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Biosafety Risk Assessment: Instrument/Method Worksheet

This worksheet is intended to be used in conjunction with the “Conducting a Biosafety Risk Assessment” Standard Operating Procedure. This worksheet is meant to aid in the “Procedure Analysis Using Risk Assessment Hazard Exposure Activities and Controls Worksheet” step, in particular when evaluating specific instruments and methods that are not easily evaluated using the Biosafety Risk Assessment Hazard Exposure Activities and Controls Repository, scientific literature, or manufacturer documentation.

Instrument/Method Being Assessed:

Definitions

A/WP	Administrative and Work Practice
Eng	Engineering
PPE	Personal Protective Equipment

Procedure

1. Consider the following hazards and controls that may pertain to any use of an instrument regardless of potential for aerosolization, splash, or splatter:

Potential Hazard(s)	Control Type	Recommended Control
Contamination of specimen container and instrument surfaces	PPE	<ul style="list-style-type: none"> • Wear latex/nitrile gloves and lab coat.
Contamination of specimen container and instrument surfaces	A/WP	<ul style="list-style-type: none"> • Disinfect instrument surfaces according to scientific literature and manufacturer documentation using a disinfectant appropriate for the potential agents and the instrument. • Perform disinfection of instrument surfaces regularly or as recommended.
Leaking specimen container, broken specimen container, and specimen droplets falling from instrument parts (like pipette tips)	PPE	<ul style="list-style-type: none"> • Wear latex/nitrile gloves, lab coat, and possibly safety glasses (specimen droplets can splash or aerosolize on contact with surfaces).
Leaking specimen container, broken specimen container, and specimen droplets falling from instrument parts (like pipette tips)	A/WP	<ul style="list-style-type: none"> • If a specimen container is visibly leaking or broken, place container in biohazardous waste or at the minimum place in a sealed bag and move to a biological safety cabinet for further handling. • Discard gloves, wash hands, and don new gloves after handling a specimen container that is visibly leaking or broken. • Immediately disinfect instrument surfaces according to scientific literature and manufacturer documentation using a disinfectant appropriate for the potential agents and the instrument.



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		<ul style="list-style-type: none"> • Use plastic tubes with seal-forming screw tops whenever possible for centrifuging. • Examine tubes for cracks, imperfections, and scratches prior to using in instrument.
Leaking specimen container, broken specimen container, and specimen droplets falling from instrument parts (like pipette tips)	Eng	<ul style="list-style-type: none"> • Ensure instrument safety shields and containment devices are in place at time of use.
Biohazardous waste	A/WP	<ul style="list-style-type: none"> • Consider effluents of clinical analyzers to be contaminated. • Dispose of clinical analyzer effluents according to state and local regulations.

2. Does this instrument or method employ any of the following techniques?

Technique Used in Instrument/Method?	Yes	No
Pipetting	<input type="checkbox"/>	<input type="checkbox"/>
Pouring	<input type="checkbox"/>	<input type="checkbox"/>
Mixing with a pipette	<input type="checkbox"/>	<input type="checkbox"/>
Mixing with a vortex mixer	<input type="checkbox"/>	<input type="checkbox"/>
Blending	<input type="checkbox"/>	<input type="checkbox"/>
Grinding	<input type="checkbox"/>	<input type="checkbox"/>
Homogenizing	<input type="checkbox"/>	<input type="checkbox"/>
Sonicating (using an ultrasonic device)	<input type="checkbox"/>	<input type="checkbox"/>
Using an oscillating saw	<input type="checkbox"/>	<input type="checkbox"/>
Using a fluid-aspirating hose	<input type="checkbox"/>	<input type="checkbox"/>
Centrifuging	<input type="checkbox"/>	<input type="checkbox"/>
Vaporizing (such as in Time of Flight (TOF) Mass Spectrometry)	<input type="checkbox"/>	<input type="checkbox"/>

3. If you answered NO to all of the techniques in step 2, there should be minimal risk of aerosolization, splash, or splatter. **Stop here.**

4. If you answered YES to any of the techniques in step 2, using the scientific literature and manufacturer documentation as a guide, are you confident that the agents present in the specimen are inactivated prior to the step 2 technique(s) being used?

	Yes	No
Are agents inactivated prior to step 2 technique(s) being used?	<input type="checkbox"/>	<input type="checkbox"/>
↳ If yes, is the inactivation process documented?	<input type="checkbox"/>	<input type="checkbox"/>

5. If you answered YES to the questions in step 4, using this instrument or method should not present a risk of aerosolization, splash, or splatter of infectious agents. **Stop here.**

6. **⚠** If you answered NO to either question in step 4, using this instrument or method presents a risk of aerosolization, splash, or splatter of infectious agents.



