



Vision: To be the Healthiest State in the Nation

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. It is meant to aid in the “Procedure Analysis Using Risk Assessment Hazard Exposure Activities and Controls Worksheet” step, especially for 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.

NOTE: Notes and Roman numeral superscript indicate endnotes that give recommendation references.

Instrument/Method Being Assessed:

Procedure

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

Technique Used in Instrument/Method?	Yes (with <u>infectious</u> substances)	Yes (only with <i>noninfectious</i> substances)	No
Opening containers ⁱ	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pipetting ⁱⁱ <u>Note</u> ②	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Using a needle or syringe ⁱⁱⁱ	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pouring ^{iv} <u>Note</u> ①	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Using inoculation needles or loops ^v	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mixing with a pipette ^{vi}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mixing with a vortex mixer ^{vii} <u>Note</u> ①	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Blending ^{viii} <u>Note</u> ②	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Grinding ^{ix} <u>Note</u> ②	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Homogenizing ^x	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Shaking ^{xi} <u>Note</u> ②	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sonicating (using an ultrasonic device) ^{xii} <u>Note</u> ①	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Using a fluid-aspirating hose ^{xiii}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Using a vacuum-assisted device ^{xiv}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Using a plate washer ^{xv}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Centrifuging ^{xvi} <u>Note</u> ①	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Producing bubbles (such as during catalase testing) ^{xvii}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Flaming inoculation needles or loops ^{xviii}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Flaming or heat fixing slides ^{xix}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Waving slides in the air or using electric fans to air-dry slides ^{xx}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Using a needle-cutting device ^{xxi}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Using a cryostat cutting blade ^{xxii}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Using an oscillating saw ^{xxiii}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Using a jet-in-air flow cytometer ^{xxiv}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ionizing (such as sonic spray ionization used with mass spectrometers in the chemistry laboratory) ^{xxv}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Performing any other procedure(s) that may impart energy ^{xxvi} ↳ Specify:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



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2. If you answered “NO” to *all* the techniques in step 1, there should be minimal risk of aerosolization, splash, or splatter. **Check here , and go to ⇒STEP 10⇐**

3. If your answers to the techniques in step 1 included *only* “YES (ONLY WITH *NONINFECTIOUS SUBSTANCES*)” and “NO”:

- If no inactivation procedure was needed to render substances noninfectious prior to any of the techniques listed in step 1 being used (typical for procedures that only involve reagents):
 - Using this instrument or method should not present a risk of aerosolization, splash or splatter of infectious agents or toxins. **Check here , and go to ⇒STEP 10⇐**
- If specimens, specimen products, culture materials, or other substances are inactivated (rendered noninfectious) prior to any of the techniques listed in step 1 being used:
 - Using the scientific literature and manufacturer documentation as a guide:

	Yes	No
Are you confident that the inactivation process inactivated all agents or toxins that are expected to be present in the specimen/product/material/substance prior to any step 1 technique(s) being used?	<input type="checkbox"/>	<input type="checkbox"/>
↳ <i>If yes, is the inactivation process documented (there is a standard operating procedure for inactivation and the performance of this procedure is recorded)?</i>	<input type="checkbox"/>	<input type="checkbox"/>

- If you answered “YES” to *both* questions above, using this instrument or method should not present a risk of aerosolization, splash, or splatter of infectious agents or toxins. **Check here , and go to ⇒STEP 10⇐**

4. **⚠** If you answered “YES (WITH INFECTIOUS SUBSTANCES)” to *any* of the techniques in step 1 or you answered “NO” to *one or more* questions in step 3, using this instrument or method presents a risk of aerosolization, splash, or splatter of infectious agents or toxins.

- If this instrument or method 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 this instrument or method only employs pipetting with no or minimal bubble creation, it is still best to consider ways to reduce the associated risk.
 - This is illustrated by CDC Brucellosis Reference Guide: Exposures, Testing, And Prevention (page 10) describing that manipulations such as automated pipetting of a suspension containing the organism may require further investigation for consideration as a major aerosol generating activity.
 - This especially important for agents that pose a risk via the inhalation route.

