncommon.

The incubation period of HAV is about 28 days with a range of 2-6 weeks. The length of the incubation period depends on the number of infectious particles consumed. The patient presents with symptoms of fever, malaise, loss of appetite, nausea, abdominal discomfort, dark urine, and jaundice. Symptoms seldom last for more than three weeks. Symptoms occur more frequently in adults; children may be asymptomatic or have a mild, unrecognized infection. Only in rare cases can HAV develop into fulminant liver failure.

Although hepatitis A was recognized as separate from other types of hepatitis during World War II, the virus wasn't isolated until 1973, by Robert Purcell. HAV is an RNA virus in the Picornavirus family. It is non-enveloped and contains a single-stranded RNA in a protein shell.

#### Diagnosis of Hepatitis A

Preliminary diagnosis of HAV is through the classical liver enzyme analysis. Today serological antibody detection methods are used for identifying clinical markers that diagnose and follow the progression of HAV infection. The serologic antibodies used as markers follow this progression: immunoglobulin M (IgM) antibodies to HAV are detectable when symptoms first present and decline after 3 to 6 months; next immunoglobulin G (IgG) antibodies appear and may remain for years after infection. The presence of IgG anti-HAV without IgM indicates a past infection and the presence of IgM anti-HAV indicates an acute infection. Another way to detect acute infection is by testing for the viral antigen, HAVAg, but this antigen is no longer present after liver enzymes have reached their peak.

Hepatitis A virus infection can also be detected using reverse transcription-polymerase chain reaction (RT-PCR) to amplify the viral RNA. This type of HAV detection is useful in epidemiological testing of samples from different origins, such as food, environment, and clinical specimens.

#### Hepatitis A Treatment and Prognosis

There are no specific medications to cure or treat hepatitis A virus. Most treatments are focused on ameliorating the symptoms of the disease, such as resting frequently, eating small meals in order to reduce the nausea, and elimination of alcoholic beverages. However those who have been exposed to an infected person may be given hepatitis A immunoglobulin, which may prevent infection. Hepatitis A symptoms usually subside within 2-6 weeks.

#### Hepatitis A Prevention

A vaccine to protect against acquiring HAV was created by Maurice Hilleman, a scientist from Merck, in the 1990s. The vaccine is 95% effective in protecting against the virus. The vaccine works for about 10 years and should be given to anyone who risks infection, such as:

- children over the age of 1
- travelers to countries where the virus is common
- those working with the virus
- people with chronic liver disease
- people with high-risk sexual behavior

The use of the Hepatitis A vaccine has dramatically decreased the incidence of HAV in the United States.

## HEPATITIS B

Hepatitis B is referred to as "long incubation hepatitis" and occurs as both an acute and chronic form. Today there are about 20,000 new cases in the United States each year. This is a sharp decrease of about 82% since 1991 when a national strategy to eliminate HBV infection was implemented in the United States. Approximately 1.25 million are infected (new and older cases) in the United States; globally, however, 2 billion people are infected, with 240 million of them being chronic carriers.

In 1965 the Hepatitis B Virus (HBV) surface antigen was isolated from the blood of aborigines in Australia and was characterized by 1979. Hepatitis B is a hepadnavirus. *Hepa*-coming from hepatropic and *dna* because it is a DNA virus. Hepatitis B interferes with the function of the liver by replicating in the liver cells called hepatocytes. A person with chronic HBV will have ground-glass hepatocytes.

Hepatitis B is spread through contact with infected bodily fluids such as blood, semen, and vaginal fluid. Although the virus is found in every bodily secretion, it is not transferred through casual contact. People who are at an increased risk of being infected with the hepatitis B virus include those who:

- have sex with a person infected with Hepatitis B virus
- have multiple sex partners especially if a condom is not used
- have other sexually transmitted diseases
- inject drugs with shared needles
- receive transfusions of blood or blood products
- undergo dialysis with for kidney disease
- are men who have sex with men

#### Hepatitis B Diagnosis

Serological markers are used to diagnose and monitor Hepatitis B virus infection. The first antigen present is the HB surface antigen (HBsAg) and is the only antigen present during the first 3-5 weeks in newly infected individuals. HBsAg is also useful because it is detectable before clinical symptoms appear. People who chronically carry HBsAg can be considered infectious.

The body normally produces antibodies to HBsAg as part of the normal immune response. Individuals who have anti-HBs antibody have had a past infection and are not susceptible to reinfection. Anti-HBs also develops in those who have been successfully vaccinated against Hepatitis B.

The hepatitis B core antigen (HBcAg) is serologically significant because it is present in the nuclei of hepatocytes only during an acute infection. In an acute infection, the antibody to HBc, anti-HBc, develops before anti-HBs. Anti-HBc appears at the onset of symptoms and can persist for life. The presence of anti-HBc indicates previous or ongoing infection with HBV in an undefined timeframe. However, the IgM antibody to hepatitis B core antigen positively indicates recent infection with HBV (< 6 months). Its presence indicates an acute infection.

The hepatitis Be antigen or HBeAg is the secreted product of the nucleocapsid gene of HBV that is found in serum during acute and chronic hepatitis B. Its presence indicates that the virus is replicating and the infected person has high levels of HBV and is highly infectious. The presence of HBeAg and HBsAg generally indicates a poor prognosis and is indicative of a chronic infection with chronic liver disease. Alternatively the presence of anti-HBe means recovery and a very low infectivity. Conversion from e antigen to e antibody is a predictor of long-term clearance of HBV in patients undergoing antiviral therapy and indicates lower levels of HBV (see Figure 1).

