New York State Histotechnological Society

On Stage

Volume 31, Issue 1 Winter 2012

Utilization of FISH on FFPE tissue sections as a valid clinical test

By: Linda Barenboim
Cancer Genetics, Inc

Although histology has existed since the late 19th century, aiding pathologists in the accurate diagnosis of cancer and other diseases, modern day techniques surpass the typical cytology stains of the past. Today a technician can take a previously H&E stained slide and re-use it to determine the genomic compliment of the cells of interest.

Formalin fixation of whole tissues was established as a method to alter the cells on a molecular level to increase their mechanical strength so as to preserve the tissue morphology. Having these fixed tissues embedded in paraffin (FFPE) makes it easier to examine this preserved tissue on a microscopic and even molecular level. Slides derived from FFPE tissue can be treated to aid in the determination of the presence of specific immunologic biomarkers. Immunohistochemistry (IHC) is widely used to understand the distribution and localization of differentially expressed proteins. In cases of certain cancers, specific expressed proteins can be identified using IHC stains. These proteins are sometimes a by-product of a genetic aberration. For example, Her2 is a protein found on the surface of a certain subset of breast cancer cells. Some breast cancer cells have a lot more Her2 receptors than others and can be easily distinguished using IHC. The actual genetic aberration that causes the overexpression of Her2 is the amplification of the *Erbb2* gene [1] [2], presenting itself often as a tandem repeat on chromosome 17 as can be seen using fluorescence in situ hybridization (FISH). The advantage of FISH is being able to detect the primary rearrangement whereas IHC targets the expressed protein. There are cases of early lesions that contain small populations of cells with clonal genomic rearrangements which are difficult to evaluate with IHC [3]. Companies like Abbott are meeting the demands for this FISH probe in their PathVysion kit which is targeted for use on breast FFPE specimens.

FISH is a widespread technique that has evolved over the last few decades from a research tool to a valuable aid in the clinical setting. Based on the same principle as Southern blot analysis (the ability of single-stranded DNA to anneal to complementary DNA), FISH probes hybridize to the specimen detecting specific genetic changes with high sensitivity and specificity in each individual cell. Its advantage over traditional cytogenetic methods is that it allows for the visualization of these specific aberrations in both dividing and non-dividing cells. In the case of certain hematologic malignancies FISH surpasses classic cytogenetics by unmasking genetic alterations, occurring at the molecular level, in those malignant cells for which no metaphase spreads could be isolated [4]. There are several different types of FISH probes; they are locus-specific probes which aid in the determination of amplifications and deletions of specific genetic loci. There are also dual-fusion and

(Continued on page 9)

On Stage is published quarterly by the New York State Histotechnological Society for its membership. Contributions, suggestions and advertisements are welcome. Please visit the NYSHS website for submission information and guidance. Permission to reprint is granted as long as source and author are acknowledged and a copy of the reprint is sent to the editors. Articles without bylines are written by the editors. Please submit manuscripts to the editor-in –chief.

Deadlines for Submission are:

September 1 - Fall

December 1 – Winter

March 1 - Spring

June 1 - Summer

Membership in the New York State Histotechnological Society, includes a subscription to *On Stage*. The annual membership fee is $20.00. Please direct membership inquiries to:

nyshsmembership@yahoo.com

Inside this issue:

Warm wishes to all at the start of a New Year!

2012 is shaping up to be a great year for NYSHS. We have lots planned and are well on our way to having a great Region 1 meeting on Long Island in April. Check out the save the date flyer in this issue. We are offering a wide range of lectures, seminars and workshops with over 20 CEU available. The program and registration will be in the mail soon. We are hosting our second Career Day at this meeting. With the help of vendors, Board Members and Students from SUNY Cobleskill, we hope to have a great turn-out and inspire some high school kids to choose a career in the histology field. Region 1 also offers great scholarships so that individuals can fund their way to meetings in the region and beyond. I am proud to announce that the Region 1 Board of Directors unanimously agreed to rename one of the scholarships in honor of Charles Churukian the long time NYS, Region 1 and NSH member. Long known as the "guru of special stains", Charles passed away last year but his memory will live on with this wonderful award.