5. At a minimum, implement as many of the following recommended controls as possible when applicable.

- One or more can be chosen.
- Indicate if you will add the control to your existing procedure (Add), if the control is already in place in your procedure (In Place), or if the control is not applicable to your procedure (NA).



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Recommended Controls	Add	In Place	NA
<ul style="list-style-type: none"> 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.^{xxvii} <ul style="list-style-type: none"> Do NOT use this instrument in a BSC without first verifying that it has not interrupted the flow of air in the cabinet.^{xxviii} 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> Use aerosol-resistant pipette tips with barrier filters.^{xxix} 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> Touch pipette tips to the inside of the well or tube before pressing the delivery plunger.^{xxx} 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> Use disposable inoculation needles and loops or use electric incinerators for metal wire devices.^{xxxi} 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> Ensure tubes are tightly sealed prior to mixing with a vortex mixer.^{xxxii} <ul style="list-style-type: none"> 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. 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> Wait for a few seconds before opening caps after vortex mixing or shaking.^{xxxiii} 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> Use the vortex mixer in a BSC.^{xxxiv} 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> If using a vacuum-assisted device, use an aspiration trap consisting of one or two suction flasks plumbed together in series with an in-line HEPA filter.^{xxxv} <ul style="list-style-type: none"> Decontaminate liquid wastes from aspiration traps with bleach before disposal.^{xxxvi} Disinfect the hose by aspirating 10–50 mL of a freshly made bleach solution into the trap.^{xxxvii} 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> Use centrifuges with sealed rotor buckets, sealed rotor cups, or sealed rotors.^{xxxviii} <ul style="list-style-type: none"> Open and unload sealed buckets, cups, and rotors within a BSC.^{xxxix} Use O-rings with rotors.^{xl} Inspect rotors, seals, and O-rings before use.^{xli} 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> Perform catalase testing using the capillary tube procedure^{xlii}, a closed tube^{xliii}, or a closed petri dish.^{xliv} 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> Use a slide-warming tray rather than a flame to fix slides.^{xlv} 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> Locate instrument/method as far away from other instruments and people as possible, especially areas of high traffic.^{xlvi} 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> If you suspect that a specimen being tested contains a Select Agent, exercise extreme caution. <ul style="list-style-type: none"> A complete list of select agents can be found at http://www.selectagents.gov/SelectAgentsandToxinsList.html. 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. <ul style="list-style-type: none"> These protocols are available at http://www.asm.org/index.php/guidelines/sentinel-guidelines. 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. 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



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Recommended Controls	Add	In Place	NA
<ul style="list-style-type: none"> Physicians and other patient care staff should flag patients or individual specimens if there is a suspicion that the patient may have a pathogen that poses a high risk to laboratory staff, even if the pathogen does not pose a significant risk to patient care staff and other patients. <ul style="list-style-type: none"> An example would be <i>Brucella</i>, which is a bloodborne pathogen in the eyes of patient care staff but a significant laboratory hazard when aerosolized or cultured. A system may already be in place for infection control purposes, such as the one in place to meet the element “hospital has system to identify (flag) patients with targeted MDROs [Multidrug-Resistant Organisms] upon readmission so appropriate precautions can be applied” on page 22 of the CDC Infection Control Assessment Tool for Acute Care Hospitals. If a flagging system is already in place for infection control, then it may be expanded to include organisms that are highly hazardous to lab staff. Alternatively, notes may be included in the test requisition. When alerted by the flag or notes, the laboratory can use an alternate algorithm for relevant specimens. This algorithm may include using additional controls like following the protocols for suspected biological threat agents and emerging infectious diseases to rule out microorganisms suspected as agents of bioterrorism described above, using a BSC for all specimen and related culture manipulation, working in a BSL-3 laboratory, wearing respirators, and other additional controls. 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. 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, consider whether any agents or toxins being considered in this biosafety risk assessment may pose a high risk.