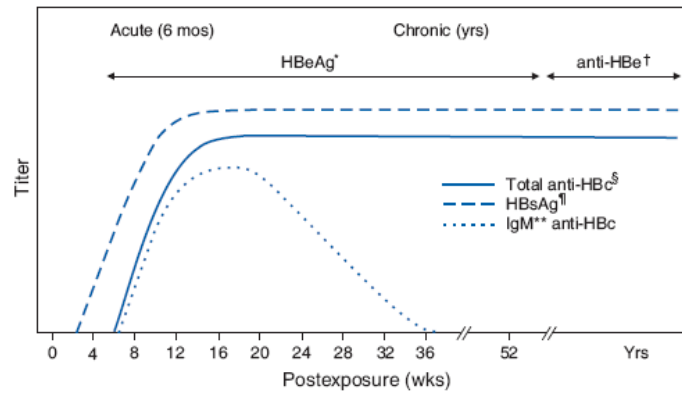


Figure 1

HBV antigens and antibodies are an excellent way to determine the status of the individual, as shown in the following table:

Interpretation of Hepatitis B Serologic Test Results*		
Test	Result	Interpretation
HbsAg anti-HBc anti-HBs	negative negative negative	Susceptible
HbsAg anti-HBc anti-HBs	negative positive positive	Immune due to natural infection
HbsAg anti-HBc anti-HBs	negative negative positive	Immune due to Hepatitis B vaccination
HbsAg anti-HBc IgM anti-HBc anti-HBs	positive positive positive negative	Acutely infected
HBsAg	negative	Interpretation unclear; 4 possibilities; Resolved infection (most common) False-positive anti-HBc, thus susceptible "Low level" chronic infection Passive transfer from positive mother to infant
anti-HBc	positive	
anti-HBs	negative	

\*Adapted from: A Comprehensive Strategy to Eliminate Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices Part II, MMWR, 12/8/2006, Vol 55/RR-16

Another way to measure disease progression is by the use of polymerase chain reaction (PCR) technique to isolate specific HBV DNA. PCR is highly specific and can be used to monitor effectiveness of antiviral therapy. Other ways to measure disease progression are liver function tests, blood electrolytes, CT of the liver to look for extent of damage, and liver biopsy.

Hepatitis B Treatment



Acute HBV infection will subside on its own and does not require medications. If patients have severe vomiting or diarrhea, they can be treated by restoring fluids. Alternatively chronic HBV infection can be treated with antiviral medication. The decision to treat a patient with antiviral medication is determined by the extent of liver damage. The liver is damaged in HBV by the virus's multiplying rapidly in the liver. This can be tested by monitoring the HBV DNA in the blood, liver function tests, and biopsy of the liver. Antiviral medications work by preventing the virus from multiplying and are thought to help reduce the incidence of cirrhosis and liver failure, but they do not work on everyone. Currently there are several preferred medications approved for use in the United States for chronic hepatitis B. These are Peginterferon (Interferon-alpha 2b), Entecavir, and Tenofovir. Antiviral medication is not a cure for HBV; it is a way to allow the liver to heal for a period of time.

#### Hepatitis B Prognosis

Only about half of new HBV infections in adults are symptomatic. The majority of those showing symptoms recover rapidly. Some will have a prolonged disease course with symptoms persisting for a long period of time. A small fraction, about 1%, has rapid progression of the disease in the acute stage and develops fulminant hepatitis. Fulminant hepatitis is a severe form of acute hepatitis that can be life-threatening if not treated immediately. The symptoms of fulminant hepatitis develop very suddenly and may include: mental disturbances such as confusion, lethargy, extreme sleepiness or hallucinations, hepatic encephalopathy, sudden collapse with fatigue, jaundice, and swelling of the abdomen.

The risk for chronic HBV infection is inversely related to age: about 90% of infants and 30% of young children develop chronic infection. Only 2-6% of adults become chronically infected. Chronic HBV infection can cause severe liver damage including cirrhosis, liver cancer, liver failure, and ultimately death. Premature death from cirrhosis or hepatocellular carcinoma is 15-25% of those with chronic infection.

#### Hepatitis B Prevention

Fortunately there is a vaccine for hepatitis B virus. The first vaccine became available in 1981 and consists of the viral envelope of the hepatitis B surface antigen, HBsAg, produced in yeast cells. This is done by injecting the DNA of HBsAg into yeast where it is grown, harvested, and purified. The vaccine is given in three separate injections. The second injection is given 1 month after the first injection and the third injection is given 6 months after the first injection. After the 3 injections the body has an immune response and creates an antibody to HBsAg called anti-HBsAg. The person who received the vaccine is now immune to HBV. The following groups should be vaccinated for hepatitis B:

- all children younger than 19 years, including all newborns - especially those born to mothers who are infected with HBV
- all health care and public safety workers who may be exposed to blood
- people who have hemophilia or other blood clotting disorders and receive transfusions of human clotting factors
- people who have end-stage renal disease including those who require hemodialysis for kidney disease
- travelers to countries where HBV infection is common
- prisoners
- intravenous (IV) drug users
- people with chronic liver disease such as Hepatitis C
- people who have multiple sex partners or have ever had a sexually transmitted disease
- household contacts of persons who are carriers of HBV
- anyone who wants to be vaccinated, regardless of risk factors

The HBV vaccine is effective. If a person has been exposed to someone with HBV and they are not vaccinated, they can be given hepatitis B immunoglobulin along with the HBV vaccine. The chance of NOT becoming infected is 80-90% with the combination of immunoglobulin and vaccine.

#### HEPATITIS C

Hepatitis C virus (HCV) is the most common chronic blood borne infection in the United States. About 3.2 million people (1.5% of the population) are chronically infected. Worldwide the estimate of infection is 130-150 million. Prevalence varies from 0.3-2.5% in Western Europe and North America, 3-7% in much of Asia and South America, to over 10% in parts of Africa, with major variations occurring within these populations.

