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Y2K: Are You Ready?

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It is 5:00 PM on New Year's Eve, 1999. You set your tissue processor for 48-hour delay for the holiday weekend and head home to celebrate the arrival of a new millennium. Are you sure your processor will be where you want it to be when you return? If you thought the Year 2000 "Crisis," commonly referred to as Y2K, will only affect the computers in your laboratory, think again!

Who Should Be Concerned?

According to Bourne,¹ if you can answer yes to any of the following, you need to be concerned about Y2K:

- You own a computer.
- You use a computer at work or your employer owns one or more computers.
- Your home or apartment has running water, electricity, telephone service or natural gas.
- Any of your personal assets are in a bank, a savings and loan, a mutual fund or common stocks.
- FICA withholding has been withdrawn from your paycheck.
- You've written a check to the IRS.
- You enjoy watching TV, listening to the radio, or going to a movie.

What is the Problem?

It is estimated that 5 percent of all U.S. businesses will go out of business because of the Y2K problem. What is the problem? There are actually three distinct problems for computers related to the turn of the century:

- Many computer programs store the year values for dates as two digits instead of four (eg 98 represents the year 1998) — when the clock rolls from 1999 to 2000, these computers may interpret the year as 1900 instead. This will result in erroneous calculations of age, loan interest, insurance premiums, and any other calculation that has to determine an age or date range.
- Not all software programs recognize the year 2000 as a leap year — the algorithm used by computer programs to calculate normal leap years is well tested. The algorithm for century leap year has never been tested!

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No reader should utilize or undertake procedures in *Histo-Logic* articles unless the reader, by reason of education, training, and experience, has a complete understanding of the chemical and physical properties of all materials to be utilized and the function of each material by which any procedure is accomplished. The procedures discussed in these articles represent the opinions and experiences of the individual authors. Sakura Finetek U.S.A., Inc. assumes no responsibility or liability in connection with the use of any procedure discussed herein.

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• Not all computers will know that 01/01/2000 is the day after 12/31/1999. That is because the computer will not know what "00" indicates. The most common incorrect date that it will interpret the date to is 01/01/1980.

To complicate matters even further, there is a potential problem with the date September 9, 1999 (9/9/99) because some programmers use the number 9999 to indicate the end of a file.



It seems that there should be a simple solution, and there are those anxiously waiting for Bill Gates to solve the problem. It is not that easy! There are millions of lines of computer code written years ago (and actually never intended to last this long) that must be corrected to allow for the four-digit year, also referred to as century-year. This code has been incorporated into millions of programs used to run our banks, the stock market, the air traffic control tower, the phone system, and the government, to name a few. We are already seeing problems associated with Y2K such as credit cards being rejected because of a "00" expiration date and insurance policies expiring after 1999.² Some systems will not even allow you to schedule patient appointments in the year 2000.

How Will Y2K Affect the Histology Laboratory?

The Y2K problem will not affect the histology laboratory as intensely as it will other areas in the laboratory or hospital. This is because many of the procedures in histology are still manual. However, any piece of equipment that has a computer chip to keep track of dates and time will need to be validated. This includes tissue processors, cryostats, automated stainers (routine and immuno), timers, Anatomic Pathology computer systems, and personal computers. How will your computer handle accessions when the year 2000 arrives? Will the system be able to display S-00-0001 before S-99-1924 or will it be out of sequence?

What Do I Need to Test?

According to Goldberg²: "In order to preserve quality patient care, maintain business operations and avoid liability, hospital directors, officers and managers must develop and implement systematic risk management strategies in the short time remaining to meet the Year 2000 challenge. Exercising due diligence on all fronts to prevent or minimize Y2K failures must become a priority for all health care institutions."