Considerations	Yes	No				
<p>Does any agent considered have a risk group of 3 or 4?</p> <ul style="list-style-type: none"> The American Biological Safety Association (ABSA) Risk Group Database at https://my.absa.org/tiki-index.php?page=Riskgroups is the quickest means of finding the risk group. Scroll or search for the agent. The number to the right of “BMBL*.” indicates the CDC’s recommendation for the risk group of the agent. If this is not present and another country’s agency has a risk group listed, this can be useful in lieu of a CDC recommendation. BMBL recommendations can also be found in the source material at http://www.cdc.gov/biosafety/publications/bmbl5/. Public Health Agency of Canada’s recommendations can be found on individual agent pages at https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment.html under “Section VII - Exposure Controls / Personal Protection.” <div data-bbox="803 1302 1372 1795" style="border: 1px solid black; padding: 5px;"> <table border="1"> <thead> <tr> <th>Genus</th> <th>Species</th> </tr> </thead> <tbody> <tr> <td>Brucella</td> <td>suis</td> </tr> </tbody> </table> <p>NIH: 3 BMBL*: 3 Australia/New Zealand: 3 Belgium: 3 Germany: 3 notes: AR EU: 3 Singapore: 3 Singapor Schedule: Switzerland: UK: 3</p> </div>	Genus	Species	Brucella	suis	<input type="checkbox"/>	<input type="checkbox"/>
Genus	Species					
Brucella	suis					



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Considerations	Yes	No
Does any agent considered have a low inhalation infectious dose? • Examples would be <i>Brucella</i> ^{xlvii} , <i>Mycobacterium tuberculosis</i> ^{xlviii} , <i>Neisseria meningitidis</i> ^{xlix} , <i>Bacillus anthracis</i> ⁱ , <i>Francisella tularensis</i> ⁱⁱ , <i>Burkholderia (Pseudomonas) mallei</i> ⁱⁱⁱ , <i>Burkholderia (Pseudomonas) pseudomallei</i> ⁱⁱⁱⁱ , <i>Yersinia pestis</i> ^{iv} , and Severe Acute Respiratory Syndrome (SARS) associated coronavirus ^{iv} .	<input type="checkbox"/>	<input type="checkbox"/>
Does any agent considered have a high risk of infection via direct contact with skin or mucous membranes? • An example would be Ebola virus. ^{lvi}	<input type="checkbox"/>	<input type="checkbox"/>

7. If you answered “NO” to *all* the considerations in step 6, the instrument or method is likely safe to use if the recommended controls in step 5 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.

Check here , and go to ⇒STEP 10⇐

8. If you answered “YES” to *one or more* of the considerations in step 6, consider how severe the risk is. Refer to the applicable laboratory procedure SOP for clues and consider a “worst case” scenario (the most concentrated or highest volume a specimen, specimen product, culture material, or substance one could expect when following this SOP).

Considerations	Yes	No
Do you expect the agents or toxins to be in a high concentration while being used with this instrument or method? • As an example for concentration, for specimens that may contain <i>Brucella</i> , the CDC Brucellosis Reference Guide: Exposures, Testing, And Prevention (page 10) includes “enriched material (e.g., a <i>Brucella</i> isolate, positive blood bottle)” and “reproductive clinical specimen (e.g., amniotic fluid, placental products)” as specimen types that may contain a high concentration of <i>Brucella</i> .	<input type="checkbox"/>	<input type="checkbox"/>
Do you expect the agents or toxins to be in a large volume while used with the instrument or method? • 50 mL or greater is a recommended starting point for considering a volume to be large. ^{lvii}	<input type="checkbox"/>	<input type="checkbox"/>

9. ⚠ If you answered “YES” to *one or more* of the considerations in step 6, 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 with whom the laboratory personnel come into contact.

- **!!!!!!** If you answered “YES” to *one or more* of the considerations in step 8, the risk is especially high.
- 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.
- Consider the following recommended controls to mitigate this risk.
- One or more can be chosen.
- Indicate if you will add the control to your existing procedure (Add), if the control is already in place in your procedure (In Place), or if the control is not applicable to your procedure (NA).



