DELAWARE HEALTH AND SOCIAL SERVICES

Division of Public Health

Laboratory

DELAWARE LABORATOR

WINTER

2010

NAVIGATING THE CHANGING TIDES OF PROFESSIONAL CERTIFICATION

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The October 23, 2009 merger of two major certification agencies in this country, the Board of Registry (BOR) and the National Credentialing Agency (NCA) created a new entity called the Board of Certification (BOC). Since practicing medical laboratory science in the 21st century cannot be done without keeping up with the hundreds of changes in methods, testable analytes and diagnostic criteria which our field experiences each year, continuing education is the keystone to earning and keeping your certification. Transitioning from current certification initials [for example, Medical Technologist, American Society for Clinical Pathology -- MT(ASCP) or Clinical Laboratory Scientist, National Credentialing Agency-- CLS(NCA)] to the new ones requires a few steps, depending on current participation in **nationally** documented continuing education. Your certification is most likely not through your local workplace, so a local documentation of continuing education is **not** sufficient.

This article will be for the generalist individuals who right now are certified as MT (ASCP) or CLS(NCA). To start the process for certification as a Medical Laboratory Scientist (MLS), I will first address those who fall into the following categories:

1. You took the BOR exam 2004 or afterward and have maintained your certification through documenting your continuing education (the "certification maintenance program" (CMP) of the former BOR), so your certification has not lapsed.
2. You took the BOR exam before 2004 and have participated in the CMP, nationally documenting your continuing education, so your certification has not lapsed.
3. You took the NCA exam at anytime between 1978 and 2009 and have maintained your certification by documenting your continuing education, so your certification has not lapsed.

For all 3 categories, your certification is considered current as of October 23, and you can immediately begin to use MLS after your name rather than MT or CLS. Two months before the expiration date, you must complete the BOC Declaration Form, document-

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ing 36 hours of continuing education within the past 3 years and send it plus the fee to the BOC. The form can be found at http://www.ascp.org/pdf/CMPDeclarationForm.aspx. Note: you should not send them your original proofs of attendance nor do you need to send copies with the declaration. Be aware that a percentage of submitted declaration forms will be audited by the BOC each year, and if selected, you'll have to provide proof of what is written on the form. NEVER send your originals… only send copies. Visit http://www.ascp.org/pdf/CMPbooklet.aspx for an overview of the CMP program.

Individuals who received their MT (ASCP) prior to 2004 and never participated in the CMP program can retain the MT(ASCP) since the former BOR designated that as a permanent entry-level certification. I personally predict within 5 years, however, that those with an MT(ASCP) as their only credential will be known as individuals who refuse to participate in, or nationally document, their continuing education. I envision this as being detrimental to hiring or job advancement. For these individuals, it is very easy to acquire the new credentials. The BOC declaration form described above can be used to list 36 hours of continuing education done within the past 3 years. Since the MLS is a generalist certification, it is expected that such an individual participate in 2 hours each of chemistry, microbiology, blood banking and hematology, plus 1 hour of safety, within those 3 years, with the remaining 27 hours being in any clinical discipline. Multiple sources of continuing education are acceptable, including hospital in-services, and are summarized in the CMP booklet at http://www.ascp.org/pdf/CMPbooklet.aspx.

Individuals who were certified through NCA but have let their certification lapse are not certified at all as of the date their certification expired. For the immediate future, they can, however, go through the same CMP process described above and obtain the MLS credential. Once certified as MLS, it will become very important for ALL certificants to document all continuing education in order to maintain certification.

The scenarios mentioned above are basically the same for colleagues certified as technicians (either MLT or CLT) to obtain the new BOC certification of MLT. If anyone has specialist or categorical certification, the kind of continuing education topics will differ for you to achieve your 36 hours over 3 years. Once again, the CMP booklet cited above will provide more information.

The very FIRST step needed, especially for those whose certification has lapsed or who never participated in the CMP program, is to create an account on the BOC website. Right now, this is occurring through the ASCP website but hopefully there will soon be an independent website for the BOC. Please note that professional society membership in ASCP is **NOT** required to maintain your certification via the BOC.