How does this affect you in the histology laboratory? Suppose you did not validate the Y2K status of your tissue processor. At midnight on December 31, 1999 the processor's internal computer clock reset the machine to January 1, 1900 and the system shuts down. Specimens are compromised. Who is to blame? Although it may cost \$600 billion to correct the Y2K problem worldwide, it is projected that legal costs and business disruptions caused by year 2000 problems may exceed \$2 trillion.³

Testing to simulate date changes is important in showing due diligence in your Y2K effort. At a minimum, the following date scenarios should be tested⁴:

- September 9, 1999 to September 10, 1999 (to confirm correct translation of 9/9/99)
- December 31, 1998 to January 1, 1999 (to check whether 99 is used to mean "no expiration date")
- December 31, 1999 to January 1, 2000 (to check century transition; January 1 should be a Saturday)
- February 28, 2000 to February 29, 2000 (to verify leap year calculation)
- February 29, 2000 to March 1, 2000 (to verify leap year calculation; March 1 should be a Wednesday)
- December 30, 2000 to December 31, 2000 (to verify system does not jump to January 1, 2001 due to not calculating 366 days in the year 2000)

To demonstrate that a reasonable effort was taken to address the Year 2000 crisis, it is not enough that you fix your Y2K problems. You must also document your effort.⁵ This will show that you have identified the risk areas associated with date processing problems and have taken action to correct or prevent the problems. You should be ready to demonstrate that everything reasonably possible was done to correct the problem and to prevent adverse impact on others in case lawsuits are initiated. How important is that date on the processor now?

Where Do I Get Y2K Information?

The best source of Y2K information is the Internet. Most companies have a website that contains Y2K specific information. For example, Sakura can be contacted at:

http://www.sakuraus.com/html/year2000.html

Other sites are available that allow access to multiple links for Y2K information. Examples include:

http://www.mccs.uky.edu/Y2K http://www.amerinet-gpo.com/Y2K http://www.year2000.com http://www.itaa.org http://hp.iwon.com/mpg-y2k

It is still not too late to address the Y2K problem and make sure your laboratory is ready.

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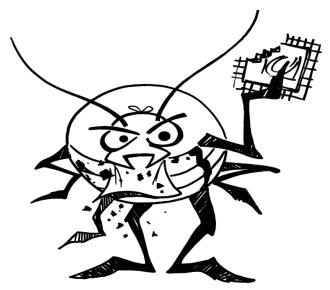
Meet Our New Director of Research and Development



Sakura Finetek U.S.A., Inc., is proud to announce the appointment of Henry Palermo to the position of Director of Research and Development. Henry boasts a background in both engineering and business. His involvement in medical product development for the last 20 years makes him highly qualified to help advance product development for Sakura. Henry spends his free time playing tennis and enjoying art, opera, and the theater. Welcome to Sakura, Henry.

Sakura Alleviates Y2K Fears

We're all looking forward to the year 2000 with both excitement and a little trepidation. The latter is due to a computer problem known as the Y2K bug, which many fear will cause a technological nightmare.



The Y2K bug appeared because of a decision years ago by computer programmers. Early computers had little memory or storage space, so programmers decided to store dates by just their last two digits.

The consequences of that decision are affecting us now because so many computerized functions rely on dates. If one computer misreads the date "01" (for 2001) as 1901, errors are inevitable. Now imagine millions of computers globally making similar miscalculations and the magnitude of the problem quickly becomes clear.

Companies and governmental bodies around the world are investing countless hours and funds into remedies for the Y2K bug. Sakura wants its customers to know that *we are prepared*. Existing Sakura instruments will *not* be affected.

Following is a list of Sakura and Sakura/Miles products that are either not date-dependent (NA) or have the limits of a date impact listed. Because Sakura products have been built to last, earlier product models are also included.

Product	Model Number	Date Limit
VIP [™] E150	4890	Dec. 31, 2079
Tissue Processor	& 4892	200101,2019
VIP TM E300	4894	Dec. 31, 2079
Tissue Processor	& 4896	,
VIP TM 1000	4617	Dec. 31, 2399
Tissue Processor		,
VIP TM 2000	4618	Dec. 31, 2399
Tissue Processor		
VIP TM 3000	4619	Dec. 31, 2399
Tissue Processor		
Tissue-Tek [®]	4640	NA
Rotary Processor		
$TEC^{\rm tm} IV$	4710	NA
Embedding Console		
TEC^{TM} IV	4709	NA
Cryo Console		
TEC [™] III	4587	NA
Cryo Console		
TEC^{TM} III	4586	NA
Embedding Console		
TEC TM III	4585	NA
Thermal Console		
DRS [™] 2000	4929	NA
Slide Stainer		
DRS™601	2201	Dec. 31, 2079
Slide Stainer		
$DRS^{TM} 60$	2001	Dec. 31, 2079
Slide Stainer		
RSG-61 [™]	6000	NA
Slide Stainer		
Cyto-Tek [®]	4325	NA
Cytocentrifuge		
SCA TM	4764 & SCA-5600	NA
Coverslipper		
Tissue-Tek [®] II Cryostat	4553	NA
•	4702 4704	NT A
Cryo 2000™ Cryostat	4703, 4704 & 4866	NA
Ci y Ostat	~ 1000	