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Recommended Controls	Add	In Place	NA
<ul style="list-style-type: none"> • Use the instrument/method in its current setting while using some or all available and practical controls as chosen above in step 5. 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> • Use an alternative instrument/method that poses a lower risk. ↳ Specify:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> • Change the way in which the instrument/method is used so that the agents are inactivated prior to the instrument or any method using techniques that could result in aerosolization, splash, or splatter. ↳ Specify:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> • 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. ↳ Specify:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> • Use “trigger points” to determine when additional controls, such as conducting all work in a BSC and wearing additional PPE, should be used. ↳ Specify: <ul style="list-style-type: none"> → Trigger points are specific circumstances or situations that cause an event (using additional controls) to occur. They may include colony growth or staining characteristics, growth from normally sterile sites (such as blood, CSF, body fluids, lymph node & other aspirates), unusual test results, etc.^{lviii} 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If a BSL-3 lab is available and this procedure is currently being performed in a BSL-2 lab: <ul style="list-style-type: none"> • Use the instrument/method in a BSL-3 lab. 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> • Use the instrument/method in a BSL-2 lab with BSL-3 controls. ↳ Specify: <ul style="list-style-type: none"> → Note that a BSL-2 lab’s facility design may not adequately mitigate the risks of the instrument/method. → Examples of BSL-3 controls include ♦ wearing respirators; ♦ wearing solid-front wrap around gowns that are fluid-resistant or fluid-impermeable; ♦ wearing coveralls that are resistant to penetration by blood, body fluids, and blood-borne pathogens; ♦ wearing two layers of gloves; ♦ taping gloves to sleeves; ♦ wearing sleeve covers over gowns or coveralls; ♦ wearing disposable plastic aprons over gowns or coveralls; and ♦ performing all specimen manipulation in a BSC or sealed centrifuge rotor bucket, rotor cup, or rotor. 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> • Use gowns or coveralls that are impermeable or fluid-resistant. → For impermeable gowns, use a surgical or isolation gown that passes ♦ ANSI/AAMI PB70 Level 4 requirements. ^{lix} → For impermeable coveralls, use a coverall made with fabric and seams/closures that passes ♦ ASTM F1671 (13.8kPa) <u>or</u> ♦ ISO 16604 ≥ 14 kPa. ^{lx} → For fluid-resistant gowns, use a surgical or isolation gown that passes ♦ ANSI/AAMI PB70 Level 3 requirements <u>or</u> ♦ EN 13795 high performance surgical gown requirements. ^{lxi} → For fluid-resistant coveralls, use a coverall made of fabric that passes ♦ AATCC 42 ≤ 1 g and AATCC 127 ≥ 50 cm H ₂ O or EN 20811 ≥ 50 cm H ₂ O <u>or</u> ♦ ASTM F1670 (13.8kPa) <u>or</u> ♦ ISO 16603 ≥ 3.5 kPa. ^{lxii}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If a BSL-3 lab is not available, BSL-3 controls cannot be used in a BSL-2 lab, and an alternative instrument/method cannot be used: <ul style="list-style-type: none"> • Refer the specimen to an appropriate lab. ↳ Specify:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



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➔STEP 10◀ The following are minimum controls that should already be in place in all BSL-2 and BSL-3 laboratories. Consider the following hazards and the corresponding recommended controls.

- If a recommended control applies to your laboratory, it is critical that you use the control.
- One or more can be chosen.
- Indicate if you will add the control to your existing procedure (Add), if the control is already in place in your procedure (In Place), or if the control is not applicable to your procedure (NA).
- Control types include Administrative and Work Practice control (AWP), Engineering control (Eng), and Personal Protective Equipment control (PPE).