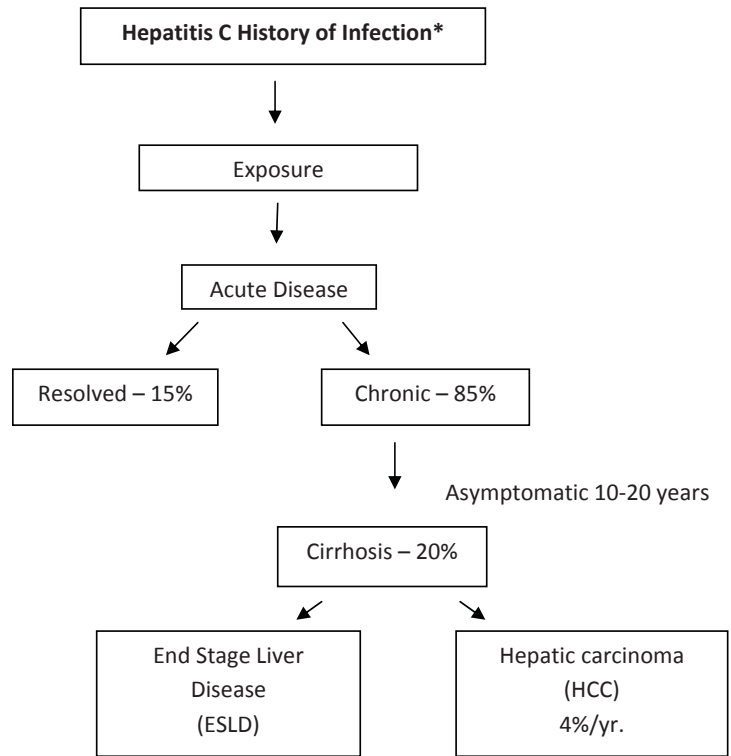
In the 1970s it was realized that there were a number of cases of hepatitis, particularly from blood transfusions, that were not due to hepatitis A or hepatitis B. The causative agent was called "non-A, non-B (NANB) hepatitis." This term was regarded as a diagnosis of exclusion because of the absence of specific serologic markers and unknown viral origin. It wasn't until 1987 that D.W. Bradley of CDC and Michael Houghton, et al., of Chiron Corp., using a novel molecular cloning approach, identified the virus and developed a diagnostic test. Homology does not exist among hepatitis A, hepatitis B, hepatitis D, or hepatitis E viruses and HCV.

Since HCV was not explicitly identified until 1989, and blood tests were not available until 1991, its emergence as a global health issue went largely undetected before that time and the analysis of the pandemic is largely retrospective. Hepatitis C had originally been considered limited to transfusion recipients. Now HCV is recognized in many other epidemiologic settings and as a major cause of chronic hepatitis worldwide.

The hepatitis C virus is one of the most important causes of chronic liver disease in the United States. It accounts for about 15% of acute viral hepatitis, 60 to 70% of chronic hepatitis, up to 50% of cirrhosis, one-third of liver cancer, and significant numbers of end-stage liver disease. See Chart I. It is the number one cause of death in those infected with HIV. Of the U.S. population, 1.6%, or an estimated 4.1 million Americans, have antibodies to HCV (anti-HCV), indicating ongoing or previous infection with the virus. Hepatitis C causes an estimated 17,000 to 20,000 deaths annually in the United States. Following a peak in 1992, incidence of

acute hepatitis C declined; however, since 2009 rates have increased from 16,000 in 2009 to almost 30,000 in 2013 (latest statistics available).

CHART #1.



\*Ref.: Ayoub, Walid, M.D. Hepatitis C Seminar, Eden Hospital Castro Valley, CA, 3/2/12

### Virus Characteristics

Hepatitis C virus is a small, enveloped, single-stranded RNA virus. HCV is closely related to flaviviruses and pestiviruses. Its genetic organization and protein products classify it in the flaviviridae family; its diversity is great enough for it to be classified as a separate genus. HCV is not related to any of the other known hepatitis viruses; however, the recently described hepatitis G virus is a distant relative. There are six known genotypes of the HCV virus, numbered 1-6. Approximately 80% of the hepatitis C patients in the United States have genotype 1; genotype 4 is more common in the Middle East and Africa. Type 1 is the hardest to treat.

The HCV genome is a positive-sense RNA molecule of approximately 9,500 nucleotides. There are highly conserved 5' and 3' untranslated regions flanking an approximately 9,000 nucleotide single open reading frame that encodes a large polyprotein of about 3,000 amino acids. This protein undergoes posttranslational processing by host and viral enzymes to form the structural and nonstructural proteins and enzymes of the virus.

The 5' terminus of the viral RNA is an untranslated region (5' UTR) known to be essential for replication; it contains elements thought to coordinate viral protein synthesis. It is not surprising that this region is highly conserved, and therefore serves as a useful target for amplification in diagnostic assays.

The polymerase enzyme of RNA viruses such as HCV lacks proof-reading ability and is therefore unable to correct copying errors made during viral replication. Many of these nucleotide changes result in a nonfunctional genome or a replication incompetent virus (lethal mutants). However, others persist and account for the tremendous viral diversity that is characteristic of HCV. This heterogeneity is extremely important in the diagnosis of infection, pathogenesis of disease, and the response to treatment. It prevents the development of conventional vaccines, allows the virus to escape eradication by the host's immune system, and affects the completeness of the response to antiviral therapies such as interferon.

### Viral transmission and damages

The presence of HCV in the liver triggers the human immune system, which leads to inflammation. Over time (usually decades) prolonged inflammation may cause scarring. Extensive scarring in the liver is called cirrhosis. When the liver becomes cirrhotic, the liver fails to perform its normal functions, leading to serious complications and even death. Cirrhotic livers also are more prone to become cancerous.

Hepatitis C is believed to be transmitted only by blood. However, unlike many other blood borne viruses (like HIV) virtually any source of blood or blood products seems to be capable of carrying the virus, even if the source is indirect – like a used razor, for example. This makes hepatitis C far more transmissible than most other blood borne viruses – including HIV.

Many hepatitis C victims contracted the disease through blood transfusions in the 1970s and 1980s. Rates of post-transfusion hepatitis during this period were determined to have been between 8% and 10%. Effective blood screening for the virus was developed and implemented by 1990, which lowered the rates of post-transfusion hepatitis to less than 5% from 1990-1993. Since then, improved testing has led to drastic reductions in risk, down to less than 1% after 1993. However, anyone who had a blood transfusion prior to

that time is at risk for having been infected. Incidence of hepatitis C infection among hemophiliacs remained high through 1993 because plasma used as a source of clotting factors to treat hemophilia was often a mixture from many different donors. However, incidence of new infection among hemophiliacs has rapidly approached zero as better methods for producing coagulation factors have been employed.

The practice of intravenous (IV) drug use provided the greatest opportunity for large-scale HCV transmission. It is responsible for about 30-40% of all identified cases of hepatitis C. As with HIV, the sharing of contaminated needles and other drug paraphernalia dramatically increases the chance of infection. Incidence of infection among IV drug users has surpassed 50% in many studies, and reached 100% in others. Cocaine users have also been shown to transmit the virus by sharing snorting straws.