The new website has gotten excellent reviews and comments from the membership. We are constantly updating the site with info and forms to speed the process and minimize the work involved in conveying valuable and timely information to you. The most recent announcements are posted on the home page and then archived on the announcements page. We also have provided an "RSS feed" so that you can review announcements or posts directly from your web browser without having to visit the site. The Yahoo message board also continues to grow with over 200 subscribers and over 50 message posts per month. All of this information is compiled and made available on the website or thru the message board for you, so please spread the word to your colleagues and co-workers. There will be plenty of updates to come so please stay tuned.

In the meantime, we hope to see you in April on long Island and that you all have a prosperous and happy new year.

Call for Nominees for NYSHS Elections

The Election Committee is now accepting nominations for the following positions for the 2012 NYSHS elections:

President
Corresponding Secretary
Membership Secretary
3 Members of the board of Directors

The call for nominations will close at the end of the general membership meeting to be held at the 2012Region 1 Symposium in Islandia, New York. For more information please visit the NYSHS website.

To be eligible to serve as an officer or board member, the nominee must be a member of NYSHS for at least one year and currently in good standing. Please be sure that before nominating a member, that they are willing to serve the Society for a minimum of a 2 year term and confirm that they will accept the nomination.

Individuals who accept the nominations must provide a CV/resume and write their own bios for the balloting process and submit them in a timely fashion to the nominations chair. Please limit biographies to a brief paragraph. Bios and ballots for the election will be sent out in May 2012

If you would like to nominate someone, please fill in the nomination form on the next page and send it to the nominations chair by snail mail.

Additional digital nomination forms are available on the NYSHS website:
http://www.nyhisto.org/

NYSHS ELECTION NOMINATION FORM

The Nominations Chairperson is accepting nominations for this year's elections. To view the open positions, please visit the website at

http://www.nyhisto.org/

To be nominated, an individual must be a member of NYSHS for at least one year and currently in good standing. They should have expressed a willingness to serve the society.

If you would like to nominate someone, please fill in the nomination form below.

I _____ nominate

_____ For the NYSHS office of:

_____

He/She has been a member of NYSHS for at least one year and is currently in good standing. He/She has also expressed a willingness to serve the society.

Nominator's Signature_____

NOMINATIONS MUST BE RECEIVED NO LATER THAN

THE CLOSE OF THE ANNUAL MEETING

Please return completed forms by email or snail mail to:

Nominations Chairperson:

Kate Caleri
57 Azalea Drive
West Seneca NY 14224
kathleen.caleri@roswellpark.org

Upcoming Events Posted on NYSHS Message Board

Date	Time	Event	Type
1/20/2012	6:00 am	Call for Region 1 Award Noimnees (litepath2000)	Club Event
1/25/2012	12:00 pm	NSH Teleconference: Assessment of HER2 (c-erbB2) Status (litepath2000)	Net Event
2/22/2012	12:00 pm	NSH Teleconference: Success or Failure of Implementing New Equipment (litepath2000)	Net Event
2/28/2012	All Day	Region1/NYSHS: Hotel Reservation Reminder (litepath2000)	Appointment
3/1/2012	12:00 am	Deadline for Submission: Onstage Spring Issue (litepath2000)	Club Event
3/1/2012	All Day	Region1/NYSHS Vendor Reminder (litepath2000)	Appointment
3/10/2012	All Day	Annual Histotechnology Professionals Day ! (litepath2000)	Vacation
3/23/2012	All Day	USCAP 101st ANNUAL MEETING (litepath2000)	Meeting
3/24/2012	All Day	RISH'S CARNIVAL MARDI GRAS CONFERENCE! (litepath2000)	Club Event
3/24/2012	All Day	USCAP 101st ANNUAL MEETING (litepath2000)	Meeting

Showing 1 - 10 of 35

Histotech Spotlight:

Lilian Antonio HTL, BSMT, MPH

By Linda Chen, HT

New York Presbyterian Hospital

Lilian Antonio is currently the Histology Supervisor at New York Presbyterian Hospital and has over 20 years of experience as Histology Supervisor since starting out at Mount Sinai Hospital in Manhattan. She has had numerous publications including contributions to *Histologic* as well as co- authoring pathology text books. Lilian's background is in medical technology and she was a laboratory instructor in blood bank, serology, microbiology, histopathology and chemistry in the 1970's. She has given lectures in statistics and histo-embryology. Her hobbies include stamp and coin collecting as well as arts and crafts.