Recommended Control	Add	In Place	NA	Type
GENERAL CONTROLS				
↳Wear gloves (nitrile, latex, chloroprene, or other suitable material – not vinyl) and lab coat, gown, smock, or uniform designated for lab use while working with hazardous materials. ^{lxiii}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	PPE
↳Ensure instrument safety shields and containment devices are in place at time of use. ^{lxiv}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Eng
↳If work is not conducted in a BSC or behind a splatter guard (such as an instrument safety shield or bench-fixed splash shield), use eye and face protection to protect against splashes or sprays. ^{lxv} Examples include safety glasses, goggles, mask, and face shield.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	PPE
HAZARD: Sharps				
↳Limit the use of needles and syringes to procedures for which there are no alternative methods. ^{lxvi}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	AWP
↳Do not resheathe needles. ^{lxvii} <ul style="list-style-type: none"> • If resheathing is absolutely required, the procedure must utilize a needle resheathing device to minimize injury and accidental inoculation.^{lxviii} 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	AWP
↳Carefully place used disposable needles, syringes, scalpels, blades, pipettes, and similar objects into properly labeled leak- and puncture-resistant containers made for disposal. ^{lxix} <ul style="list-style-type: none"> • Replace sharps containers that are two-thirds to three-fourths full.^{lxx} • Sharps containers must close securely for transport to decontamination areas.^{lxxi} 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	AWP
↳Use safer sharps (e.g., autoretracting needle/syringe combinations, disposable scalpels). ^{lxxii} <ul style="list-style-type: none"> • Plasticware should be substituted for glassware whenever possible.^{lxxiii} 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Eng
HAZARD: Contamination of specimen container, instrument surfaces, sample probes, and liquid-level sensors				
↳Disinfect instrument surfaces per scientific literature and manufacturer documentation using a disinfectant appropriate for the potential agents and the instrument. ^{lxxiv}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	AWP
↳Perform disinfection of instrument surfaces regularly or as recommended.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	AWP
↳Limit the amount of hand movement near the sample probe and liquid-level sensors. ^{lxxv}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	AWP
HAZARD: Spilling and excess aerosol generation when filling sample cups and aliquot tubes				
↳Fill using mechanical devices (e.g., transfer pipettes). Never decant (pour). ^{lxxvi}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	AWP



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Recommended Control	Add	In Place	NA	Type
HAZARDS: Leaking specimen container; broken specimen container				
↳ 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. ^{lxxvii}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A/WP
↳ After handling a specimen container that is visibly leaking or broken, discard gloves, wash hands, and don new gloves.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A/WP
HAZARDS: Spilling of sample containers, trays, and plates; specimen droplets falling from instrument parts (like pipette tips)				
↳ For centrifuging, use plastic tubes with seal-forming screw tops whenever possible. ^{lxxviii}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A/WP
↳ Examine tubes for cracks, imperfections, and scratches prior to using in instrument. ^{lxxix}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A/WP
↳ Handle sample trays and sample plates with caution, and cover them when not being sampled to prevent spillage. ^{lxxx}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A/WP
↳ Secure specimen containers, culture tubes, shell vials, and other cylindrical vessels in racks whenever possible. ^{lxxxi}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A/WP
↳ If spills occur, immediately disinfect work surface and instrument surfaces per scientific literature and manufacturer documentation using a disinfectant appropriate for the potential agents and the instrument. • NOTE: For spills that occur outside of a BSC and involve agents that pose a risk via the inhalation route, consider leaving the area immediately and not reentering for 30 minutes (air change rate ≥ 12 air changes per hour) to 60 minutes (air change rate < 12 air changes per hour or unknown). ^{lxxxii}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A/WP
↳ Use commercial plastic-backed bench paper in BSCs and on laboratory work benches to absorb falling droplets. ^{lxxxiii}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A/WP
HAZARD: Biohazardous waste				
↳ Consider effluents of clinical analyzers to be contaminated. ^{lxxxiv}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A/WP
↳ While handling, storing, and transporting effluents, use containers constructed to contain all contents and prevent leakage. ^{lxxxv}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A/WP
↳ Dispose of effluents per federal, state, and local regulations. ^{lxxxvi}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A/WP
HAZARD: Contamination of sample probes that require manual wiping after sampling				
↳ When manually wiping sample probes, use gauze pads with impermeable plastic coating on one side. ^{lxxxvii}	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A/WP



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11. **OPTIONAL:** Use the following box to summarize notes of any additional controls that will be needed or items that will require further research based on this worksheet's findings.

