

# Lab Updates

July 2008

An archive of *Lab Updates* is posted on Our Net or external web site: <http://www.ummlabs.org>



## Inside this issue:

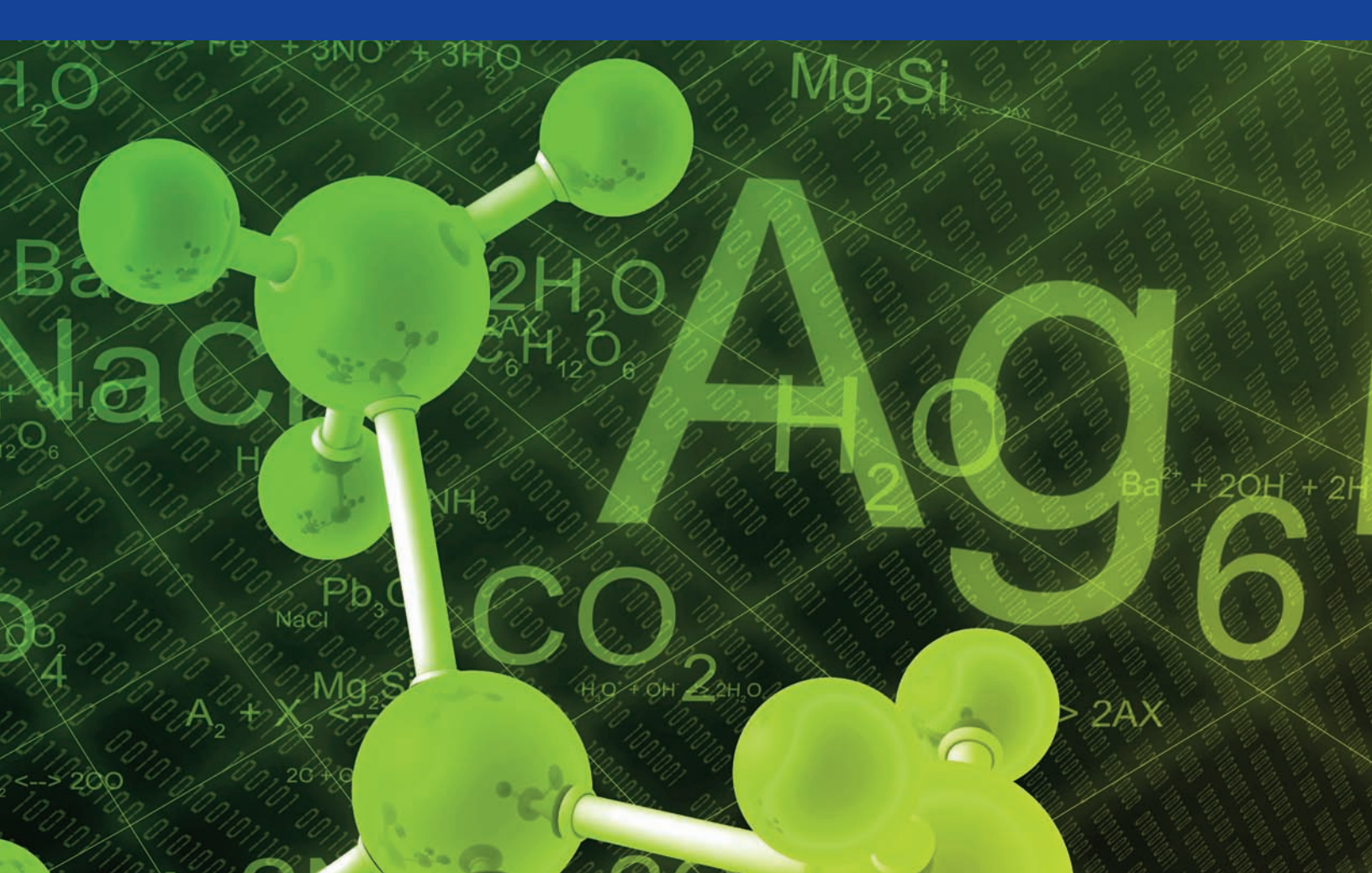
Laboratory Document  
Control Center

Malaria Update

Featured Patient Service Center

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## Laboratory Document Control Center

### UMass Memorial Medical Center Laboratories

One Biotech Park, Suite 200  
365 Plantation Street  
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FAX: 508-334-4210  
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Medical Center customer liaison*

**Betsy Harder**  
*Sr. Director, Lab Outreach Program  
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**I**N THE PAST, UMMMC LABORATORIES, like most clinical labs, maintained regulatory compliance by using manual paper-based systems for document control. This labor intensive process required navigating hundreds of standard operating procedures in many directions for yearly approval. It was a challenge to maintain communication and retrieval of the most up to date documents for 600 staff located at multiple sites.

