Put It on the Board, 1/18

Some safety issues more gray than black and white

Most laboratory safety rules are free from ambiguity. Anyone who handles specimens must wear personal protective equipment, for example. Some issues are less clearly defined, though, and require a deeper dive into the guidelines.

That is where Dan Scungio, MT (ASCP), SLS, CQA(ASQ), comes in.

As laboratory safety officer for Sentara Healthcare, he maintains safety programs at sites throughout Virginia and northern North Carolina. In his consulting work as Dan the Lab Safety Man, Scungio digs into regulations to answer safety questions for an international audience of laboratory personnel via his website and presentations.

Scungio

Scungio took some of the most commonly asked laboratory safety scenario questions to the October 2017 Global Summit on Best Practices in Preanalytics, organized by Greiner Bio-One North America. The trickiest part about the presentation, he says, was telling his audience of safety officers, managers, and other laboratory personnel that not every question has a clear-cut answer.

“Laboratorians tend to like to think in terms of black and white. We just want a definitive answer,” Scungio says. But “sometimes you have to look for your own answer based on your own laboratory and situation.”

For example, regulatory agencies and organizations say little about whether phlebotomists should wear lab coats when drawing blood, he says. “OSHA says, ‘You need to wear gloves,’ and they don’t really talk about lab coats for phlebotomy,” he says. The CAP also does not specifically address a dress code beyond gloves for blood collection, he adds.

Scungio dug deeper and found an OSHA letter of interpretation, which says that phlebotomists do not need to wear lab coats during venipuncture. “But that is not really the end of the story,” he says.

A 2008 study reveals that nearly 75 percent of the 180 phlebotomists who responded to a survey reported having experienced blood spatter above their glove line while drawing blood.

“I’ve drawn blood a lot in my career and never had that issue. But this is a high percentage of phlebotomists saying it happened,” Scungio says, adding that the study was performed by a lab coat manufacturer.

Having phlebotomists wear lab coats raises other questions. “Should we wear the same lab coat from patient to patient? Because now you’re wearing personal protective equipment, and we certainly don’t wear gloves from patient to patient,” Scungio says. “We don’t even use the same tourniquet from patient to patient anymore, or the same needle hubs.”

His advice to laboratorians is to perform a risk assessment at their site based on the safety issues staff have experienced. “You have to make that determination for yourself,” he says.

Emergency eye washes and showers are another popular topic. The CAP and OSHA say that for hazardous chemicals, an eye wash must be no more than 55 feet or 10 seconds of travel distance from the hazard, Scungio

says. “If you have a door in the way of that 55 feet and 10 seconds and it opens toward you while you’re traveling, that’s considered an obstruction. That’s not allowed,” he adds.

OSHA also requires a shower, depending on the amount of hazardous chemical in the laboratory. Curiously, no regulation addresses having an eye wash or shower for bloodborne pathogens, “but you would want that if you have an exposure,” Scungio says.

“I always talk about face protection as the bottom line,” he says. “If you’re using face protection when you should be, you shouldn’t have to worry about needing an eye wash.”

Regarding the issue of gloves and microbiology, “We’re probably 50/50 with compliance in this across the country, based on labs I work with,” Scungio says. While there is no clear regulation—OSHA’s letter of interpretation on the subject says glove use is “strongly encouraged”—Scungio sees no room for indecisiveness.

“They plate cultures with their gloves on because they’re handling specimens. If you’re handling those plates with gloves on, you certainly should handle them with gloves on the very next day when you’re taking them out of the incubator to look at them. You can’t have it both ways. Either the surface is contaminated or it’s not.”

More often than not, a regulation will address a laboratory safety question. “If you can’t find it in black and white, and none of your resources is able to help you, then make the determination based on what is the best safety practice,” Scungio says.

The 2018 Global Summit on Best Practices in Preanalytics will be held Oct. 15–18 in Charlotte, NC. —*Amy Carpenter Aquino*
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Siemens acquires Fast Track Diagnostics

Siemens Healthineers has signed an agreement to acquire Luxembourg-based Fast Track Diagnostics, a global supplier of diagnostic tests. The acquisition increases the menu of the Siemens Healthineers Versant kPCR Molecular System by more than 80 assays and syndromic panels, Siemens said in a Dec. 15 statement.

Fast Track’s tests are real-time PCR kits that target respiratory infections, gastroenteritis, meningitis, hepatitis, and other conditions.