Notes



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Sources

1. APHL (Association of Public Health Laboratories) ASM (American Society for Microbiology) Clinical Laboratory Preparedness and Response Guide (Blue Book)
 - 1.1. https://www.aphl.org/aboutAPHL/publications/Documents/WORK_BlueBook.pdf
2. APHL (Association of Public Health Laboratories) Template for Public Health Laboratory Risk Assessment for Ebola Virus Disease (EVD) Testing
 - 2.1. <https://www.aphl.org/programs/preparedness/documents/aphl-template.pdf>
3. ASM (American Society for Microbiology) Sentinel Level Clinical Laboratory Protocols for Suspected Biological Threat Agents and Emerging Infectious Diseases – Introduction, General Recommendations and Biochemical Test Procedures
 - 3.1. <https://www.asm.org/index.php/guidelines/sentinel-guidelines>
4. CDC (Centers for Disease Control and Prevention) Brucellosis Reference Guide: Exposures, Testing, And Prevention (Updated February 2017)
 - 4.1. <https://www.cdc.gov/brucellosis/pdf/brucellosi-reference-guide.pdf>
5. 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
 - 5.1. <http://www.cdc.gov/vhf/ebola/healthcare-us/laboratories/safe-specimen-management.html>
6. CDC (Centers for Disease Control and Prevention) Guidance on Personal Protective Equipment (PPE) To Be Used By Healthcare Workers during Management of Patients with Confirmed Ebola or Persons under Investigation (PUIs) for Ebola who are Clinically Unstable or Have Bleeding, Vomiting, or Diarrhea in U.S. Hospitals, Including Procedures for Donning and Doffing PPE
 - 6.1. <https://www.cdc.gov/vhf/ebola/healthcare-us/ppe/guidance.html>
7. CDC (Centers for Disease Control and Prevention) Infection Control Assessment Tool for Acute Care Hospitals
 - 7.1. <https://www.cdc.gov/infectioncontrol/pdf/icar/hospital.pdf>
8. CDC (Centers for Disease Control and Prevention) MMWR (Morbidity and Mortality Report) Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories
 - 8.1. <http://www.cdc.gov/mmwr/pdf/other/su6101.pdf>
9. CLSI (Clinical and Laboratory Standards Institute) M29-A4 (Vol. 34 No. 8) Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition
 - 9.1. <https://clsi.org/standards/products/microbiology/documents/m29/>
10. Fung DYC, Petrishko DT. Capillary Tube Catalase Test. *Applied Microbiology*. 1973;26(4):631-632.
 - 10.1. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC379865/>
11. Public Health Agency of Canada Pathogen Safety Data Sheets and Risk Assessment
 - 11.1. <https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment.html>
12. U.S. Department of Health and Human Services (HHS)/Centers for Disease Control and Prevention (CDC)/National Institutes of Health (NIH) Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition
 - 12.1. <http://www.cdc.gov/biosafety/publications/bmbl5/>

These resources are the product of research from respected biosafety sources that were combined to help create a biorisk program. Please follow your own professional judgement, your institution's established guidelines, and any applicable local, state, and federal requirements.



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Note①: CDC Brucellosis Reference Guide: Exposures, Testing, And Prevention (page 10) states that “widespread aerosol generating procedures include, but are not limited to: centrifuging without sealed carriers, vortexing, sonicating, or accidents resulting in spillage or splashes (i.e. breakage of tube containing specimen).” One could expect that pouring is like accidents resulting in spillage or splashes.

Note②: CDC Brucellosis Reference Guide: Exposures, Testing, And Prevention (page 10) states that “other manipulations such as automated pipetting of a suspension containing the organism, grinding the specimen, blending the specimen, shaking the specimen or procedures for suspension in liquid to produce standard concentration for identification may require further investigation (i.e. inclusion of steps that could be considered major aerosol generating activities).”