Tattooing, as well as many body piercing practices, such as acupuncture and ear-piercing, have contributed to the spread of HCV, even in industrial nations. Needle-stick injuries, contaminated medical equipment, and blood spills in health care settings are also responsible for many cases of HCV.

Heterosexual or homosexual activity with multiple sexual partners has been clearly identified as a mode of transmission, but the exact risk is unknown. Because of the lack of sufficient information, persons in long-term, monogamous relationships are advised not to change sexual practices. Day-to-day contact with another household member who has hepatitis C has also been strongly implicated. Maternal-to-infant transmission has been documented as a mode of spread. Certain specialized risks have also been identified – such as manicures, shared toothbrushes, or straight razors in barber shops.

In more than 40% of all cases, the infected individuals cannot identify a source for their infection. It is believed that most of these are caused by known risk factors – however in more than 10% of all cases, no risk factor can be identified. There are clearly other, as yet unidentified, modes of transmission.

#### Signs and symptoms

Although hepatitis C damages the liver, 80% of people with the disease do not have symptoms. (See Chart I) In those who do, symptoms may not appear for 10-20 years, or even longer. Even then, the symptoms usually come and go and are mild and vague. Unfortunately, by the time symptoms appear, the damage may be serious. A minority of people have symptoms during the early acute phase of the infection. These symptoms typically develop 5-12 weeks after exposure to HCV.

Over time, the liver in people with chronic infection may begin to experience the effects of the persistent inflammation caused by the immune reaction to the virus. Blood tests may show elevated levels of liver enzymes, a sign of liver damage, which is often the first suggestion that the infection may be present. However, up to 40% have a persistent normal alanine transaminase (ALT) but three-quarters of these have liver damage. Since the ALT levels may fluctuate in and out of the normal range, the ALT test should be repeated a number of times.

Patients may become easily fatigued or complain of nonspecific symptoms as the disease progresses. As cirrhosis develops, symptoms increase and may include weakness, weight loss, rash, and some mental disturbances such as confusion and lethargy.

#### Acute Hepatitis C

Acute hepatitis C refers to the first 6 months after infection with HCV although symptoms may appear within a day if infection was caused by any method of intravenous injection. Between 60% and 70% of people infected develop no symptoms during the acute phase. If infection was caused by direct access to the blood stream, the virus may cross the blood brain barrier 100 times more easily. In the minority of patients who experience acute phase symptoms, these are generally mild and nonspecific, and rarely lead to a specific diagnosis of hepatitis C. Symptoms of acute hepatitis C infection include decreased appetite, nausea, vomiting, fatigue, abdominal pain, itching, muscle aches, and fever, i.e., flu-like symptoms. Jaundice, a yellowing of the skin or eyes, is rare at this early stage of infection.

The hepatitis C virus is usually detectable in the blood by polymerase chain reaction (PCR) within one to three weeks after infection, and antibodies to the virus are generally detectable within three to 15 weeks. Spontaneous viral clearance rates are highly variable; between 10 and 60% of persons infected with HCV clear the virus from their bodies during the acute phase, as shown by normalization of the liver enzymes ALT and AST (aspartate transaminase), and plasma HCV-RNA clearance (this is known as spontaneous viral clearance). However, persistent infections are common and most patients develop chronic hepatitis C.

#### Chronic Hepatitis C

Chronic hepatitis C is defined as infection with the hepatitis C virus persisting for more than six months. Clinically, it is often asymptomatic, and it is mostly discovered accidentally (e.g. usual physical check-up).

The natural course of chronic hepatitis C varies considerably from one person to another. However, recent data suggest that among untreated patients, roughly one-third progress to liver cirrhosis in less than 20 years. Another one-third progress to cirrhosis within 30 years. The remainder of patients appears to progress so slowly that they are unlikely to develop cirrhosis within their lifetimes.

Once chronic hepatitis C has progressed to cirrhosis, signs and symptoms may appear that are generally caused by either decreased liver function or increased pressure in the liver circulation, a condition known as portal hypertension. Possible signs and symptoms of liver cirrhosis include ascites (accumulation of fluid in the abdomen), bruising and bleeding tendency, varices (enlarged veins, especially in the stomach and esophagus), jaundice, and a syndrome of cognitive impairment known as hepatic encephalopathy. Hepatic encephalopathy is due to the accumulation of ammonia and other substances normally cleared by a healthy liver.

Mean ALT and bilirubin levels of patients with hepatitis C are significantly lower than those of patients with HBV, but the extensive overlap of the ranges of elevation precludes identification of the type of viral hepatitis by the use of these assays. Usually prothrombin and albumin results are normal, but may become abnormal once cirrhosis has developed.

The levels of elevation of liver tests do not correlate well with the amount of liver injury on biopsy. Viral genotype and viral load also do not correlate with the amount of liver injury. Liver biopsy is the best test to determine the amount of scarring and inflammation. Radiographic studies, such as ultrasound or CT scan, do not always show liver injury until it is fairly advanced. However, noninvasive tests (blood sample) are coming, with FibroTest and ActiTest, respectively, estimating liver fibrosis and necrotic inflammation. These tests are

validated and recommended in Europe. FDA procedures have been initiated in U.S.

### Clinical Laboratory Testing for HCV

There are three major types of assays available for HCV testing: Enzyme Immunoassay (EIA), Western Blot or Recombinant Immunoblot Assay (RIBA), and Polymerase Chain Reaction (PCR).

Hepatitis C tests are used to screen for and diagnose a hepatitis C virus infection, to guide therapy and/or to monitor the treatment of an HCV infection.

An HCV antibody test is used to screen for infection. It detects the presence of antibodies to the virus, indicating exposure to HCV. This test cannot distinguish between someone with an active or a previous HCV. The HCV RNA test that detects viral RNA in the blood is used to determine if there is an active infection.