In an effort to improve quality and efficiency, in January 2008, UMMMC Laboratories began implementation of MasterControl Software, an electronic document control solution with the following core capabilities:

- Automated routing, revision control, approval, archival of documents
- Ensures documentation integrity so employees always have the most updated document
- Full audit trail and reporting
- Electronic signature management control
- Ensures 21 CFR Part 11 compliance with security and integrity of documents
- Web-based, accessible to all authorized users from virtually anywhere

According to the College of American Pathologists CAP Standard–GEN.20375 Phase II, the Document Control System will assure

1. All copies of policies and procedures are current
2. Personnel have read the policies/procedures relevant to their job
3. All policies/procedures have been authorized by the laboratory director
4. Policies and procedures are reviewed at least annually by the laboratory director or designee
5. Discontinued policies/procedures are archived in a separate file for a minimum of 2 years after the date of discontinuation (5 years for Transfusion Medicine)



## Laboratory Document Control Center

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UMMMC, Laboratories

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## Life Cycle of a Document

### Automated / Electronic Approval Process (NEW)

The "Document Lifecycle" is the electronic process documents follow throughout the system for their creation, revision and archiving.  
Understanding this Lifecycle determines where any document is in its "life" or process.  
- 2006 MasterControl®

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## Life Cycle of a Document

### Typical Manual Process

*"Ideally, a policy that outlines processes, responsibilities and delegations, and compliance requirements should be available and followed..."*  
- William Castellani, MD, FCAP Inter-Regional Commissioner Laboratory Accreditation Program September 19, 2007

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## Life Cycle of a Document

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Currently, UMass Memorial Laboratories Managers and Directors have built all 600 users and over 1000 standard operating procedures in the Document Control Center. A CAP inspection in May 2008 was a success, in part, to this new program. In Summer 2008, all staff will be trained and will be using the new system.

Overall, The Document Control Center has assisted our laboratory team to assure regulatory compliance, efficiency and hold compliance costs down.

The next step includes implementation of a Training Module that links released documents to performance validation automatically.

**Reference:**

**Clinical and Laboratory Standards Institute.** *Laboratory Documents: Development and Control; Approved Guideline–5th Edition* [CLSI GP2-A5]; Wayne, PA 2006

**ISO/IEC 15189:2007.** *Medical Laboratories–Particular Requirements for Quality and Competence*

**Code of Federal Regulations.** *Title 21–Food and Drugs: Chapter I–Food and Drug Administration, Part 11–Electronic Records; Electronic Signatures* [21 CFR 11]