Report From NSH

25th Anniversary Celebration Showcases Our History.

At this year's annual meeting held from September 10-17 in Salt Lake City, Utah, the National Society for Histotechnology (NSH) commemorated its 25th anniversary with an exhibit of histologic artifacts that included the first automated, tissue-processing instrument introduced to the histology laboratory, the **Autotechnicon**[®] (1939), as well as the first paraffin, tissue-embedding system from **Tissue-Tek**[®] **TECTM**.



Automation entered the histology laboratory with the introduction of the Autotechnicon® in 1939.



Tissue embedding took a new direction in 1963 with this paraffin system.

It may come as a surprise to many of our readers, but Sakura is the original manufacturer of most of the **Tissue-Tek®**, **Cyto-Tek®**, and **VIPTM** products that have served customers so well over the years.

Also on display was Sakura's exciting new product acquisition, the **Cyto-Tek® MonoPrepTM**, an affordable alternative to existing monolayer slide preparation systems.

For a more complete look at our proud past, we invite you to search the Histo-Logic[®] archives on our website at **www.sakuraus.com**.



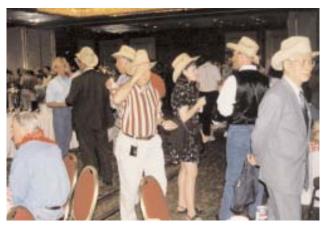
The MonoPrepTM System consists of disposables and reagents developed and tested to achieve optimum results every time.



The Salt Palace Convention Center in Salt Lake City, Utah was the site for this year's 25th Anniversary NSH Symposium/Convention.

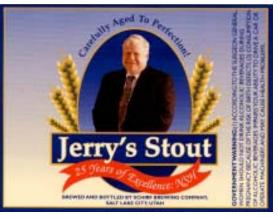
A Look at NSH, Country-Western Style.

This year's **NSH Party** took on a country-western flair, with a foot-stomping affair co-sponsored by **Sakura**, **Allegiance**, and **Richard Allen**. More than 600 turned out for a celebration that included tasty



NSH partygoers hobnob and kick up their heels, country-western style, at this year's celebration.

food, lively music, line dancing lessons, and exclusive private-label refreshments, including *Jerry's Stout* and *Tak's Lager*, in honor of these two beloved gentlemen from **Richard Allen** and **Sakura**.



Full-bodied. Robust. Need we say more?



Elvis lives!

Letter From the Editor:

It has been my pleasure to have been the Scientific Editor for Histo-Logic for the past five years. It does not seem that long ago that I was contacted by Lee Luna to write an article for the Histo-Logic, an article that allowed me to receive the Golden Forceps Award for 1986. It was one of the high points of my professional career.

It is now time to pass the banner to another. My job responsibilities have shifted over the past few years and I am out of direct contact with the histology laboratory. Although I have tried to keep in touch with my friends and colleagues, it has become more difficult each year. I still love the smell of warm paraffin and xylene, and can still follow my nose to find the histology laboratory in every hospital I visit! I plan to keep in touch with my friends and "family" and hope to see you in the near future.

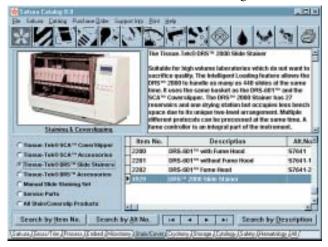
Please give your new scientific editor the same support you have given me. This is a wonderful publication that has served us for over 27 years. It deserves our best!