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- 6.1. If this instrument employs any of the techniques other than pipetting with minimal bubble creation, it is critical that you evaluate this method for the risk posed by these techniques. Even if it only employs pipetting with no or minimal bubble creation, it is still best to consider ways to reduce the associated risk.
7. At a minimum, consider the following recommended controls:
 - 7.1. Wear latex/nitrile gloves, lab coat, and safety glasses.
 - 7.2. Ensure instrument safety shields and containment devices are in place at time of use.
 - 7.3. Use centrifuges with sealed rotor buckets or sealed rotors.
 - 7.4. If additional instrument safety shields are available for purchase separate from the instrument itself, consider purchasing and using them.
 - 7.4.1. An example would be using aerosol containment covers over ELISA plate washers.
 - 7.5. Place the instrument or perform the method in a biological safety cabinet (BSC) to contain aerosols if possible and if doing so will not interrupt the flow of air in the cabinet.
 - 7.5.1. Do NOT use this instrument in a BSC without first verifying that it has not interrupted the flow of air in the cabinet.
 - 7.6. Use pipette tips with barrier filters.
 - 7.7. Ensure tubes are tightly sealed prior to mixing with a vortex mixer.
 - 7.7.1. Use the vortex mixer in a BSC if possible.
 - 7.7.2. Do not seal a tube with a cap or other covering that will also be used with other tubes. Using the same cap or covering with multiple tubes can lead to cross-contamination.
 - 7.8. Locate instrument as far away from other instruments and people as possible, especially areas of high traffic.
 - 7.9. If you suspect that a specimen being tested contains a select agent, exercise extreme caution.
 - 7.9.1. A complete list of select agents can be found at <http://www.selectagents.gov/SelectAgentsandToxinsList.html>.
 - 7.9.2. If you are in a sentinel level clinical laboratory, follow the protocols for suspected biological threat agents and emerging infectious diseases to rule out microorganisms suspected as agents of bioterrorism or to refer specimens to public health laboratories for confirmation.
 - 7.9.2.1. These protocols are available at <http://www.asm.org/index.php/guidelines/sentinel-guidelines>.
 - 7.9.3. Unless you are in a public health laboratory working in a BSL-3 lab and using proper inactivation procedures prior to testing, do not use automated instruments with specimens that are suspected to contain select agents.
8. Using the scientific literature and the resources described in the “Consideration of Biological and Chemical Hazards” step of the “Conducting a Biosafety Risk Assessment” Standard Operating Procedure as a guide, do any of the agents being considered in this biosafety risk assessment have a low inhalation infective dose?

	Yes	No
Does any agent considered have a low inhalation infective dose?	<input type="checkbox"/>	<input type="checkbox"/>

9. Do you expect the agents to be in a high concentration while being used with this instrument or method? Refer to the applicable laboratory procedure SOP for clues and consider a “worst case” (the most concentrated specimen one could expect when following this SOP).

	Yes	No
Are the agents in a high concentration while used with the instrument or method?	<input type="checkbox"/>	<input type="checkbox"/>



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10. Do any of the agents being considered in this biosafety risk assessment have a high risk of infection via direct contact with skin or mucous membranes?

	Yes	No
Does any agent considered have a high risk of infection via direct contact?	<input type="checkbox"/>	<input type="checkbox"/>

11. If you answered NO to all of the questions in steps 8, 9, and 10, the instrument or method is likely safe to use provided that the recommended controls in step 7 are used along with other good laboratory practices as described in the biosafety risk assessment, the scientific literature, and the manufacturer documentation. Regularly consult the Biosafety Risk Assessment Hazard Exposure Activities and Controls Repository, scientific literature, and manufacturer for new biosafety recommendations. **Stop here.**

12. **⚠** If you answered YES to one or more of the questions in steps 8, 9, or 10, using this instrument or method with the agents being considered in this biosafety risk assessment could be potentially dangerous to the health and safety of laboratory personnel, the environment, and people the laboratory personnel come into contact with.

- 12.1. The lab manager, lab supervisor, or lab director should consult with the instrument manufacturer and trusted colleagues to determine, with the aid of the most up-to-date scientific literature, whether the instrument or method in question can be safely used with these potential agents in the current setting.
- 12.2. Consider using an alternative instrument or method that poses a lower risk.
- 12.3. Consider changing the way in which the instrument or method is used so that the agents are inactivated prior to the instrument or to any method using techniques that could result in aerosolization, splash, or splatter.
- 12.4. Consider changing the way in which the instrument or method is used so that the techniques that could result in aerosolization, splash, or splatter are eliminated or reduced.
- 12.5. If a BSL-3 lab is available and this procedure is currently being performed in a BSL-2 lab, consider conducting the procedure in a BSL-3 lab. The extra controls used in a BSL-3 lab may sufficiently mitigate the risks posed by this procedure and allow one to use this instrument or method with minimal risk posed to personnel, environment, and contacts.
- 12.6. If a BSL-3 lab is not available and an alternative instrument or method cannot be used, consider referring the specimen to an appropriate lab.

13. Based on a considered evaluation of this instrument or method and its risks, which of the following courses will be taken? One or more can be chosen.

Course(s) To Be Taken	Chosen
Use the instrument/method in its current setting while using all available and practical controls.	<input type="checkbox"/>
Use an alternative instrument/method that poses a lower risk.	<input type="checkbox"/>
Change the way in which the instrument/method is used so that the agents are inactivated prior to the instrument or to any method using techniques that could result in aerosolization, splash, or splatter.	<input type="checkbox"/>
Change the way in which the instrument or method is used so that the techniques that could result in aerosolization, splash, or splatter are eliminated or reduced.	<input type="checkbox"/>
Use the instrument/method in a BSL-3 lab.	<input type="checkbox"/>



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Refer the specimen to an appropriate lab.	<input type="checkbox"/>
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Sources

1. APHL (Association of Public Health Laboratories) Template for Public Health Laboratory Risk Assessment for Ebola Virus Disease (EVD) Testing
 - 1.1. <http://www.aphl.org/aphlprograms/preparedness-and-response/documents/aphl-template.pdf>
2. CDC (Centers for Disease Control and Prevention) Guidance for U.S. Laboratories for Managing and Testing Routine Clinical Specimens When There is a Concern About Ebola Virus Disease
 - 2.1. <http://www.cdc.gov/vhf/ebola/healthcare-us/laboratories/safe-specimen-management.html>
3. CDC (Centers for Disease Control and Prevention) MMWR (Morbidity and Mortality Report) Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories
 - 3.1. <http://www.cdc.gov/mmwr/pdf/other/su6101.pdf>
4. CLSI (Clinical and Laboratory Standards Institute) M29-A3 (Vol. 25 No. 10) Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Third Edition

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