The following tests may be used to diagnose a current infection and to guide and monitor treatment:

- HCV RNA test. Qualitative test is used to distinguish between a current or past infection.
  - HCV Viral Load (HCV RNA test, quantitative) detects and measures the number of viral RNA particles in the blood. Viral load tests are often used before and during treatment to help determine response to therapy by comparing the amount of virus before and during treatment. Some newer viral load tests can detect very low amounts of viral RNA.
  - Viral genotyping is used to determine the genotype of the HCV present. There are 6 major types of HCV; the most common (genotype 1) is less likely to respond to treatment than genotypes 2 or 3 and usually requires longer therapy. Genotyping is often ordered before treatment is started to give an idea of the likelihood of success and how long treatment may be needed.
- Interpretation of the HCV screening and follow-up tests is in the following table:

HCV Antibody	HCV RNA	HCV Infection
Negative		No infection (or too early after exposure)
Positive or indeterminate	Negative	Past infection or no infection (false pos. screen)
Positive or weak	Positive	Current Infection

### Liver Biopsy

Liver biopsy is not necessary for diagnosis but is helpful for grading the severity of disease and staging the degree of fibrosis and permanent architectural damage. Hematoxylin and eosin stain and Masson's trichrome stain are used to grade the amount of necrosis and inflammation and to stage the degree of fibrosis. Specific immunohistochemical stains for HCV have not been developed for routine use. Liver biopsy is also helpful in ruling out other causes of liver disease, such as alcoholic liver injury, nonalcoholic fatty liver disease, or iron overload.

HCV causes the following changes in liver tissue:

- Necrosis and inflammation at the edge of the portal areas, so-called "piecemeal necrosis" or "interface hepatitis"
- Necrosis of hepatocytes and focal inflammation in the liver parenchyma
- Inflammatory cells in the portal areas ("portal inflammation")
- Fibrosis may exist in:
  - \* an early stage, being confined to the portal tracts
  - \* an intermediate stage consisting of expansion of the portal tracts and bridging between portal areas or to the central area
  - \* a late stage of frank cirrhosis characterized by architectural disruption of the liver with fibrosis and regeneration

Several scales are used to stage fibrosis. One common classification is a scale from 0 to 4 where stage 0 indicates no fibrosis; stage 1 indicates enlargement of the portal areas by fibrosis; stage 2 indicates fibrosis extending out from the portal areas with rare bridges between portal areas; stage 3 indicates many bridges of fibrosis that link up portal and central areas of the liver; and stage 4 indicates cirrhosis.

Assigning scores for severity, grading, and staging of hepatitis is helpful in managing patients with chronic hepatitis. The degree of inflammation and necrosis can be assessed as none, minimal, mild, moderate, or severe. The degree of fibrosis can be similarly assessed. Scoring systems are particularly helpful in clinical studies on chronic hepatitis.

### Treatment

Until new drugs were approved in May, 2011, in 2013, 2014, and 2015, the standard treatment for Hepatitis C was with peginterferon and ribavirin. This regimen required injections and had serious side effects.

In May 2011 the FDA approved Boceprevir (Victrelis, Merck & Co.) and Telaprevir (Incivek, Vertex Pharmaceuticals). Both drugs block an enzyme that helps the virus reproduce. If used alone the virus would become resistant. The drugs, given in addition to the standard treatments using the injected drug, peginterferon, and the pill, ribavirin, decreased resistance and increased effectiveness. The combination of the drug treatment increased the sustained virologic response rate to about 70%.

However, in late 2013 the FDA approved two new direct acting antiviral drugs, Sofosbuvir and Simeprevir. One or the other of these drugs, when used in combination with peginterferon and ribavirin, obtained sustained virologic response of 80-95% of patients.

Most recently, in late 2014 and in 2015, drug treatment regimens were approved, as follows: (see [www.hepmag.com/articles/2512\\_18756.shtml](http://www.hepmag.com/articles/2512_18756.shtml))

- Harvoni, a combination of sofosbuvir and ledipasvir cures 90% of genotype 1 hepatitis C in 12 weeks.
- Veikira Pac, a combination of ombitasvir, paritaprevir, and ritonavir plus dasabuvir pills cures over 95% in 12 to 14 weeks.
- Sovaldi plus ribavirin is used for Hepatitis C genotypes 2 and 3.

- In July 2015 delectasvir in combination with sofosbuvir was approved for treating genotype 3. These newer medications are super-expensive and may not be covered by some insurance. Other drugs are presently being reviewed.

#### Prevention

Hepatitis C virus can only be transmitted through blood transfer, but exposure to even small amounts of blood must be avoided:

- Never share needles
- Don't share personal care items
- Choose tattoo and piercing parlors carefully
- Practice safe sex
- Healthcare workers must take precautionary measures to avoid needle-stick injuries and avoid coming into direct contact with blood. Equipment used in drawing blood should be discarded safely or sterilized appropriately.

Recent investigations have shown that excluding blood from donors who are positive for d anti-HBcAg from the blood supply and use of third-generation anti-HCV testing has reduced the incidence of post-transfusion hepatitis C.

Vaccines and immunoglobulin products do not exist for prevention or treatment of hepatitis C. Development of immunization appears unlikely in the near future because these products would require antibodies to all the genotypes and variants of hepatitis C; however, some type of vaccine may eventually be developed.

#### HEPATITIS D

Hepatitis D virus was discovered in 1977 by Mario Rizzetto as a nuclear antigen in patients infected with HBV who had severe liver disease. Hepatitis D is a unique sub-viral satellite infection. It is a small defective RNA containing virus that cannot replicate independently, but requires the Hepatitis B antigen for replication. Individuals cannot contract HDV unless they have had hepatitis B or are co-infected with HBV and HDV. Modes of transmission of HDV are very similar to HBV infections. Each year approximately 7,500 individuals contract HDV, and chronic HDV infections are responsible for approximately 1,000 deaths in the United States. It is found throughout the world and is more prevalent in the Mediterranean area.

HDV requires the help of viral particles from HBV to replicate and infect other hepatocytes. It is believed that HDV infections occur through the binding of the HDV virion to the same cellular receptor as the HBV.

In general during the acute phase of the infection HDV carriers develop severe hepatitis and 70-80% progress onward to chronicity. Infection with HDV causes more severe disease than infection with HBV alone, including faster progression to liver cirrhosis and greater possibility of developing liver cancer. Hepatitis D combined with hepatitis B has the highest mortality rate of all hepatitis infections.

#### Hepatitis D Diagnosis:

Diagnosis of HDV relies on the detection of antibodies against hepatitis D antigen and serum HDV RNA, as well as HBV markers.

#### Hepatitis D Prevention:

There is no vaccine for hepatitis D but it can be prevented by giving hepatitis B vaccine to persons who are not infected by hepatitis B. Currently widespread use of the vaccine for hepatitis B has resulted in a decline in the incidence of hepatitis D.