The Sakura Electronic Catalog — An Invaluable Resource Right at Your Fingertips

Have you received your copy of the new Sakura Electronic Catalog, Version 8.0? If the answer is yes, then you've most likely discovered these user-friendly additions:



• The new and exciting Tissue-Tek® DRS[™] 2000 Slide Stainer for Histology and Cytology. The combination of intelligent loading and proven reliability makes the DRS[™] 2000 the instrument of choice for workflow improvement. Take a look at the Stain/Cover section of the Catalog.



- The Tissue-Tek[®] Neutra-Guard[™] Products for formaldehyde neutralization: fast and cost-effective! Look in the Safety section.
- The Tissue-Tek[®] Mesh Biopsy Cassettes. Check out the Embed section.
- Information on instrument spare parts, grouped by instrument.
- PLUS...a CD-ROM format is now available!

What's more, now you can print those sections of the Catalog you want — including pictures, descriptions, and prices. You can even print in color and customize your printouts! Select a product group and try the Print function. To customize your printout, select catalog Print Setting in the Print menu.



We hope you like all the improvements. If you haven't received a copy of the Sakura Electronic Catalog, we'd like to know. Simply call us toll-free, at 1-800-725-8723, and we'll see that a catalog is sent right out to you.

Sakura Receives ISO 9001 Certification

ISO 9000 is the hottest subject in management circles today. But what does it mean? And why is it so important?

ISO 9000 certification means that Sakura has met certain objective standards regarding the quality of its management system. In fact, we received ISO <u>9001</u> certification, which is the most comprehensive form, covering design, development, production, installation, and servicing.

Sakura has discovered numerous benefits to meeting ISO 9001 standards, such as more efficient operations, standardized business procedures, better communication, and improved customer satisfaction. Because our management system has been identified as meeting objective quality standards, Sakura has gained a competitive edge in the domestic and international marketplace.



Let's take a quick look at how ISO 9000 developed and the process by which Sakura received certification. ISO 9000 was first published in the late 1980s by the Geneva-based International Organization for Standardization, a federation of national standards bodies.

Around the same time, the European Union was emerging, with a definite need to establish quality standards for trade between the various countries. ISO 9000 was chosen as the basic quality management system for selling certain products within the European Union. The idea rapidly gained acceptance elsewhere.

More than 80 countries worldwide now accept ISO 9000 as the standard for ensuring consistent quality. Over 130,000 businesses globally—15,000 in North America—have received this certification.

A long, multistep process was required for Sakura to receive certification. We began working toward this goal in February 1998, receiving certification on August 14, 1998. Sakura management was thoroughly committed to the project from the start.

Detailed planning was vital to the success of the project. Documentation was reviewed, revised, and/or implemented. Training was carried out. Internal assessments were done. Finally, a formal audit was performed by an objective, independent organization called a Registrar. The auditors toured our facility, interviewed employees at various levels, and reviewed documentation in order to determine whether Sakura met ISO 9001 standards. Sakura also received EN46001 certification. This is the European equivalent of FDA regulations for medical devices. The auditors will return periodically for follow-up surveillance checks.

Biomechanical Safety

Kathy McGowan Clinical Affairs Specialist

Most laboratories readily comply with regulatory agency safety standards because to do otherwise is not an option. However, even histology labs that comply with these regulations may overlook biomechanical stresses that are task-related to our profession.

Over the years we have seen the laboratory workload increase dramatically due to new technical procedures, consolidation of lab sites, and/or downsizing. There has been an increase in physical, emotional, and intellectual demands associated with producing quality work. Along with increased job responsibilities comes an increase in physical as well as mental stresses.

Often biomechanical stress remains unidentified in lab safety assessments due to a main focus on electrical and chemical issues. For example, back pain is often blamed solely on improper lifting. Consider conducting a biomechanical assessment of your work area. Chances are good that your lab, like most, needs more space. However, as you cope with the space you do have, make sure it is adequate for safe working conditions.

I have been in labs where technicians stand to cut. That's great if the microtome is on a bench top at the right height to prevent stress on the spine. While bench tops are standard heights, histotechs come in a variety of heights. If you are tall, you can raise your microtome with a platform and thereby avoid excessive bending. However, if you are short, sitting in an adjustable chair is the better choice.