- i APHL Template for Public Health Laboratory Risk Assessment for Ebola Virus Disease (EVD) Testing – page 6; CDC MMWR Guidelines for Safe Work Practices – page 9; BMBL – page 36
- ii APHL Template for Public Health Laboratory Risk Assessment for Ebola Virus Disease (EVD) Testing – page 6; CDC MMWR Guidelines for Safe Work Practices – pages 8 and 28; BMBL – page 14
- iii CDC MMWR Guidelines for Safe Work Practices – page 8
- iv CDC MMWR Guidelines for Safe Work Practices – page 9
- v CDC MMWR Guidelines for Safe Work Practices – page 8
- vi CDC MMWR Guidelines for Safe Work Practices – pages 9, 28, and 29; BMBL – page 36
- vii APHL Template for Public Health Laboratory Risk Assessment for Ebola Virus Disease (EVD) Testing – pages 5 and 6; CDC MMWR Guidelines for Safe Work Practices – pages 9 and 28; BMBL – page 14
- viii CDC MMWR Guidelines for Safe Work Practices – pages 9 and 28; BMBL – page 14
- ix CDC MMWR Guidelines for Safe Work Practices – page 9; BMBL – page 36
- x CDC MMWR Guidelines for Safe Work Practices – page 29; BMBL – page 292
- xi CDC MMWR Guidelines for Safe Work Practices – page 9; BMBL – page 36
- xii CDC MMWR Guidelines for Safe Work Practices – pages 9 and 28; BMBL – page 14
- xiii CDC MMWR Guidelines for Safe Work Practices – pages 38 and 39
- xiv CDC MMWR Guidelines for Safe Work Practices – page 25
- xv CDC MMWR Guidelines for Safe Work Practices – page 33
- xvi APHL Template for Public Health Laboratory Risk Assessment for Ebola Virus Disease (EVD) Testing – pages 5 and 6; CDC Guidance for U.S. Laboratories for Managing and Testing Routine Clinical Specimens When There is a Concern About Ebola Virus Disease; CDC MMWR Guidelines for Safe Work Practices – pages 8 and 28; BMBL – page 36
- xvii CDC MMWR Guidelines for Safe Work Practices – page 9
- xviii CDC MMWR Guidelines for Safe Work Practices – page 8
- xix CDC MMWR Guidelines for Safe Work Practices – page 9
- xx CDC MMWR Guidelines for Safe Work Practices – page 72
- xxi CDC MMWR Guidelines for Safe Work Practices – page 26
- xxii CDC MMWR Guidelines for Safe Work Practices – page 43
- xxiii CDC MMWR Guidelines for Safe Work Practices – pages 38 and 39
- xxiv CDC MMWR Guidelines for Safe Work Practices – page 69
- xxv CDC MMWR Guidelines for Safe Work Practices – page 67
- xxvi BMBL – page 14
- xxvii CDC Guidance for U.S. Laboratories for Managing and Testing Routine Clinical Specimens When There is a Concern About Ebola Virus Disease
- xxviii CDC Guidance for U.S. Laboratories for Managing and Testing Routine Clinical Specimens When There is a Concern About Ebola Virus Disease
- xxix CDC MMWR Guidelines for Safe Work Practices – page 29
- xxx CDC MMWR Guidelines for Safe Work Practices – page 29
- xxxi CDC MMWR Guidelines for Safe Work Practices – page 16
- xxxii CDC MMWR Guidelines for Safe Work Practices – page 29
- xxxiii CLSI M29-A4 – page 33
- xxxiv CDC MMWR Guidelines for Safe Work Practices – page 65