#### Hepatitis D Therapy:

Interferon-a is currently the therapy in use for Chronic HDV infections, however hepatitis D requires a higher dose and the treatment period needs to be longer than for patients with hepatitis B.

#### HEPATITIS E

Hepatitis E virus (HEV) was first identified in 1955, in an outbreak in New Delhi, India.

HEV is a non-enveloped single stranded RNA containing virus. It is the sole member of the genus Hepevirus.

HEV is transmitted primarily by the fecal-oral route via water borne and food contaminated sources. The most frequent source of infection is fecally contaminated drinking water. Therefore HEV outbreaks are most common in developing countries. Outbreaks most commonly occur after heavy rainfalls and monsoons because of their disruption of the water supplies. At particular risk are people living in refugee camps and overcrowded housing after natural disasters. There have been some reports that the virus was isolated from wild pigs and deer, as well as some species of rats and there is the possibility of zoonotic transfer.

Symptomatic Hepatitis E is uncommon in the United States. Infected individuals usually have a history of travel to a country where hepatitis E is endemic. Nonetheless rare cases have been found in people who have no history of travel to endemic countries. Surprisingly recent studies have found a high incidence of antibodies to HEV in the general population in the U.S.

#### Symptoms of Hepatitis E

The clinical presentation of HEV is very similar to hepatitis A; however the severity of the infection is greater than HAV infections.

#### Hepatitis E Diagnosis:

Diagnosis of HEV infections relies upon the presence of IgM anti-HEV markers. There are EIA and immunochromatography assays available and there is an increased use of PCR assays for limited confirmatory roles. The incubation period for HEV is 21-42 days. The virus can be detected in bile and feces by about seven days after infection.

#### Hepatitis E Prognosis:

In most cases the infection is somewhat mild, but in pregnant women HEV can be very severe. Literature indicates that mortality can be up to 20% in pregnant females.

#### Hepatitis E Prevention:

Currently, there are no commercially available HEV vaccines approved for use in the United States.

## HEPATITIS G

Two viral agents related to hepatitis have been identified as G virus (HGV) and GB virus type C (GBV-C). Molecular characterization has shown them to be virtually identical. This virus has been detected worldwide and has been found in high prevalence in the U.S. It is common to find people with hepatitis C that are co-infected with GBV-C. The clinical significance is not well understood, but most evidence suggests that GBV-C does not cause hepatitis in humans.

## CONCLUSION

Viral hepatitis continues today as a major public health concern, but because of improvements in food handling, water purification, improved testing of donor blood, the use of vaccines, and new medications, the numbers of infections and deaths have diminished for most of the hepatitis types. The exception is Hepatitis C, whose incidence has increased in the past few years. Although there is no vaccination for Hepatitis C, newer medications offer hope of cure to those infected.

Hepatitis causes damage to the liver, an organ that is essential for life; however the use of new medications allows the liver time to recover from the infection in many cases. The increased use of clinical laboratory testing in the areas of antibody detection and polymerase chain reaction technology has given the healthcare provider new tools. With many new cases reported each year of the several different types of hepatitis with varying degrees of severity, it is important for laboratorians to understand how to interpret test results and report them appropriately.

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## REVIEW QUESTIONS

Course #DL 004

Choose the **one** best answer

1. All of the following are functions of the liver except
  - a. produces blood clotting factors
  - b. converts harmless chemicals into harmful ones
  - c. stores sugars, fats, and vitamins
  - d. manufactures enzymes and hormones
2. Hepatitis A
  - a. is called the long incubation hepatitis
  - b. was isolated by Purcell in 1973
  - c. occasionally develops into a chronic stage
  - d. is most commonly diagnosed by enzyme immune-assay (EIA)
3. Hepatitis A infection is spread through:
  - a. contact with blood
  - b. droplets from sneezing
  - c. fecal-oral pathway
  - d. coughing from infected individuals
4. Hepatitis A is a:
  - a. SS-DNA virus
  - b. DS-DNA virus
  - c. RNA virus
  - d. TLC virus
5. Methods of prevention of Hepatitis A include all except
  - a. good hand washing procedures
  - b. avoiding using contaminated needles
  - c. vaccination
  - d. avoiding high risk sexual behavior
6. Hepatitis B viral infection is frequently referred to by the name:
  - a. long incubation hepatitis
  - b. short incubation hepatitis
  - c. non A-non B hepatitis
  - d. infectious hepatitis
7. Hepatitis B virus is a:
  - a. picornavirus
  - b. hepadnavirus
  - c. flavivirus
  - d. calicivirus
8. Hepatitis B virus is spread through contact with:
  - a. body fluids
  - b. contaminated water
  - c. food
  - d. feces
9. One way to test the progression of hepatitis B viral infection is:
  - a. HPLC
  - b. atomic absorption
  - c. electron microscopy
  - d. polymerase chain reaction
10. One of the antiviral medications currently used to treat hepatitis viral infection is:
  - a. quinadine
  - b. peginterferon
  - c. laudinum
  - d. heptoplasmin

11. A patient is HBsAg negative, anti-HBc negative, anti-HBs positive. The most likely interpretation is:
- hepatitis B susceptible
  - immune due to hepatitis B infection
  - immune due to hepatitis B vaccination
  - chronically infected with HBV
12. In order for the vaccine for hepatitis B viral infection to be effective, a person needs to have how many injections of the vaccine?
- 1
  - 2
  - 3
  - 4
13. Hepatitis C viral infection is spread through contact with contaminated:
- saliva
  - food
  - water
  - blood
14. According to the course which hepatitis has shown an increase in incidence in the U.S. since 2009?
- hepatitis A
  - hepatitis B
  - hepatitis C
  - hepatitis D
15. Hepatitis C viral infection has an incubation period of:
- 1-2 weeks
  - 1-4 weeks
  - 2-15 weeks
  - 1-6 weeks
16. The newest treatment for patients with hepatitis C viral infection is:
- Harvoni
  - alpha and beta interferon
  - boceprevir
  - ribavirin and pegylated interferon
17. Patients with hepatitis D viral infections have had previous or are co-infected with:
- hepatitis A virus
  - hepatitis B virus
  - hepatitis E virus
  - non-A, non-B virus
18. Which of the following is not a mode of transmission of hepatitis E?
- contaminated blood
  - fecal-oral route
  - wild pigs that have been used for food
  - wild deer that have been used for food
19. In the United States hepatitis E most often occurs
- along with hepatitis G
  - in sporadic epidemics
  - in people who have returned from a developing country
  - in post-transfusion patients
20. A vaccine is not available for which type of viral hepatitis?
- hepatitis A virus
  - hepatitis B virus
  - hepatitis C virus
  - hepatitis D virus