Leadership of the American Society for Clinical Laboratory Science (ASCLS), the oldest non-physician clinical lab professional society in the United States, want to help in whatever way needed to make this transitioning period easier to navigate. As the ASCLS President this year, I encourage you to voice your questions and concerns (my phone number and e-mail provided above) and, together, declare to the general public and our employers that not just anyone can do what we do. Documentation of our continuing education efforts speaks volumes of our commitment to the patients whom we serve.

See pages 4 and 7 for 2010 training opportunities.

DELAWARE'S PUBLIC HEALTH LABORATORY IMPLEMENTING SECOND TIER TESTING FOR CYSTIC FIBROSIS

PATRICIA M. SCOTT, LABORATORY MANAGER

About Cystic Fibrosis

Cystic fibrosis (CF) is the most common recessive genetic disorder found in Caucasians with an incidence of 1 in 2,500 live births. The main clinical symptoms are characterized by functional abnormalities in the airway epithelium, the exocrine pancreas, the gastrointestinal tract, and the secretory duct of the sweat gland, leading to pancreatic and pulmonary insufficiency[i]. There is now evidence indicating that early treatment may be important in determining subsequent clinical outcomes for children with cystic fibrosis.

The most common genetic mutation causing the disease has been identified on the tenth exon of the CFTR gene as a deletion of three nucleotides. The loss of the nucleotides removes a phenylalanine codon at position 508 (DF508) in the first ATP binding domain[ii]. There is a difference in frequency of DF508 mutation in CF cases depending on the population. The frequency is about 50% in cases in southern Europe, about 90% in the most northern part of Western Europe, and about 70% in North America[iii]. Over 1000 mutations have now been identified, and several occur with reasonable frequency while others are rare. Some mutations are associated with milder forms of disease and should be considered in the management of the disease and as a diagnostic tool.

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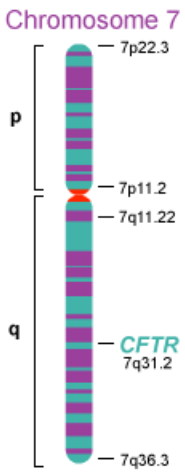
Implementing Cystic Fibrosis Testing, continued

Cystic fibrosis is one of the 29 core conditions listed in the 2006 American College of Medical Genetics (ACMG) Report, *Newborn Screening, Toward a Uniform Screening Panel and System*. The Cystic Fibrosis Foundation (CFF) recommends and has been pushing for all states to routinely screen for cystic fibrosis in all newborns and recently reported that all 50 states presently do so.

Cystic Fibrosis Testing in Delaware

The laboratory testing program for newborn screening (NBS) at Delaware's Public Health Laboratory (DPHL) is now 11 years old. The addition of CF testing was recommended by the Delaware Newborn Screening Advisory Committee as the final step needed to report all of the Core disorders recommended by the ACMG Report.[iv] Immunoreactive trypsinogen (IRT) testing for CF officially began in October of 2006. The IRT/IRT method (immunoreactive tyrpsinogen analysis on two separate specimens) was chosen because Delaware is a mandatory two-specimen state, and Colorado reported great success using an IRT/IRT algorithm[v].

After validation was completed and appropriate cut-offs were decided upon, a normal range was established using two months of initial specimens (2454 samples). The borderline cut-off was set at 70 ng/mL, elevated cut-off at 100 ng/mL and clearly elevated at 120 ng/mL. The top 3% of every IRT run are retested in duplicate to verify the abnormal result. For these babies, IRT is tested again in duplicate on the baby's second specimen. When complete, one of these final interpretations is assigned: *Within Normal Limits, Inconclusive, Suspicious,* or *Presumptive Positive*.



From October 2006 – December 2008, three cases of cystic fibrosis were identified giving Delaware an incidence rate of 1:9,400 births, which falls below the national average of 1:3,721. A breakout by race shows very different prevalence rates: 1:2,500 Caucasians, 1:8,000 Hispanics, 1:15,300 African Americans, and 1:32,000 Asian Americans. A total of 63 sweat tests, the confirmatory test for CF, were requested during this period.