Excessive bending forward puts tremendous stress on the lower thoracic and lumbar spine. This type of strain can occur while leaning over the cryostat for prolonged periods of time when it is placed at an improper counter height. Such repetitive strain can produce back problems. A better alternative is to sit in an adjustable chair while cutting frozen sections.

A few more words on sitting: Your knees should be in front of you, bent at 90° with adequate leg space (Fig 1). I have seen histotechs sit down to embed or cut, and their body is twisted in two directions. There should be no compromise here! Move your equipment to a space that is unencumbered by other equipment or supplies.









Fig 4.

If you are male, chances are you keep your wallet in your back pocket. Sitting on a wallet throws the hips out of alignment and puts stress on the spine and muscles. This posture will actually create muscular weakness throughout the entire spine.

Watch your head! Leaning forward places a lot of stress on the neck, cervical spine, and muscles. Your head weighs about 10 - 12 pounds and this type of repetitive strain can cause headaches, neck pain, pain radiating down the arms and hands, and pain radiating down the back. Pain and muscular tension between the shoulder blades are also common.

Push back from your microtome for a sixty-second break. Take your left hand and reach over to your right shoulder, grabbing and squeezing and lifting the trapezius muscle (Fig 2). Repeat a few times and then switch to the other side. Next, lift both shoulders up toward your ears and rotate the shoulders backwards, releasing tension in this area (Fig 3). Repeat a few more times. Finally, clasp your hands behind your back and pull your hands down and back (Fig 4). Feel better? Great! Now take on those blocks and special stains!

(I would encourage supervisors to lead these mini stress relievers a few times during the day. Your staff will appreciate it.)

Cyto-Tek[®] MonoPrep[™] Slide Preparations for Fine Needle Aspirations

Sherif F. Yacoub, MD, PhD; Mariana V. El-Amin, MD; Yvette Rubianes-Collazo, MD, CT (ASCP); and Tracy Kunkel, CT (ASCP)

The diagnostic accuracy of fine needle aspirates (FNAs) ranges between 90 - 100 percent when the sample is procured, prepared, and interpreted by a well-trained cytopathologist team.^{1,2}

Limitations in diagnostic accuracy are often related to problems associated with conventional slide preparations known as smears. These problems are sometimes related to preservation, as well as large aggregates of cells, which, in turn, may render inaccurate diagnoses. Because the smear is a multilayer of cells, overlapping may obscure nuclear morphology. This is particularly significant in determining whether a case is benign or malignant. If the smear is bloody, diagnostic cells are often obscured by red blood cells (RBCs), making interpretation more difficult. As a result of these inherent problems, multiple samples are regularly prepared to assist in acquiring an accurate diagnosis. This will lead to prolonged processing, evaluation, and turnaround time for the lab.

Recently, Cyto-Tek[®] MonoPrep[™], a new liquid-based filter monolayer preparation, has been introduced to the cytology marketplace. The Cyto-Tek[®] MonoPrep[™] System is an inexpensive, disposable liquid-based filter system that does not require instrumentation or capitalization. In general, liquid-based preparation methods provide an attractive alternative to conventional smears for clinicians involved in procuring

Slide preparation made simple.

PULL. SNAP. FIX. PEEL.

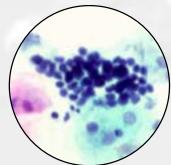
Obtain a suitably prepared liquid specimen. **Pull** the plunger until it locks in place to draw the sample. **Snap** the assembly open and transfer the filter to a slide. **Fix**, blot, and allow to dry. **Peel** the filter from the slide. Four simple steps to high-quality, high-yield, lowcost monolayer slides.

With the **Cyto-Tek® MonoPrep[™] System**, the high technology lies in the patented design, not in the use, making the process easy and affordable, and the results consistent. For fine needle aspirates, urines, bronchial washings and sputum, pleural and peritoneal cavity

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PEEL.



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PULL.

SNAP.

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Proven Reliability

FIX.