How did you first become interested in the field of Histotechnology?

-In 1978, an opportunity presented itself for me to set up a Histopathology laboratory in Ogun State, Nigeria from the ground up and being of MT background, I felt that it was a challenge that I could not pass up. As I set up the laboratory, I became interested in the diversity of the field and began to specialize in histology.

What would you consider the most rewarding part of being in this field?

-The opportunity to develop innovative new techniques and passing them to others and seeing the techniques in practice towards accurate diagnosis and improved patient care.

What would you consider the most challenging part of your job as supervisor of a busy, high volume laboratory?

-Managing the people of the laboratory. Like the ten fingers of our hands, not one person is the same as the other within the lab. I have learned over the years that delegating responsibilities, inclusion of personnel, and positive reinforcement can go a long way…and sometimes, a little candy doesn't hurt either.

(Continued on page 8)

What are your thoughts on the New York state requirement of licensure in order to practice Histology?

-It is a positive way for the field of Histology to be deemed a profession and Histotechs recognized as Professionals. It also in some ways "standardized" the quality of slides being produced by making sure that the tech behind the slide is not only trained with adequate techniques, but has the education to understand the theories behind them as well.

What major changes in the field do you think have had the greatest impact on your career?

-We would have to start with automation. The automation of the stainers, microtomes, and coverslipper has allowed consistent quality slides to be produced while reducing the risk of repetitive motion damage to the histotech. The growth in immunohistochemistry and molecular histology have also advanced this field by leaps and bounds. Growth in these sub-fields have allowed me to experience and learn new techniques.

What's new in histology that you are most excited about?

-Digital Pathology. The fact that a pathologist can read a slide thousands of miles away from the patient and provide an expert opinion and diagnosis is very exciting. Patients can now have a "team" of experts from possibly all over the world read their slides and in the long run provide better patient care.

What changes would you like to see in the future of histotechnology?

-A more eco-friendly laboratory. I would like to see more effective "greener" chemicals that have a low impact on the environment. I hope to see an overall reduction in hazardous waste in daily operations of a high volume laboratory. I am hopeful that more recyclable materials will be used in the making of general histology lab supplies such as disposable molds, and the packaging of stain kits, etc.

-The "error free" laboratory. No more mislabeled specimen, blocks, or slides. I am hoping that AB&T will help resolve some of these issues and prevent future errors in diagnosis, and that we will no longer hear on the news that a patient had have unnecessary surgery due to a "lab" error.

How has the field of histotechnology become a "family" affair for you?

-My eldest daughter is currently working in a histology laboratory in NJ. She became interested in histology while visiting me at Mt Sinai (she was working there as well, in the BioMed dept). She was interested enough to go back to school, obtain her ASCP certification, and sacrificed her Saturdays so I could train her on the bench. She enjoys the field and has been encouraging her sister to join in on the fun. My youngest daughter will be enrolling in a histology certification program hopefully next year.

What is the one advice you would give to future histotechs?

-Always keep learning. Having practiced histology on three continents has shown me that education is the key. If given the opportunity, educate yourself: attend seminars, continue the pursuit of a higher degree, learn all the theoretical background information, and get all the technical bench experience you can get. The field of histology is continuously evolving into so many exciting branches that it will continue to challenge anyone who enters the field.

A special thanks to Lilian for taking time out of her busy schedule to offer her insights to the field!

(Continued from page 1)

break-apart probes, both aimed at the evaluation of specific chromosomal translocation using differing probe configurations.

It is well known that certain recurrent cytogenetic abnormalities are the hallmark of some subtypes of mature B -cell lymphomas. The presence of t(14;18)(q32;q21) is the hallmark of follicular lymphoma (FL), observed in 80-90% of cases, which distinguishes it from other B-cell malignancies, such as mantle cell lymphoma (MCL) [3, 5]. The specific rearrangement t(14;18)(q32;q21) describes the translocation of the *IGH* and *BCL2* genes. One can use a dual-fusion FISH probe designed specifically for the visualization of the t(14;18), which yields a yellow fusion signal only in the presence of a translocation. However, this same rearrangement can be visualized using a break-apart probe for *IGH* which in a normal cell would yield a yellow fusion signal or in the case of a translocation would appear as individual red and green signals present on separate chromosomes. Performing FISH on FFPE specimens allows the clinician to determine the presence or absence of specific genetic aberrations in cells whose tissue architecture is preserved as well as opening the door to the utilization of a greater variety of tissue types, including solid tumors. A pathologist now just circles the area of interest on an H&E stained slide thus selecting a subgroup of cells that may have specific genetic aberrations that can be evaluated by FISH.