Expanding to Include Cystic Fibrosis DNA Mutation Testing

In 2007 the Newborn Screening Advisory Committee recommended that the DPHL add cystic fibrosis molecular testing to look for mutations on the cystic fibrosis transmembrane receptor (CFTR) gene. A delayed implementation was followed by an economic downturn and staff shortages, and it looked like it might be a while before this testing could be implemented. That all changed, when in March of 2009, the DPHL applied for a federal grant through the Centers of Disease Control and Prevention (CDC), RFA-EH-09-003: Program to Enhance State Public Health Laboratory Capacity for Newborn Bloodspot Screening.

The goal of DPHL's grant application was to improve the efficacy of screening for CF within Region 2, the New York Mid-Atlantic Consortium (NYMAC) for Genetic and Newborn Screening Services, by establishing a regional CF-DNA testing laboratory. By offering to act as a regional laboratory and provide free CF-DNA mutational testing within the region, we would be able to bring the testing in to Delaware with no start up costs to the state. The region would benefit by access to confirmatory testing, thereby reducing false-positive results. Positive predictive values should improve and the need for sweat testing would be minimized within the region.

In October 2009, notification was received that DPHL had been awarded one of the three $150,000 grants offered, and so the process of implementing CF-DNA testing in Delaware began.

A vendor for tests kits needed to be selected and an invitation to bid was posted, with Third Wave selected as the successful bidder. The Third Wave In-Plex Method is an in vitro diagnostic (IVD) that simultaneously tests for the 23 ACMG recommended mutations plus 17 addition muta-

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NYMAC

The NYMAC (New York-Mid-Atlantic Consortium for Genetic and Newborn Screening Services) was established in September 2004 as one of seven regional collaboratives in the country funded by the Genetic Services Branch in the Health Resources and Services Administration (HRSA)'s Maternal and Child Health Bureau. The charge of this group is to **develop a regional approach to address the maldistribution of genetic resources in the New York-Mid-Atlantic region**, which includes Delaware, District of Columbia, Maryland, New Jersey, New York, Pennsylvania, Virginia and West Virginia. The status of testing for Cystic fibrosis DNA mutations within the region:

New York – Already performing DNA mutational analysis
New Jersey – IRT plus one mutation, DF508
Pennsylvania – Hospitals contract with PerkinElmer Genetics & New England Regional Laboratory
Maryland – IRT/IRT algorithm
Delaware – IRT/IRT algorithm

Resources, continued from page 3

tions in the CFTR gene using patented Invader® Technology. The chemistry is composed of two simultaneous isothermal reactions. A primary reaction specifically and accurately detects single-based pair changes, insertions, deletions and changes in gene and chromosome number. A second reaction is used for signal amplification and result readout.

While purchase orders for procuring necessary equipment and supplies are pending state approval, DPHL staff are setting up a validation plan. It will be necessary to demonstrate that we can identify all 40 mutations and the challenge will be in finding true positive specimens. CDC has offered assistance in providing the necessary samples for validation of the method.

The implementation process will involve making changes to our present data system, MSDS by Natus, in order to accommodate the new test and develop a means of reporting results to Delaware and out-of-state submitters, whether that is via hard copy, electronic report, or a web-based report. States have been queried, and four states in the NYMAC region have the potential to benefit from the services: Delaware, Maryland, New Jersey and Virginia. Early contact with staff in those states will be necessary to address obstacles well before we are ready to begin reporting results.

We recognize that there will be many challenges in this implementation, some that have been anticipated, some that have not. We appreciate the advice and assistance that has been extended to us from many sources, including but not limited to experienced molecular staff within DPHL, experts in quality control, newborn screening and cystic fibrosis from CDC, and to the staff of the newborn screening laboratory who will ultimately be responsible for implementing the test and bringing this project to fruition.

Resources:

[i]Instuctions for Use, PerkinElmer DELFIA® Neonatal IRT A005-110, May 2007: 3.

[ii]Kerem,B-S., Rommens,J.M., Buchanan, J.A., et al. Identification of the Cystic Fibrosis Gene: Genetic Analysis, Science, 1989, 24 (4922):1073-80.

[iii]The cystic fibrosis Genetic Analysis Consortium (1994): Population variation of common cystic fibrosis mutations. Hum.Mutat, 4, 167-177.

[iv]Newborn Screening: Towards a Uniform Screening Panel and System. Genet Med. 2006; 8(5) Suppl: S12-S252.