Through the acquisition, Siemens Healthineers will now include Fast Track’s sites in Luxembourg, Malta, and India, as well as its workforce of about 80 employees.
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Opdivo OK’d for adjuvant treatment of melanoma

The FDA approved in December Opdivo (nivolumab) injection for intravenous use for the adjuvant treatment of patients with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection.

In the phase three CheckMate -238 trial, Opdivo significantly improved recurrence-free survival versus an active comparator, Yervoy (ipilimumab), in patients with stage IIIB/C or stage IV melanoma after surgery, according to the company. This benefit was observed across important subgroups, including in both *BRAF* mutant and *BRAF* wild-type patients.

In the CheckMate -238 trial, Opdivo demonstrated an 18-month recurrence-free survival rate of 66.4 percent (95 percent confidence interval: 61.8 to 70.6) compared with 52.7 percent for Yervoy (95 percent CI: 47.8 to 57.4), with the median RFS not yet reached in either group. Opdivo reduced the risk of disease recurrence by 35 percent versus Yervoy (hazard ratio: 0.65; 95 percent CI: 0.53 to 0.80; $P<0.0001$).

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Horizon to develop FFPE reference standards

Horizon Discovery Group entered into an agreement last month with Roche Diagnostics to assist in the development of immunohistochemistry assays.

Horizon will develop and provide reference standard material expressing neurotrophic tropomyosin receptor kinase (NTRK) fusion biomarkers. NTRK gene rearrangements have emerged as promising targets for cancer therapy, and a number of novel compounds have been developed against the fusion proteins that arise from these molecular alterations. Their effective application depends on the accurate determination of the genotype of patients, primarily through IHC-based testing.

Horizon's reference standards will be derived from cell lines generated using the company's gene editing platform to include knock-ins of NTRK 1, 2, and 3 fusion cDNA (each under the control of multiple promoters), to achieve low to high levels of protein expression in selected cell lines. The cells will be supplied in formalin-fixed, paraffin-embedded format. The project is expected to be completed within 12 months.

This agreement builds on the Horizon-Roche partnership announced in 2016, which consisted of the development, manufacture, and commercialization of cell line derivative materials for use as IHC reference standards in cancer tissue diagnostics, to support the development and validation of IHC assays.

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FDA approves Ortho's Vitros HIV Combo test

The FDA approved Ortho Clinical Diagnostics' Vitros Immunodiagnostic Products HIV Combo Reagent Pack and Calibrator for use on Ortho's Vitros 3600 Immunodiagnostic System.

Vitros HIV Combo, a fourth-generation test, detects HIV-1 and HIV-2 antibodies and p24 antigen.

In comparison studies, assay sensitivity was evaluated on seroconversion panels. The Vitros HIV Combo test showed earlier detection of acute HIV infection in six of 32 seroconversion panels (agreement for 25 of 32 panels) when compared with a leading commercially available fourth-generation Ag/Ab test, according to Ortho Clinical Diagnostics.

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Perjeta approved for adjuvant treatment of HER2+ early breast cancer

The FDA approved in December Genentech's Perjeta (pertuzumab), in combination with Herceptin and chemotherapy (the Perjeta-based regimen), for post-surgery treatment of HER2-positive early breast cancer at high risk of recurrence. The FDA also converted the previously granted accelerated approval of the Perjeta-based regimen to full approval for neoadjuvant treatment of HER2-positive, locally advanced, inflammatory, or early-stage breast cancer (either greater than 2 cm in diameter or node-positive).

The FDA-approved use of the Perjeta-based regimen for adjuvant treatment of HER2-positive early breast cancer at high risk of recurrence is based on results of the phase three APHINITY study.

Perjeta is also approved for use in combination with Herceptin and docetaxel in people who have HER2-positive breast cancer that has metastasized and who have not received anti-HER2 therapy or chemotherapy for metastatic breast cancer.
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3rd respiratory assay cleared on Panther Fusion

Hologic received 510(k) clearance from the FDA for its Panther Fusion AdV/hMPV/RV assay, a multiplexed assay that runs on the Panther Fusion system.

The new assay detects adenovirus, human metapneumovirus, and rhinovirus. It complements the Panther Fusion Flu A/B/RSV assay and the Panther Fusion Paraflu assay, both of which were cleared last fall.

“Clearance and launch of the new Fusion AdV/hMPV/RV assay completes our initial set of modular assays for respiratory viruses,” said Tom West, president of the diagnostic solutions division at Hologic.

The Panther Fusion assays offer a modular approach to syndromic respiratory testing via the ability to run one, two, or all three assays from a single patient specimen.