The ability to assess the genetic aberrations in FFPE specimens has a great potential in the diagnosis of Non-Hodgkins Lymphoma (NHL). In the case of NHL there is a variety of malignancies that are difficult to distinguish using histology alone therefore FISH is a valuable adjunct test [3]. FISH probes such as *BCL6* break apart and *IGH* break apart can be used on clinical NHL FFPE specimens. The same technology can also now be applied to solid tumors, as in the case of the *ALK* FISH probe for use in lung cancer patients. *ALK* translocation is observed in approximately 5% - 16% of non-small cell lung cancer (NSCLC) cases in the form of an inv(2)(p21p23) as determined by FISH and serves as a biomarker for response to therapy [6]. As technology continues to develop the utility of FISH on FFPE specimens broadens accordingly. There have been groups developing an automated FISH scanning system to use on nuclei that have been extracted from FFPE [7] as well as tissue microarrays containing archival FFPE tissue [8]. The utility of FISH on FFPE specimens continues to be a valuable adjunct test in the clinical setting.

References

1. Kallioniemi, O.P., et al., *ERBB2 amplification in breast cancer analyzed by fluorescence in situ hybridization.* Proceedings of the National Academy of Sciences of the United States of America, 1992. **89**(12): p. 5321-5.
2. Fukushi, Y., et al., *Detection of numerical aberration in chromosome 17 and c-erbB2 gene amplification in epithelial ovarian cancer using recently established dual color FISH.* European journal of gynaecological oncology, 2001. **22**(1): p. 23-5.
3. Heim, S. and F. Mitelman, *Cancer cytogenetics*. 3rd ed2009, Hoboken, N.J.: Wiley-Blackwell. x, 736 p., 4 p. of plates.
4. Kearney, L., *The impact of the new fish technologies on the cytogenetics of haematological malignancies.* British journal of haematology, 1999. **104**(4): p. 648-58.
5. Huret JL, D.P., Bernheim A. *Atlas of Genetics and Cytogenetics in Oncology and Haematology*. 2004; Available from: http://AtlasGeneticsOncology.org.
6. Camidge, D.R., et al., *Anaplastic lymphoma kinase gene rearrangements in non-small cell lung cancer are associated with prolonged progression-free survival on pemetrexed.* J Thorac Oncol, 2011. **6**(4): p. 774-80.
7. Reichard, K.K., et al., *Automated analysis of fluorescence in situ hybridization on fixed, paraffin-embedded whole tissue sections in B-cell lymphoma.* Modern pathology : an official journal of the United States and Canadian Academy of Pathology, Inc, 2006. **19**(8): p. 1027-33.
8. Ye, H., et al., *Chromosomal translocations involving BCL6 in MALT lymphoma.* Haematologica, 2008. **93**(1): p. 145-6.

Validation in the IHC Laboratory

By: George Hoernig HT(ASCP)QIHC

Biocare Medical

Regulatory agencies are now requiring the validation of new antibodies, protocols, and platforms. Validation protocols should contain an adequate number of positive and negative cases, and determining that number can be difficult. Certain regulatory agencies require a prescribed number of cases to be validated and concordance recorded to become certified to run FDA Approved tests (HER2/*neu*), while other procedures are left to the discretion of the Laboratory Director. The College of American Pathologist published their new guidelines on July 11, 2011, and in the new guidelines there are questions relating to validation, not only in the Anatomic Pathology section, but also in the Molecular section.

CAPANP-22750: Antibody Validation

The laboratory has documented validation of new antibodies, prior to use in patient diagnosis.

CAP MOL. 30785 Validation Studies

LDTs or Modified FDA-Approved/Cleared Tests Phase II

There is documentation that the laboratory has performed analytic validation studies to establish the performance characteristics (including accuracy, precision, reportable range, reference range, analytic sensitivity, and analytic specificity) of laboratory-developed tests, when applicable.