[v]Sontag,M.K., Hammond,K.B., Zielenski,J., Wagener,J.S., Accurso,F.J. (2005) Two-tiered immunoreactive trypsinogen-based newborn screening for cystic fibrosis in Colorado: screening efficacy and diagnostic outcomes. J.Pediatr. 2005 Sep; 147(3 Suppl):S83-8.

2010 TRAINING OPPORTUNITIES

The Association of Public Health Laboratories and the Clinical and Laboratory Standards Institute 2010 teleconferences

Winter/Spring Teleconference Series

Visit http://www.aphl.org/clsi for online registration and to download the course flyer

Date	Teleconference	Speaker
March 25, 2010 1:00 – 2:00pm	MRSA: Understanding the Real Issues Beyond the Media Hype	Fred C. Tenover, PhD, D(ABMM) Cepheid, Sunnyvale, CA
April 15, 2010 1:00 – 2:00pm	Mycobacteria: Specimen Collection & processing to Optimize ID	Betty (Betz) A. Forbes,PhD. D (ABMM), Clinical Support Center, Medical College of Virginia
May 6, 2010 1:00 – 2:00pm	Does Your Lab Measure Up? Meeting ISO Accreditation Requirements	Michael A. Noble, MD, FRCP(C), Dept. of Pathology & Lab Medicine, University of British Columbia, Vancouver, BC, Canada
May 20, 2010 1:00 – 2:00pm	New Guidance for Laboratories: Validating Automated Systems for Immunohematological Testing	Katharine Downes, MD, Dept. of Pathology, University Hospital of Cleveland
June 3, 2010 1:00 – 2:00pm	The Top 10: CLSI Guidance to Address Most Common CMS Deficiencies	Judith A. Yost, MA, MT (ASCP), Director, Div. Laboratory Services, Centers for Medicare & Medicaid Services, Baltimore
June 17, 2010 1:00 – 2:00pm	Safety First! Protection of Lab Workers from Lab-Acquired Infections	Donald R. Callihan, PhD., Sr. Clinical Microbiologist, BD Diagnostic Systems, Sparks, MD

NEW MOLECULAR TESTING FOR SEXUALLY TRANSMITTED DISEASES IN THE MICROBIOLOGY SECTION

DONNA S. COLATRELLA, MLT (ASCP) AND
DEBRA RUTLEDGE, MBA, BS MT (ASCP)

The Delaware Public Health Laboratory (DPHL) recently acquired and validated new innovative technology for sexually transmitted disease (STD) detection. The microbiology section at DPHL implemented the Tigris DTS system as of November 16th 2009 for chlamydia and gonorrhea testing. The instrumentation and assay reagents are both a product of GEN-PROBE based in San Diego, California.

The acronym DTS stands for direct tube sampling. The Tigris DTS is an integrated nucleic acid amplification testing system which fully automates all steps necessary to perform nucleic acid amplification testing. The system detects ribosomal nucleic acid (RNA) from a variety of specimen types including urine, cervical and urethral swabs. We plan on validating the method for vaginal, oral and rectal swab specimens in the near future.

Tigger, as we call him here at the lab, detects nucleic acid from specimens using the APTIMA 2 Combo Assay. Initially this assay uses target capture which isolates and purifies the nucleic acid from the sample. Next, transcription-mediated amplification (TMA) amplifies the target nucleic acid to produce multiple copies of RNA for easier detection. Then the hybridization protection assay detects the amplified nucleic acid using light-emitting nucleic acid probes. The final step in this assay utilizes dual kinetic assay technology, enabling multiplex detection from a single sample. Kinetic profiles are derived from the measurement of photon output during the detection phase. There are two types of chemiluminescent detection

reactions for a signal: either very rapid kinetics called "*Flasher*" for CT detection or a slower kinetic type called "*Glower*" which detects GC.

The two main components of the Tigris DTS System are the computer workstation and the analyzer. In the computer workstation, the software directs the analyzer modules to perform each assay step. Tigger's analyzer houses all the fluids, reagents, consumables and patient samples as well as all the mechanical parts needed in one contained system. The system eliminates contamination during testing because the assay reagents and specimens are in the upper bay of the analyzer and the fluids inventory and waste are in a lower bay.