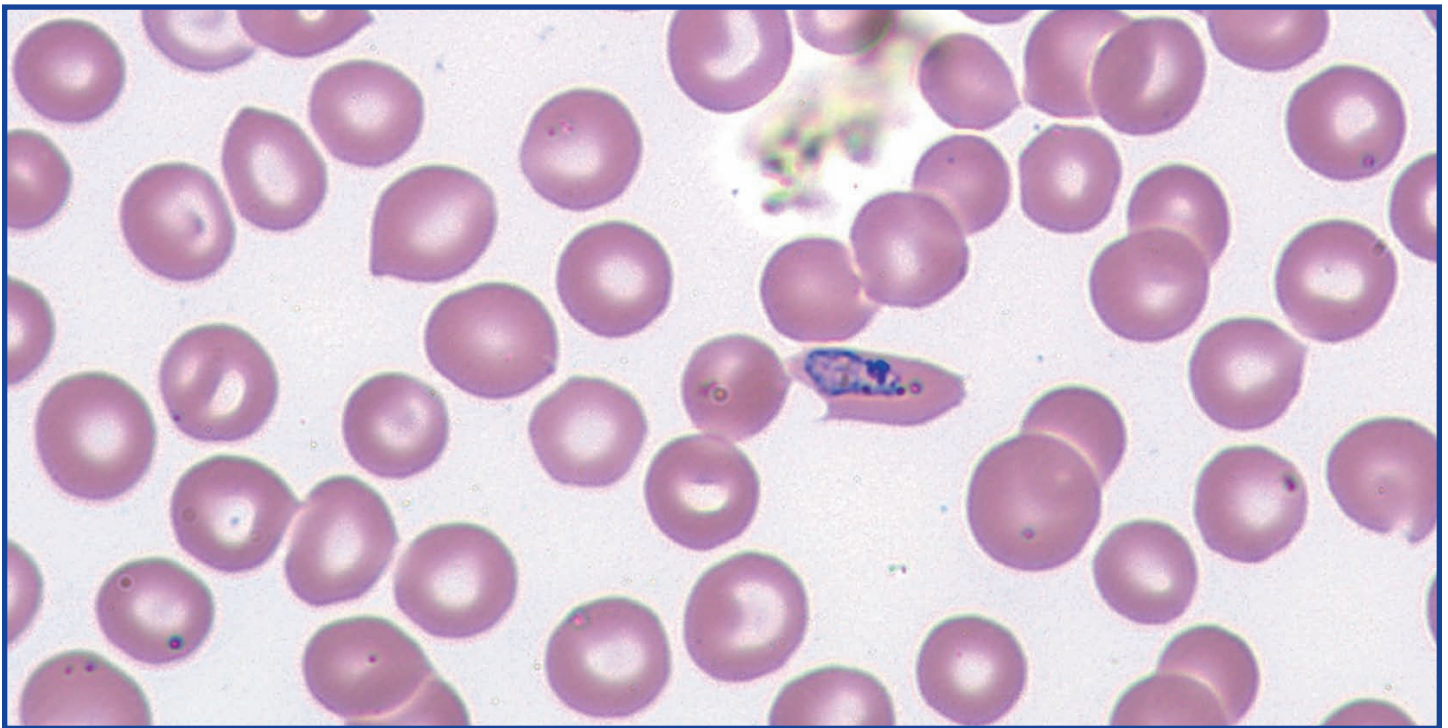
**CAP– General Checklist Sep07**

**Master Control® Software–Training Program Jan08**

*If you have questions, comments or suggestions, please contact:*

Angela Nardella, Manager, Regulatory Affairs at 508-334-2827  
or via email at [Nardella@umhmc.org](mailto:Nardella@umhmc.org)





## Malaria

Malaria is one of the oldest diseases known to mankind. References to malaria-like illness date back to writings almost five thousand years old. It is assumed that malaria was introduced into the Americas by Europeans, and the disease became endemic in North America as far north as Canada. The range in North America gradually declined so that there was no longer endemic disease in the US by the middle of the 20th Century. Though endemic disease no longer occurs in our country, at present, malaria parasites cause more deaths than any other infectious disease world-wide.

The vast majority of cases of malaria are due to intra-erythrocytic infection by four *Plasmodium* species: *P. falciparum*, *P. vivax*, *P. ovale* and *P. malariae*. The laboratory test for malaria diagnosis is the Blood Parasite Examination (mnemonic=BP). (The Blood Parasite Examination is also used for the diagnosis of *Babesia*, *Trypanosoma* and *Microfilaria* infections.) In most labs, these infections are diagnosed by microscopic inspection of peripheral blood smears. Because malaria, especially falciparum malaria, may be associated with rapid clinical deterioration, and even death, a Blood Parasite Examination should be ordered STAT for initial diagnostic studies in patients with a high clinical risk for malaria. (Major signs and symptoms of malaria include fever and chills, splenomegaly and anemia, without other cause, in a patient with recent travel history to an endemic area.)

EDTA anticoagulated blood should be submitted for malaria diagnosis. Because the number of circulating parasites may vary significantly on a day-by-day basis, specimens should be collected on each of three successive days. We recommend that blood be collected every six to eight hours (until positive) for optimal detection in suspected cases. In patients in whom malaria is diagnosed, blood should be re-examined 24, 48 and 72 hours after initiation of therapy in order to document the effectiveness of therapy. In successfully treated patients, the level of parasitemia (i.e., the percentage of erythrocytes infected) should drop very quickly. In patients with drug resistant parasites, the level may remain stable, or even increase.

In the past year, UMassMemorial Laboratories performed a Blood Parasite Examination on 299 specimens. Just over 10% of specimens were positive for a blood parasite; five patients were diagnosed with falciparum malaria, three with vivax malaria and two with *Plasmodium* infection. During this period, two patients were diagnosed with babesiosis. The Figure above shows a blood smear demonstrating two *Plasmodium* infected Red Blood Cells recently identified in our laboratory.

If you have questions, comments or suggestions, please contact:  
Dr. Michael Mitchell, Director, Microbiology Laboratory,  
508-334-7160 or via email at [MitchelM@ummhc.org](mailto:MitchelM@ummhc.org)

# New Patient Service Center

We are one of the largest laboratory providers in New England

UMass Memorial Laboratories has opened a Patient Service Center (phlebotomy draw station) at 139A Hazard Ave., Building #4, Suite 15, Enfield, CT.

The vision of UMass Memorial Laboratories is:

- To be a leading provider of laboratory services throughout New England, meeting the needs of patients and providers in the region, and
- To be one of the top ten academic medical center-based laboratories in the United States



## ***Enfield PSC*** ***139A Hazard Avenue, Building #4,*** ***Suite 15, Enfield, CT***

The Enfield PSC is located at 139A Hazard Ave., Enfield, CT. The hours are Monday through Friday 7:30am-4:30pm, closed 12:15-1:15pm. The phone number at the Enfield PSC is 860-763-0136.

*Providing a higher level of service.  
If you don't believe it, put us to the test!™*



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