MOL.31130 Validation Study Comparison

The results of each validation study are compared to another valid assay, such as comparison to another test method or specimen exchange with a laboratory performing the same type of test.

Whenever there is a question regarding validation studies no matter where in the questionnaire they have to be addressed and you need to be in compliance, keep in mind there may be some questions in the general section that could pertain to validation or IHC in general.

When talking validation the question on everyone's mind is, what is an adequate validation study? Unfortunately there are no hard recommendations on what is considered an adequate number of cases to run for each antibody. The notes for CAP ANP.22750 state "The scope of the validation is at the discretion of the laboratory director and will vary with the antibody. For a well-characterized antibody with a limited spectrum of antigenic targets, like chromogranin or prostate specific antigen, the validation can be limited. A panel of 10 positive and 10 negative neoplasm's would be sufficient in this setting. For an antibody that is not well characterized and/or has a wide range of reported reactivity, a more extensive validation is necessary. The number of tissues tested should in this circumstance be large enough to determine whether the staining profile matches that previously described, an exception to the above requirements is that studies may not be feasible for antigens such as ALK that are only seen in rare tumors." As you can see they do give a number but they preface by saying the scope of the validation study is at the discretion of the laboratory director. They also mention different type of antibodies will have different numbers of cases based on the range of targets labeled as well as the acceptance of the antibody as a "routine" marker for diagnosis. If for instance you bring in Neuron Specific Enolase, which labels a wide variety of antigenic sites but has been well publicized your validation study would be less exten-

(Continued on page 13)

New York State Legislative Update

Amy Farnan Legislative Chair
Albany Memorial Hospital

The New York State Education Department (SED) is nearing the end of the grandfathering period for licensure in New York State. The growing pains of this process continue as there are a number of individuals trying to meet the education requirement deadline by Sept. 2013. Many are looking for educational avenues to fulfill the necessary requirement for licensing eligibility.

There are a number of individuals within and from outside New York State that have a degree and their HT (ASCP) certification and did not apply for licensing during the initial grandfathering period. These individuals now find themselves in the unenviable position of trying to complete a formal histology program by the 2013 deadline. As of December 2011, there are two programs registered by the New York State Education Department that meets the requirements for Histology training: SUNY Cobleskill and Broome County Community College (BCC). Unfortunately, the program at Cobleskill does not have distance learning capabilities making it difficult for individuals to obtain the necessary course work. BCC offers an online histology certificate program but the program is not yet ready to open. The New York State Histotechnological Society is reaching out to other out of state, online programs in an effort to have them register with the SED. This will hopefully give individuals more options to meet the licensing requirements as well as provide an opportunity to those seeking to come to New York to gain employment. In the meantime, individuals who are taking online course work, with in- or from outside of NYS must submit the course work to the SED so that they may determine if it is "substantially equivalent" and meets the curricular requirements for NYS.

In addition, the SED does not recognize the HTL certification as a pathway for licensure at this time. An individual must take the HT exam in order to receive their license because this is the minimum required standard. For example, an individual that meets the educational requirement and has their HTL certification must take the HT ASCP exam in order to obtain a license and to practice in NYS., while this may seem trivial, there is a legal basis. Currently, bachelor's level histology programs do not exist with in New York State. As a result, the SED will only recognize the technician level education and therefore the HT level exam. However, the SED is willing to explore the "HTL" path if and when bachelor's level programs are accredited within NYS. The NYSHS has begun seeking out academic institutions that are interested in opening bachelor's programs and will continue to advocate for this path to be accepted by the SED.

For more info visit the office of professions website at:

http://www.op.nysed.gov/

(Continued from page 10)

sive then say a new a new antibody with only a couple of literature citations that labels only one or two antigentic sites. So if the laboratory director decides that a well publicized antibody only needs 5 positive and 5 negatives and documents it in the procedure manual then theoretically you have meet the requirements as published. Whatever your laboratory director decides is adequate for each antibody the key is to document in the procedure manual, and keep all documentation, blocks, slides, and relevant paperwork and have it readily accessible to the inspectors.