Currently the DPH lab tests over 30,000 specimens annually. Approximately 8% are positive for chlamydia and 1% are positive for gonorrhea. DPH STD and family planning programs provide grant support and program management. The lab and DPH program staff work as a team to meet the goals of the Centers for Disease Control & Prevention Region III Infertility Prevention Project. DPHL provides this testing to all state service centers, school-based wellness centers, state universities, and our Title X contracted community based organizations.

Automation has the ability to significantly reduce testing errors and increase laboratory testing productivity. We can do more testing with fewer staff. Furthermore, repetitive pipetting can cause staff ergonomic problems which automation eliminates. Tigris has the ability to test up to 1000 samples in an eight hour shift, greatly increasing the capacity of DPHL for STD testing. In order to utilize this new equipment to its fullest potential we are seeking to increase our workload by providing STD testing to other agencies that may need to provide this testing for their clients.

WE DO IT FOR THE BABIES!

DELAWARE PUBLIC HEALTH LABORATORY

In the Delaware Newborn Screening Program, lab couriers collect specimens from birthing centers throughout the state every weekday and deliver them to the Delaware Public Health Laboratory in Smyrna, for testing. The laboratory tests for inherited diseases that may be unapparent at birth, but that without early detection and treatment can lead to serious medical consequences including mental retardation, disability and even death. For this reason, as soon as testing is completed, significant findings are called to the program follow-up staff who then communicate results to medical providers across the state. The process is quite intricate and the timing and communications are critical. This process was severely challenged during the dual blizzards that walloped the state in February. A State of Emergency closed the laboratory for three of the five days during the week of 02/08/10.

Knowing a major storm was to hit on the afternoon of Friday 02/05/10, testing and courier staff converged in the

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DELAWARE PUBLIC HEALTH LABORATORY

You're Invited

Open House

Free drinking water kits for first 100 attendees!!

April 21, 2010
Public Health Lab
30 Sunnyside Rd, Smyrna
Guest Speaker: Dr. Karyl Rattay
Director of Public Health
At 11:30 a.m.
Event is from 9 a.m. to 4 p.m.
Tours start: 9 -11 a.m. and 1- 3 p.m.

Meet professionals
who achieve results.
Tour our laboratory and speak with
our public health partners.
Great opportunity for students
looking for a career in the sciences.
For our partners, a chance to see the
laboratory processes.
Displays and tours available.

RSVP by: April 5, 2010
Liz Moore : 302-223-1520
302-653-2877 (fax)

DELAWARE HEALTH AND SOCIAL SERVICES
Division of Public Health
Delaware Public Health Laboratory

Visit our website: www.dhss.delware.gov/dhss/dph/lab/labs.html

Agents of Bioterrorism: Annual Sentinel Laboratory Update

April 29, 2010
OR
April 30, 2010

Sponsored by the National Laboratory Training Network
and the
Delaware Public Health Laboratory

Description: This hands-on laboratory workshop begins with an overview of laboratory safety and a review of the Laboratory Response Network (LRN) structure to include discussion on select agents. The afternoon will include hands-on exercises based on case studies using "mimic" and real agents. These exercises are designed to enhance the microbiologist's capability to recognize the culture and microscopic characteristics of lethal strains of potential agent of bioterrorism.

Location: 30 Sunnyside Road, Smyrna, DE 19977

Continuing Education: The association of Public Health Laboratories (APHL) is approved as a provider of continuing education programs in the clinical laboratory sciences by the ASCLS P.A.C.E. Program. Participants who successfully complete this program will be awarded 6 contact hours.

Registration Deadline: April 15, 2010. Pre-registration is required.
Visit http://www.nltn.org./106-10.htm to register online
If you have difficulty with the online registration, email registrar@aphl.org or call 240.485.2727
General questions: Contact Monet King at APHL, 240.485.2731 or monet.king@aphl.org
Program content and local information: Contact Marion Fowler, marion.fowler@state.de.us

We Do It for the Babies!, continued from page 5

back hallway of the laboratory to figure a way to get Friday's specimens back to the laboratory sooner, with an idea to get the testing started and demographic data entry completed before the impending storm. Multiple staff from both the follow-up program and the laboratory made plans and gladly helped out by stopping at hospitals near their homes to pick up the specimens so that the specimens could get back to the lab sooner. Extra hands chipped in to get the data entry completed before the end of the day. The cooperation by so many hands to get the work done in advance of the storm was heart lifting.