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- xxxv CDC MMWR Guidelines for Safe Work Practices – pages 25 and 26
- xxxvi CDC MMWR Guidelines for Safe Work Practices – page 26
- xxxvii CDC MMWR Guidelines for Safe Work Practices – page 26
- xxxviii CDC Guidance for U.S. Laboratories for Managing and Testing Routine Clinical Specimens When There is a Concern About Ebola Virus Disease; CLSI M29-A4 – page 45
- xxxix CLSI M29-A4 – page 45
- xl CDC MMWR Guidelines for Safe Work Practices – page 32
- xli CLSI M29-A4 – page 69
- xlii Fung/Petrishko – Capillary Tube Catalase Test
- xliii APHL ASM Clinical Laboratory Preparedness and Response Guide (Blue Book) – page 36; ASM Sentinel Level Clinical Laboratory Protocols for Suspected Biological Threat Agents and Emerging Infectious Diseases – Introduction, General Recommendations and Biochemical Test Procedures – page 10
- xliv APHL ASM Clinical Laboratory Preparedness and Response Guide (Blue Book) – page 36; ASM Sentinel Level Clinical Laboratory Protocols for Suspected Biological Threat Agents and Emerging Infectious Diseases – Introduction, General Recommendations and Biochemical Test Procedures – page 10
- xlv CDC MMWR Guidelines for Safe Work Practices – page 35
- xlvi CDC Guidance for U.S. Laboratories for Managing and Testing Routine Clinical Specimens When There is a Concern About Ebola Virus Disease
- xlvii <https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment/brucella-b-abortus-b-canis-b-melitensis-b-suis-material-safety-data-sheets-msds.html>; BMBL – page 127
- xlviii <https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment/mycobacterium-tuberculosis-complex.html>; BMBL – page 146
- xlix <https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment/neisseria-meningitidis.html>; BMBL – page 150
- l <https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment/bacillus-anthraxis-material-safety-data-sheets-msds.html>; BMBL – page 124
- li <https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment/francisella-tularensis-material-safety-data-sheets-msds.html>; BMBL – page 138
- lii <https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment/burkholderia-pseudomonas-mallei-material-safety-data-sheets-msds.html>; BMBL – page 128
- liii <https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment/burkholderia-pseudomonas-pseudomallei-material-safety-data-sheets-msds.html>; BMBL – page 129
- liv <https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment/yersinia-pestis-material-safety-data-sheets-msds.html>; BMBL – page 160
- lv <https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment/severe-acute-respiratory-syndrome-sars-associated-coronavirus.html>; BMBL – page 225
- lvi <https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment/ebolavirus.html>
- lvii CLSI M29-A4 – pages 43 and 73
- lviii APHL ASM Clinical Laboratory Preparedness and Response Guide (Blue Book) – page 140; CDC MMWR Guidelines for Safe Work Practices – page 63
- lix CDC Guidance on PPE To Be Used By Healthcare Workers during Management of Patients with Confirmed Ebola or PUIs for Ebola who are Clinically Unstable or Have Bleeding, Vomiting, or Diarrhea in U.S. Hospitals, Including Procedures for Donning and Doffing PPE
- lx CDC Guidance on PPE To Be Used By Healthcare Workers during Management of Patients with Confirmed Ebola or PUIs for Ebola who are Clinically Unstable or Have Bleeding, Vomiting, or Diarrhea in U.S. Hospitals, Including Procedures for Donning and Doffing PPE
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- lxii CDC Guidance on PPE To Be Used By Healthcare Workers during Management of Patients with Confirmed Ebola or PUIs for Ebola who are Clinically Unstable or Have Bleeding, Vomiting, or Diarrhea in U.S. Hospitals, Including Procedures for Donning and Doffing PPE
- lxiii CDC MMWR Guidelines for Safe Work Practices – pages 33, 66, 69, and 73; CLSI M29-A4 – page 21; BMBL – pages 36 and 37
- lxiv CDC MMWR Guidelines for Safe Work Practices – pages 33, 66, 69, and 73
- lxv CDC MMWR Guidelines for Safe Work Practices – page 17
- lxvi CDC MMWR Guidelines for Safe Work Practices – page 26
- lxvii CDC MMWR Guidelines for Safe Work Practices – page 26
- lxviii CDC MMWR Guidelines for Safe Work Practices – page 26
- lxix CDC MMWR Guidelines for Safe Work Practices – page 27
- lxx CDC MMWR Guidelines for Safe Work Practices – page 27
- lxxi CDC MMWR Guidelines for Safe Work Practices – page 27
- lxxii CDC MMWR Guidelines for Safe Work Practices – page 10
- lxxiii CLSI M29-A4 – page 29
- lxxiv CLSI M29-A4 – page 63
- lxxv CDC MMWR Guidelines for Safe Work Practices – pages 33, 66, 69, and 73
- lxxvi CDC MMWR Guidelines for Safe Work Practices – pages 33, 66, 69, and 73
- lxxvii APHL Template for Public Health Laboratory Risk Assessment for Ebola Virus Disease (EVD) Testing – page 2
- lxxviii CLSI M29-A4 – page 70
- lxxix CLSI M29-A4 – page 70
- lxxx CDC MMWR Guidelines for Safe Work Practices – pages 33, 66, 69, and 73
- lxxxi CDC MMWR Guidelines for Safe Work Practices – page 28
- lxxxii CLSI M29-A4 – page 72
- lxxxiii CDC MMWR Guidelines for Safe Work Practices – page 29
- lxxxiv CDC MMWR Guidelines for Safe Work Practices – pages 33, 66, 69, and 73
- lxxxv CLSI M29-A4 – page 59
- lxxxvi CDC MMWR Guidelines for Safe Work Practices – pages 33, 66, 69, and 73
- lxxxvii CDC MMWR Guidelines for Safe Work Practices – pages 33, 66, 69, and 73