

TITLE:	Serum Banking [SOP#UNMC-IBC037]
OVERVIEW:	The <i>CDC/NIH's Biosafety in Biomedical and Microbiological Laboratories</i> , 5th Edition states the following (dependent on the type of laboratory containment used): (for ABSL-2/BSL-2 laboratory) "when appropriate, a baseline serum sample should be stored" and (for ABSL-3/BSL-3 laboratory) "each institution should consider the need for collection and storage of serum samples from at risk personnel". These guidelines DO NOT require the collection and storage of serum samples but require that the institution establish policies and procedures regarding the collection and storage of serum.
APPLIES TO:	All individuals working within the ABSL-2/BSL-2 and ABSL-3/BSL-3 laboratories.
DEFINITION(S):	Not applicable
PROCEDURES:	The University Institutional Biosafety Committee discourages the routine collection of serum for storage and/or for routine screening of employees. In most cases, serum can be collected at the time of exposure to evaluate an employee for exposure risk. In the rare instance when serum banking and/or testing is considered, the primary investigator in collaboration with the Institutional Biosafety Committee will perform a risk assessment to determine if the collection of serum is warranted. Refer to Appendix A for issues to consider when performing this risk assessment.
RECORD KEEPING:	Any records associated with the storage of serum samples must be maintained for at least the duration of employment. Any records associated with the testing of serum samples would need to be retained for the duration of employment plus thirty (30) years in accordance with the OSHA requirements in 29 CFR 1910:1020.
OTHER INFORMATION:	The cost of maintaining a serum banking program can be considerable and needs to be evaluated prior to initiation.
	Legal issues surrounding the collection of serum also need to be considered. A question to consider, "would the availability of a pre- work serum sample be of benefit to the University and/or to the employee?"
	While the banking of serum could potentially be useful in follow-up

University of Nebraska Medical Center Biosafety Policies and Procedures

	for epidemiological investigations, it is not useful in minimizing or preventing potential exposures (laboratory-acquired infections will occur whether or not the serum is banked)
REFERENCES:	 U.S. Department of health and Human Services, CDC/NIH. 2007. Biosafety in Microbiological and Biomedical Laboratories, 5th Edition. U.S. Department of Labor, OSHA Bloodborne Pathogen Standard, 29 CFR 1910:1020
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University of Nebraska Medical Center Biosafety Policies and Procedures

Appendix A Risk Assessment Issues

1. Is it necessary to know the exposure status in order to confirm that an infection had resulted from an agent with whom a person is working?

2. Is the organism worked with in the laboratory present in the general community and could personnel be exposed outside of work?

3. Could serum be collected at the time of exposure (acute serum) to determine the immediate immune status to a particular agent?

4. Will the serum be collected and tested routinely to determine immune status or will the serum be stored for future testing only?

5. Are individuals available with the appropriate training to collect and process the serum sample for storage?

6. Are security measures available to protect the confidentiality of records associated with the serum sample so only approved personnel have access to the records and samples?

7. If the serum is to be tested, are specific procedures available on how these samples will be tested, who will have access to the results, and on how the results be will be reported?

8. Is the freezer where the serum is to be stored secured and only accessible to authorized personnel as well as, alarmed and attached to emergency power?

9. Are procedures in place to determine how the serum sample will be disposed upon an employee's termination of work?