FNAs. Pathologists are beginning to embrace these new liquid-based preparation techniques because they decrease the number of slides required, as well as the time it takes to screen them.³

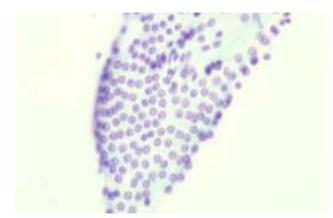
The process requires the placement of cells directly into a fixative solution, which also limits the amount of air-drying artifact on the slide. Accordingly, key morphologic features are easily distinguishable in single-cell preparations including small cell clusters, which can be examined for architectural features. This combination of nuclear detail and architectural cell clusters are some of the important criteria for making an accurate cytologic diagnosis,



Cyto-Tek[®] MonoPrep™

particularly in FNA preparations. Another advantage of the Cyto-Tek[®] MonoPrep[™] process is that cells can be kept in fixative (Cyto-Tek[®] MonoSol[™] solution) for up to three weeks, allowing the preparation of additional slides at a later date for special stains or other ancillary procedures, such as immunocytochemistry.^{4,5}

Recent FNA studies showed that the cellularity in the Cyto-Tek[®] MonoPrep[™] samples was largely comparable to that of conventional smears.^{4.8} Cobb et al⁷ studied the use of the Cyto-Tek[®] MonoPrep[™] in preparing thyroid FNAs, and reported that the Cyto-Tek[®] MonoPrep[™] method was simple, accurate, and inexpensive. The slides were uniform, less bloody, exhibited excellent preservation, and retained diagnostic advantages. In another study of breast FNAs, Florentine et al⁸ evaluated the Cyto-Tek[®] MonoPrep[™] system for palpable masses and com-



Thyroid FNA processed by Cyto-Tek[®] MonoPrep[™] device (40×)

pared the result with conventional smears. The diagnostic yield was comparable to conventional smears; preservation and staining of the cells was excellent. Enhanced quantitative and qualitative differences were noted in the morphology of the cells in the nucleoli of both ductal and myoepithelial cells in the Cyto-Tek[®] MonoPrep[™] slides. These changes have been reported by Perez-Reyes et al⁹ in a previous study using the ThinPrep[™] thin-layer preparation processor.

In summary, the Cyto-Tek[®] MonoPrep[™] method yielded slides with superior cytologic features. This technique also demonstrates a good correlation with the conventional smears in different FNA applications, and offers an attractive, inexpensive alternative to the smears in any medical laboratory setting, especially in communities where clinicians are inexperienced in slide smearing techniques. Small labs that process only a few specimens a week should find it highly useful because they do not need to invest in expensive processing instrumentation.

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Immucor[®] Canada Inc. Announces Name Change... To SOMAGEN Diagnostics

At the recent NSH Congress in Salt Lake City, Sakura's Canadian distributor, Immucor[®] Canada Inc. announced a change in their name. The Canadian company is now known as SOMAGEN Diagnostics. To celebrate the name change and thank customers for their continued support, SOMAGEN hosted a large contingent from all regions of the country to a traditional Japanese dinner. Representatives from Sakura attended, including surprise guest waiter, Tak.



S O M A G E N

"The new name reflects the change and evolution of our business," says SOMAGEN Vice President Kevin Blackburn. "The Immucor name was well known, but was tied too closely to blood banking and no longer reflected our leading role in markets such as histology." SOMAGEN has emerged as the leader in Canadian distribution for specialized clinical laboratory products. The relationship with Sakura provides customers with the powerful tandem benefits of quality products, technical service, and customer support.

For those who already know SOMAGEN Diagnostics, but only as Immucor Canada Inc., rest assured that the people you are accustomed to working with are still there. They're at the same location. And they can still be reached at 1-800-661-9993. For those who don't know them, they look forward to serving you in the future.

To receive your own copy of *Histo-Logic*,[®] or to have someone added to the mailing list, submit home address to: Sakura Finetek U.S.A., Inc., 1750 West 214th Street, Torrance, CA 90501.

The editor wishes to solicit information, questions, and articles relating to histotechnology. Submit these to: Terri Staples, *Histo-Logic* Editor, 1000 16th Avenue South, Birmingham, AL 35205. Articles, photographs, etc, will not be returned unless requested in writing when they are submitted.



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