

COMMISSION ON LABORATORY ACCREDITATION
Laboratory Accreditation Program
LABORATORY GENERAL
CHECKLIST

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March 2003

: excerpt :

GEN.71032 Phase I

N/A YES NO

Has the laboratory discontinued use of plain glass capillary tubes for specimen collection and specimen handling?

NOTE: A 2/22/99 advisory letter from the U.S. Food and Drug Administration, National Institute for Occupational Safety and Health, Centers for Disease Control, and the Occupational Safety and Health Administration concerns the potential risk of injury and/or infection due to accidental breakage of glass capillary tubes. To reduce the risk of injury due to breakage of glass capillary tubes, laboratories should adopt blood collection devices that are less prone to accidental breakage, including:

1. capillary tubes not made of glass,
2. glass capillary tubes wrapped in puncture-resistant film,
3. products that use a method of sealing that does not require manually pushing one end of the tube into putty to form a plug,
4. products that allow the hematocrit to be measured without centrifugation.

COMMENTARY:

For safety reasons, the laboratory should discontinue use of plain glass capillary tubes for specimen collection and specimen handling. A 2/22/99 advisory letter from the U.S. Food and Drug Administration, National Institute for Occupational Safety and Health, Centers for Disease Control, and the Occupational Safety and Health Administration concerns the potential risk of injury and/or infection due to accidental breakage of glass capillary tubes. To reduce the risk of injury due to breakage of glass capillary tubes, laboratories should adopt blood collection devices that are less prone to accidental breakage, including:

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: end of excerpt :

This document is available at:

http://www.cap.org/html/checklist_html/cklst_gen.html

Glass Capillary Tubes: Joint Safety Advisory About Potential Risks

(You are encouraged to copy and distribute this Advisory)

February 1999

Dear Colleague:

The Food and Drug Administration (FDA), the National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), and the Occupational Safety and Health Administration (OSHA) want to alert you to the potential risk of injury and/or infection from bloodborne pathogens, including human immunodeficiency virus (HIV), hepatitis B and hepatitis C viruses, due to accidental breakage of glass capillary tubes, and to recommend certain steps that can minimize the risk.

Background

Glass capillary tubes are used for the collection of blood in a variety of healthcare settings, including hospitals, ambulatory care facilities, physicians' offices, blood donation facilities, and blood testing centers. Accidental breakage of these slender, fragile tubes has been reported when the tubes are inserted into putty to be sealed and during centrifugation [1]. Breakage of the tubes during putty insertion may result in a penetrating wound and blood inoculation to the user. One such injury resulted in the transmission of human immunodeficiency virus (HIV) to a physician who has since died of acquired immunodeficiency syndrome (AIDS) [2]. Glass capillary tubes can break during centrifugation and cause blood to splatter, potentially exposing personnel to bloodborne pathogens. The broken glass fragments can injure the user, resulting in a percutaneous exposure to blood.

At one acute care facility, the injury rate associated with glass capillary tubes was 2.6 per 100,000 tubes purchased in 1992 [3]. Approximately 108 million glass capillary tubes are sold each year in the United States, suggesting that approximately 2,800 injuries may occur nationwide if a similar injury rate occurs at other healthcare facilities [3]. Two systems for surveillance of hospital-based healthcare worker injuries have reported injuries from glass capillary tubes, some of which caused blood exposure and resulted in the need for antiretroviral post-exposure prophylactic therapy [4].

Recommendations

To reduce the risk of injury due to breakage of capillary tubes, FDA, NIOSH, and OSHA recommend that users consider blood collection devices less prone to accidental breakage, including:

1. Capillary tubes that are not made of glass [5].
2. Glass capillary tubes wrapped in puncture-resistant film,
3. Products that use a method of sealing that does not require manually pushing one end of the tube into putty to form a plug, or
4. Products that allow the blood hematocrit to be measured without centrifugation.

Although FDA, NIOSH, and OSHA cannot recommend specific products, blood-collection devices with these characteristics are currently available, and their use may reduce the risk of injury and blood exposure.

Reporting and Recordkeeping

The Safe Medical Devices Act (SMDA) of 1990 requires hospitals and other user facilities to report deaths, serious illnesses, and injuries associated with the use of medical devices, including capillary tubes. Readers should follow procedures established by their own facilities for such mandatory reporting of adverse events. Practitioners who become

aware of any medical device-related adverse event or product problem/malfunction should report to their designated Medical Device User Facility Reporting contact person. Even if a medical device-related incident or product quality problem is not required to be reported under the SMDA, health professionals are encouraged to report any medical device related concerns to MedWatch, the FDA's voluntary reporting program. Submit reports to MedWatch by phone at 1-800-FDA-1088, by FAX at 1-800-FDA-0178, via the MedWatch website at www.fda.gov/medwatch, or mail to MedWatch, FDA, HF-2, 5600 Fishers Lane, Rockville, Maryland 20852-9787.

Occupational illnesses and injuries sustained from capillary tubes may be recordable under OSHA's recordkeeping requirements (see 29 CFR Part 1904: Recording and Reporting Occupational Injuries and Illnesses). Additionally, post-exposure follow-up for employees may be indicated [see OSHA's Instruction CPL 2-2.44C (March 6, 1992): Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens Standard, 29 CFR 1910.1030].

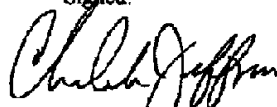
Getting More Information

If you have any questions on this Advisory, please contact:

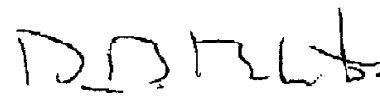
- **FDA:** Office of Surveillance and Biometrics, FAX at (301) 594-2968 (attn: Carol L. Herman, Public Health Analyst, by e-mail at czh@cdrh.fda.gov);
- **CDC:** National Institute for Occupational Safety and Health, 1 (800) 35-NIOSH (1-800-356-4674); or
- **OSHA:** Directorate of Technical Support, Office of Occupational Health Nursing, at (202) 693-2120 (attn: Elise Handelman).

Copies of this Safety Advisory and additional relevant information can be found on the following webpages:

www.fda.gov/cdrh/safety.html
www.cdc.gov/niosh/homepage.html
www.osha-slc.gov/SLTC/needlestick/

Signed:

Charles N. Jeffress
Assistant Secretary
OSHA


Linda Rosenstock
Director
NIOSH


D. Bruce Burlington, M.D.
Director
CDRH, FDA

References

1. Jagger, J., Hunt, E.H., and Pearson, R.D.: Sharp object injuries in the hospital; causes and strategies for prevention. *Am J Infec Control* 18(4):227-231, 1990.
2. Aoun, H.: When a house officer gets AIDS. *N Eng J Med* 321(10):693-696, 1989.
3. Jagger, J., Bentley, M., and Perry, J.: Glass capillary tubes: eliminating an unnecessary risk to healthcare workers. *Adv Exp Prev* 3(5):49-55, 1998.
4. Jagger, J. and Deitchman, S.: Hazards of glass capillary tubes to healthcare workers. *JAMA* 280(1):31, 1998.
5. Hudson, M., Morgan-Capner, P., and Wilson, M.: Potential hazards with fine bore capillary tubes used by non-pathology staff. *J Hosp Infec* 28(4):323-324, 1994.

Updated February 22, 1999