Clinical Laboratory Standards Institute (C.L.S.I)

Clinical Laboratory Standards Institute has published a new document,

Quality Assurance For Design Control and Implementation of Immunhistochemistry Assays; Approved Guideline- Second Edition; I/LA28-2 Vol 31 No 4

that gives an in-depth discussion on how validation and verification is performed both from the vendor stand point as well as the end user. It goes on to define verification; "Verification is determining that an assay performs according to the recommendations of the manufacturer. Verification by the end user laboratory is the process that ensures the laboratory can obtain the expected results of the IHC test when it is used, according to the manufacturer's instructions for use on the recommended control materials and human specimens. It gives a further clarification on what to do if the end user can not verify what the manufacturer claims, "Verification in the end user laboratory refers to the testing processes used to confirm the that the total test system of the assay meets the performance specifications for patient testing established through the validation activities of the assay developer. If the end user laboratory's verification results do not meet the specifications of the total test system, the end user laboratory should not release patient results until the laboratory meets the specified performance characteristics.

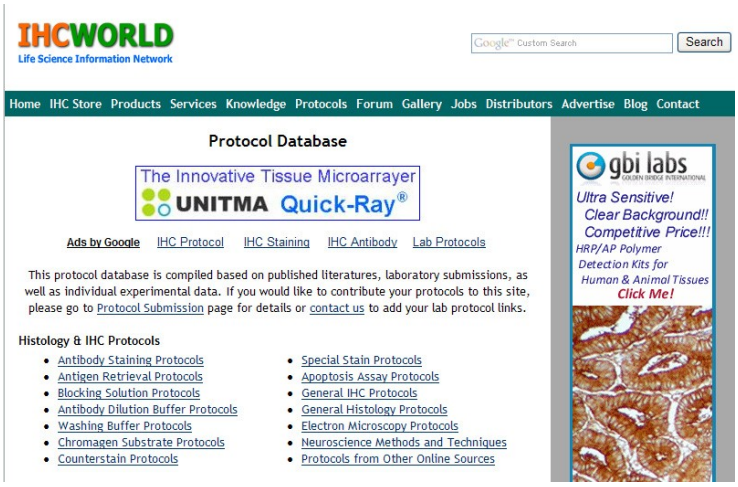
This document also goes into detail about lot to lot verification suggesting that not only lot to lot needs verification but also the same lot in different shipments, and it does explain the reasoning behind the recommendation. "End users should examine each shipment received, even if from the same lot, although a portion of the same lot was received, tested, and approved previously. Subsequent shipments may be subjected to different conditions (including shipping and storage), which may cause changes in materials so, although one shipment of a particular lot meets specifications, another may not."

The FDA mandates for certain prognostic indicators, ER, PgR, and Her2-Neu that there be a certain number of tests both positive, and negative, as well as weakly positive be ran, and the laboratory can demonstrate concordance with an already certified laboratory before a laboratory can start testing and reporting results. This in itself can be an article and will not be discussed in depth here, but for further clarification please refer to

(Continued on page 16)

Keep this in your site!

IHC World is a great protocol database. The protocols range from IHC, special stains, lab manuals etc. The protocols are written in NCCLS format and they are great resource when updating your procedure manual or looking for a new stain!



http://www.ihcworld.com/protocol_database.htm

Join The NYSHS Message Board

Do you have questions? Do you want quick answers? Are you looking for a job or have a job opening? Do you want the latest news and info from the histotechnology World?

Join the New York State Histotechnology Society Message Board.

It's easy; just visit the message board website at http://tech.groups.yahoo.com/group/ NYSHS1972/

Want to place an ad in the newsletter?
Advertising space is always available.
Contact Stephanie Krauter at
nyshsadcoordinator@yahoo.com for more information.

Call for Nominees for 2012 Region 1 Scholarships

Charles Churkian Memorial Scholarship

This financial award is presented annually at the Region 1 meeting to a histologist who must demonstrate financial need, involvement in State or Regional or national activities promoting Histotechnology and demonstrate motivation and reason for wanting to attend a meeting. Deadline is March 28th 2012

Region 1 Scholarship

This financial award is presented annually at the Region 1 meeting to a histologist or supervisor who must demonstrate financial need, involvement in State or Regional or national activities promoting Histotechnology and demonstrate motivation and reason for wanting to attend an annual meeting Deadline is March 28th 2012