The next week we were slammed by a second Nor'easter. Both before and after this storm, the strains on laboratory staff were significant. All testing that required overnight incubations was lost when yet another State of Emergency was declared and travel restrictions prevented staff from coming to work for two more days. Laboratory staff did make their way in to set up testing on Thursday night and then again to read tests on Saturday morning. Workloads on Friday and Monday were 2-3 times normal and only half of the staff was able to come in because of road conditions and facility closures. Everyone chipped in to get the work out as soon as possible and even accommodated a STAT testing request by our genetic consultant, worried over a very sick infant in the neonatal intensive care unit.

Through it all not one complaint was heard. Couriers, program follow-up, laboratory, and administrative staff were all glad to go out of their way, glad to move out of their comfort zone, glad to go beyond the requirements of the job, glad to travel treacherous roads, GLAD to do it all for the babies!

EMPLOYEE NEWS

CONGRATULATIONS TO DEBBIE RUTLEDGE!

Dr. Getchell congratulates Debbie Rutledge on receiving the laboratory "Employee of the Quarter" award

Debbie has been the Microbiology Section Lab Manager I at DPHL since 1998 supervising 9 employees and responsible for testing for parasites, syphilis, chlamydia, gonorrhea, tuberculosis, and other bacteria. After Jack Liou, Lab Manager II, left at the end of 2008, she resumed her position as Bioterrorism Coordinator and also took on responsibility for the University of Delaware Fellowship program. Then, when Rebekah Parsons left in the middle of 2009, Debbie assumed all of the duties of the Lab Manager I for the Molecular Virology Section. That meant she was supervising an additional 7 employees performing testing for influenza, rabies, HIV, etc. and responsible for the Food Emergency Response Network cooperative agreement (FERN) as well.

We were pleased to be able to fill the Lab Manager II position during the state hiring freeze, and in January we were delighted to promote Debbie into that position. With all of her knowledge and experience she was a perfect fit. Congratulations are also in order for Debbie for receiving her MBA from Wilmington University this January and for being named DPHL's Employee of the Quarter (4th). Nominated by staff in virology and microbiology, Debbie was praised as being an extraordinary boss, leading both sections with enthusiasm and authority. It was quite a month for a very deserving laboratory scientist!

WELCOME BOBBI JO TURNER

The newborn screening section is very happy to welcome back Bobbi Turner as a molecular scientist responsible for the cystic fibrosis DNA mutation testing project. Bobbi worked at the DPH Laboratory during 2005-2007 as a microbiologist in the virology and newborn screening sections and is a great fit for this laboratory. Bobbi earned a Bachelor of Science degree in Biology from the University of Towson. Prior to joining the Division of Public Health, she worked in cancer & HIV research through SAIC at Fort Detrick in Frederick, Maryland and then in quality control at Intervet in Millsboro, DE.

DELAWARE'S DIVISION OF PUBLIC HEALTH LABORATORY

Delaware Public Health Laboratory
30 Sunnyside Road
Smyrna, DE 19977
302.223.1520
Fax: 302.653.2877

Built: 1990

Business Hours: 8 a.m. – 4:30 p.m.

Purpose: The Division of Public Health Laboratory currently offers consultation and laboratory services to state agencies, Delaware Health and Social Services and Division of Public Health programs including:

- HIV surveillance and prevention
- Immunization
- Food Safety
- Epidemiology
- Newborn Screening
- STD prevention
- TB Elimination
- Drinking water
- Preparedness

Karyl Rattay, MD, MS, FAAP, FACPM
Director, Delaware's Division of Public Health

Jane P. Getchell, DrPH Director,
Delaware Public Health Laboratory

Christina Pleasanton, MS
Deputy Director, Delaware Public Health Laboratory

If you have questions regarding these articles or would like to receive a hard copy of this newsletter, contact the Delaware Public Health Laboratory at 302.223.1520. To receive this newsletter by email, contact liz.moore@state.de.us.

"To Protect and Enhance the Health of the People of Delaware"

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