**Record answers on answer sheet page 25.**

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DL-995	[ ] Hemolytic Disease of the Newborn [ B ]	DL-993	[ ] Coccidioidomycosis (Valley Fever) [ I ]	DL-990	[ ] Clostridium difficile 027 [ I ]
DL-992	[ ] Organ Specific Autoimmune Diseases [ I ]	DL-988	[ ] The Great Imposter – Lyme Disease [ I ]	DL-984	[ ] Cost Effective Clinical Microbiology [ I ]
DL-989	- Neutrophilia – available on CAMLT website only [ B ]	DL-986	[ ] Candida & its Role in Opportunistic Mycoses [ I ]	DL-980	[ ] E. coli O157:H7 Infection [ I ]
DL-987	[ ] An Update on Autoimmune Diseases [ B ]	DL-982	[ ] Chlamydiae & Their Role in Human Disease [ I ]	DL-974	[ ] Anaerobic Bacteriology for the Clinical Laboratory [ I ]
DL-985	- Hematology Case Studies/Platelets – on website only [ B ]	DL-979	[ ] Papillomaviruses & Cervical Cancer [ I ]	DL-968	[ ] Intro to HIV, HIV Infection & AIDS - 2014 [ B ]
DL-983	[ ] Prion Diseases [ I ]	DL-967	[ ] Thyroid Hormones and Thyroid Diseases [ I ]		
DL-976	[ ] Update on West Nile Virus [ I ]	DL-966	[ ] Cystic Fibrosis and Microbial Infections [ I ]		
DL-975	[ ] Megaloblastic Anemia [ I ]	DL-957	[ ] A Bacterial Carcinogen – Helicobacter pylori [ I ]		
DL-973	[ ] Hb A1c Testing of Patients with Hemoglobinopathies [ I ]	DL-956	[ ] Patty Pancreas [ I ]		
DL-965	[ ] Infectious Disease: A Gender Bias [ B ]	DL-950	[ ] Smallpox [ B ]		
DL-963	[ ] Patient Identification [ B ]	DL-906	[ ] Ergonomics – Intermediate Self-Study Package for Safety [ I ]		
DL-958	[ ] A Plague on U.S. [ B ]	DL-905	[ ] The Bug Everyone Has/ Epstein-Barr Virus Case Study [ B ]		
DL-954	[ ] Updated Review of Blood Collection Equipment [ B ]				
DL-922	[ ] Hematology Case Study/Hypochromic, Microcytic Anemia [ B ]				
DL-909	[ ] A Safety Plan for Laboratories [ B ]				

**DISTANCE LEARNING ORDER FORM – MEMBERS: \$12 PER CE UNIT | NON-MEMBERS: \$15 PER CE UNIT**  
 SUBMIT DISTANCE LEARNING ORDER FORM, WITH PAYMENT, TO: CAMLT | 39656 MISSION BLVD. | FREMONT, CA 94539

Name: (Please print) \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Day phone: \_\_\_\_\_

Preferred email address: \_\_\_\_\_ CA DPH License/Certificate #: \_\_\_\_\_

Method of Payment: [ ] Check [ ] VISA [ ] MasterCard

Card #: \_\_\_\_\_ Expiration Date: \_\_\_\_\_ 3-digit Security Code: \_\_\_\_\_

Signature (Required of all Registrants): \_\_\_\_\_



# DISTANCE LEARNING

(Home Study)

## Course Registration Form

&

## Answer Sheet

INSTRUCTIONS: Upon completion of one or more Distance Learning courses, answer the test questions using the answer sheet below. Copies of answer sheets are acceptable. Submit the following to CAMLT:

1. Signed Registration Form/Answer Sheet
2. Evaluation Form, and
3. Fee (member: \$12/CE unit  
non-member: \$15/CE unit)

MAIL TO: CAMLT  
39656 Mission Blvd.  
Fremont, CA 94539-3000

Please Print Clearly

Name: \_\_\_\_\_

Home Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_ Zip: \_\_\_\_\_

Home Tel: (\_\_\_\_) \_\_\_\_ - \_\_\_\_ X \_\_\_\_\_

Work Tel: (\_\_\_\_) \_\_\_\_ - \_\_\_\_ X \_\_\_\_\_

Employed at: \_\_\_\_\_

CDPH License/Certificate # \_\_\_\_\_

METHOD OF PAYMENT:

( ) Member ( ) Non-member

( ) Check Payable to: CAMLT  
(Returned checks subject to a \$20 fee)

( ) VISA or ( ) MasterCard (indicate card type)

Card #: \_\_\_\_\_ Exp. Date: \_\_\_\_\_

3 digit security code on back of card: \_\_\_\_\_

Signature: \_\_\_\_\_

Course Title: \_\_\_\_\_

Course Number: \_\_\_\_ - \_\_\_\_

SIGNATURE (REQUIRED FOR PROCESSING)

circle the one best answer

- |      |       |       |       |       |
|------|-------|-------|-------|-------|
| 1. a | 7. a  | 13. a | 19. a | 25. a |
| b    | b     | b     | b     | b     |
| c    | c     | c     | c     | c     |
| d    | d     | d     | d     | d     |
| 2. a | 8. a  | 14. a | 20. a | 26. a |
| b    | b     | b     | b     | b     |
| c    | c     | c     | c     | c     |
| d    | d     | d     | d     | d     |
| 3. a | 9. a  | 15. a | 21. a | 27. a |
| b    | b     | b     | b     | b     |
| c    | c     | c     | c     | c     |
| d    | d     | d     | d     | d     |
| 4. a | 10. a | 16. a | 22. a | 28. a |
| b    | b     | b     | b     | b     |
| c    | c     | c     | c     | c     |
| d    | d     | d     | d     | d     |
| 5. a | 11. a | 17. a | 23. a | 29. a |
| b    | b     | b     | b     | b     |
| c    | c     | c     | c     | c     |
| d    | d     | d     | d     | d     |
| 6. a | 12. a | 18. a | 24. a | 30. a |
| b    | b     | b     | b     | b     |
| c    | c     | c     | c     | c     |
| d    | d     | d     | d     | d     |

## Distance Learning Evaluation Form

This evaluation form **MUST BE RETURNED TO CAMLT** along with your review questions. Your comments help us to provide you with better continuing education materials in the home study format. We welcome and encourage any additional comments. Please respond to the following statements by circling the number that agrees with your assessment of the statement with "5" meaning you strongly agree, "4" meaning you agree, "3" meaning you have no opinion, "2" meaning you disagree and "1" meaning you strongly disagree.