Region 1 Histotech of the Year Award

This prestigious award is given annually to the Histotechnologist in recognition of an individual who has shown the qualities of dedication and service to the Histotechnology profession within their state or within the region. *Membership in their State Society or NSH is required.* To apply, the individual nominating the candidate must write a letter detailing how he/she meets the criteria and have a similar letter submitted from his/her supervisor, pathologist or co-worker. Deadline is March 1 2012

For more information and eligibility requirements, please visit:

http://www.nyhisto.org/meetings/current-nys-meeting/region-1-awards/

Applications for scholarships and nominees for the Histotech of the Year Award or any questions about the application process should be sent to the Region 1 Director :

Angela M. Fogg, HT ASCP
Region 1 Director
5 Hammersley Ave
Poughkeepsie, NY 12601
angelafogg@aol.com

(Continued from page 13)

"**American Society of Clinical Oncology/College of American Pathologists Guideline Recommendations for Immunohistochemical Testing of Estrogen and Progesterone Receptors in Breast Cancer (Unabridged Version)"**
M.Elizabeth H. Hammond *et al.* **Archives of Pathology and Laboratory Medicine- Vol 134, July 2010.**

The CAP regulations pertaining to ER ,PgR and Her2 are

Mol.39323 Her2 by ISH

ANP.22976 ER/ PgR Validation

So in summary to run an adequate validation procedure the laboratory director must establish the guidelines for the number of cases to be ran for the antibody, it must be documented in the procedure manual, and all documentation pertaining to the validation/verification be kept and readily available.
Documentation you should have available are

- Manufacturers data sheet
- Literature references
- Protocol used
- Number of cases
- Expected results
- Actual results
- Reports from inter-laboratory validations

You can drastically reduce the economic impact on validation procedures by using tissue micro-arrays. The previously cited CLSI article states that, "A standardized TMA is used as a (near) universal control slide for IHC assays. As few as seven tissue cores can represent >95% of all IHC markers currently used in diagnostic IHC." If your lab can make its own tissue micro-arrays using your tissue routinely processed you will have created a test slide with multiple cases that best mimics your processes, so therefore would give you the best results not only for optimization but also for validation studies.

References

College of American Pathologists, Anatomic Pathology Checklist, 07.11.2011

College of American Pathologists, Molecular Pathology Checklist, 07.11.2011

Clinical Laboratory Standards Institute, Quality Assurance for Design Control and Implementation of Immunohistochemistry Assays; Approved Guidelines- Second Edition, Vol.31 Number 4, I/LA28-A2

! Save The Date !

Region 1 Conference and Symposium April 27th and 28th 2012

Islandia Marriott Long Island

Over 20 CEU's

Topics include:

Forensics
Anatomic Pathology
Cytopathology
Digital Pathology
Research IHC
FDA Regulations
Microwave Tech–nology
Digital Pathology
Specimen Tracking
and more ... .

-Career Day
-Exhibit Hall
Wine &
Cheese
Reception
-Region 1
Awards
-Luncheon &
Raffles

Hosted by the New York State Histotechnological Society
For more information visit the NYSHS website at:
http://www.nyhisto.org/

New York State Histotechnological Society

2011-2012 Officers

President	Luis Chiriboga	NYU School of Medicine	litepath2000@yahoo.com
Vice President	Angela Fogg	Columbia Memorial Hospital	angelafogg@aol.com
Corresponding Secretary	Emily Ash	Roswell Park Cancer Institute	emily.ash@roswellpark.org
Membership Secretary	Amy Farnan	Albany Memorial Hospital	nyshsmembership@yahoo.com
Treasurer	Michelle Fuller	University of Rochester Medical Center	michelle_fuller@urmc.rochester.edu
Past President	Mary Georger	University of Rochester Medical Center	mary.georger@rochester.edu
Director	Linda Chen	Weil Cornell Medical Center	kooki55@hotmail.com
Director	Pam Colony	SUNY Cobleskill	colonyp@cobleskill.edu
Director	Sarah Mack	University of Rochester Medical Center	Sarah_mack@urmc.rochester.edu
Director	Laurie Marien		lmarien@roadrunner.com
Director	Diana Scott	University of Rochester Medical Center	Diana_scott@urmc.rocester.edu
Director	Leanne Strope	Cancer Genetics	dstrope@stnyrr.com
Student Representative	Sarah Lamoureux	SUNY Cobleskill	LamourS531@Cobleskill.edu