1. Overall, I was satisfied with the quality of this course.  
5 4 3 2 1
2. The objectives of this course were met.  
5 4 3 2 1
3. Difficulty was consistent with the no. of CE hours.  
5 4 3 2 1
4. I will use what I learned from this course.  
5 4 3 2 1
5. It took me \_\_\_\_\_ hours to complete this course.
6. What did you like or dislike about this program?



# California Association for Medical Laboratory Technology Membership Application

### Personal Information:

Name \_\_\_\_\_

Check one: ( ) Ms. | ( ) Mrs. | ( ) Mr. | ( ) Dr.

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_ Zip \_\_\_\_\_

LFS License/Certificate # \_\_\_\_\_

Day Phone \_\_\_\_\_

### Preferred Email address:

Check here to opt out of email list

### Employment Information:

Employer \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_ Zip \_\_\_\_\_

Work Phone \_\_\_\_\_

CAMLT asks you to contribute to one or both of these worthwhile entities:

#### LAB-PAC

The CAMLT Political Action Committee helps your association advocate on behalf of you and your profession. Help support quality clinical laboratory medicine in the California legislative arena.

*LAB-PAC contributions are NOT tax deductible.  
You must be a U.S. citizen to donate.*

#### Education and Research Foundation

Your tax deductible contribution supports scholarship programs, outreach efforts and students pursuing careers in the clinical laboratory sciences.

Separate checks should be enclosed for each of these worthy causes.

Applicants are considered for membership in the category which meets their maximum qualifications.

I declare that in making application for membership, I have met the qualifications listed for the category to which I am applying.

Applicant Signature \_\_\_\_\_

Recruiter (if known) \_\_\_\_\_

#### CAMLT's new address as of July 10, 2015:

39656 Mission Blvd., Fremont, CA 94539  
Scan/email to: office@camlt.org  
Fax to: 510-792-3045 Voice Phone: 510-792-4441

### Membership Categories:

Active - \$120 annually

An individual who 1) Holds a license or certification in a clinical laboratory profession issued by the California Department of Public Health or 2) Holds a baccalaureate degree from an accredited college or university and is eligible to sit for a CDPH approved examination; or 3) Holds a Masters or Doctorate degree in science, education or administration and is actively employed in clinical laboratory science.

Collaborative - \$65 annually

An optional special non-voting, non-office holding membership category open to licensed Medical Laboratory Technicians or Certified Phlebotomy Technicians, who desire to support the association. All other membership benefits are afforded. These members are also eligible to apply for active membership if they desire to vote and/or hold office in the association.

Associate - \$75 annually

An individual who has an interest in the field of clinical laboratory science and/or supporting the purposes or goals of CAMLT, but is not otherwise eligible for membership.

Student - \$10 annually

An individual who possesses a valid training license from Laboratory Field Services or who is enrolled in an LFS approved program leading to licensing as a CLS, or MLT or certification as a CPT. Students at accredited universities or colleges that lead to eligibility for licensure or certification from LFS are also eligible to join as student members.

Lifetime - \$1250 one time fee

Meets Active member requirements and submits the one time application fee.

20/20 Option - Additional \$20 annually

An additional \$20 payment at the time of application or renewal entitles the member a 20% discount on CAMLT state sponsored C.E. fees for the year (not applicable to Distance Learning).

Membership Dues \_\_\_\_\_

20/20 Option \_\_\_\_\_

**Total payable to CAMLT** \_\_\_\_\_

LAB-PAC Contribution (separate check) \_\_\_\_\_

E & R Foundation Donation (separate check) \_\_\_\_\_

AUTOMATIC RENEWAL AVAILABLE! You now have a convenient new option to pay your CAMLT membership dues!

Automatic renewal: Credit card listed will be charged on the renewal date each year for the same member category. Notice of renewal will be sent fifteen (15) days before the charge is entered to allow for changes in member category or updates to credit card information.

Sign here to enroll for the automatic renewal option: \_\_\_\_\_ Date: \_\_\_\_\_

Checks to: CAMLT, LAB-PAC and/or E & R as appropriate - OR -

Credit Card Payment:  Visa  Master Card

Card# \_\_\_\_\_ Exp. \_\_\_\_\_

Three-digit security code (on back of credit card): \_\_\_\_\_

Date \_\_\_\_\_ Signature \_\_\_\_\_

# 2016 CONTINUING EDUCATION CALENDAR

Program planning in progress  
Watch [www.camlt.org/calendar](http://www.camlt.org/calendar) for details

March 5	Eastland and Foothill Chapters' Spring Symposium City of Hope, Duarte
March 5-6	Tulare/Kings Chapter Seminar Visalia
March 12-13	Fresno Chapter Seminar Fresno
March 19-20	Spring Seminar South Kaiser Regional Laboratory, North Hollywood
April 16-17	Spring Seminar North UC Davis Medical Center, Sacramento
September 16-18	CAMLT's 77 <sup>th</sup> Annual Meeting, Exhibits & Workshops Pasadena Hilton



## Power Through Professionalism!

77th Annual Meeting and Exhibits

September 16-18, 2016  
Pasadena Hilton

WANT MORE INFORMATION? CONTACT:

TEL: 510/792-4441

FAX: 510/792-3045

WEBSITE: [WWW.CAMLT.ORG](http://WWW.CAMLT.ORG)

CAMLT EXECUTIVE OFFICE  
39656 Mission Blvd.  
FREMONT, CA 94539-3000