NYSDOH Environmental Laboratory Approval Program – Critical Agents Checklist

LAB ID and/or LABORATORY NAME:	
ASSESSOR NAME:	**DATE:**

CRITICAL AGENTS by NYSDOH Approved Method *B. anthracis (Swabs and Swipes); B. anthracis (Powders, Fluids, Bulk Mat); Botulinum Neurotoxin; Brucella; Burkholderia mallei, Burkholderia pseudomallei; F. tularensis; Orthopox; Ricin Toxin; Y. pestis*	
Method Number: ELAP method number 9900 **SOP Number:** **Revision Number:** **SOP Date:** **Personnel / Data Records observed:**	**Method Number:** ELAP method number 9900 **SOP Number:** **Revision Number:** **SOP Date:** **Personnel / Data Records observed:**
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References:

Biosafety in Microbiological and Biomedical Laboratories, US Department of Health and Human Services, Public Health Service (CDC and NIH), 5th Edition (February 2007)

Public Health Law Section 502, NYCRR Subpart 55-2.13 Requirements for laboratories engaged in testing for critical agents in environmental samples (Effective October 6, 2004).

NELAC 2003 Standard, Chapter 5 and Appendix D.3., EPA/600/R-04/003

The NELAC Institute (TNI) 2009 Standard, Volume 1, Module 2 and Module 5

Question	Y	N	NA	Codes	Comments
1. ORGANIZATION AND MANAGEMENT CA00001					
Does the laboratory have an Institutional Biosafety Review Board or an Institutional Biosafety Committee?				CA00002	
Is the laboratory registered with the Department of Health and Human Services to possess, transfer and receive the select agents for which it is ELAP certified?				CA00003	
Does the laboratory accept only the sample types for which it is certified (e.g., Swabs and Swipes or Powders, Fluids and Bulk Materials)?				CA00004	
2. PERSONNEL CA00005					
Are all relevant analytical procedures performed by analysts who are approved by the Department?				CA00006	
Is there documentation that employees collecting and/or transporting environmental samples receive training on the potential hazards associated with their work activities and the necessary precautions to prevent exposure to hazardous material?				CA00007	
Is there documentation that employees collecting and/or transporting environmental samples are trained in hazardous material handling techniques? Is the documentation maintained for **3 years**?				CA00008 CA00008A	
Is there documentation that employees handling CDC Select Agents, derivatives, and waste material receive annual training on the potential hazards associated with their work activities and the necessary precautions to prevent exposure to such hazardous material?				CA00009	
Are baseline serum samples collected as appropriate and stored for all laboratory and other at-risk personnel?				CA00010	
Do personnel receive annual updates or additional training as necessary for procedural changes?				CA00011	
Are records kept to show that (before working with unknown samples or known pathogens) all analysts have demonstrated proficiency in proficiency in required practices including standard microbiological techniques, sterile techniques, pathogen handling, and safe practices? Other examples: specific analytic methods used to identify biothreat agents; in the practices and operations specific to the laboratory facility, such as prior experience in handling human pathogens or cell cultures, or toxins; or a specific training program provided by the laboratory director or other competent scientist proficient in safe practices and techniques				CA00012	

Question	Y	N	NA	Codes	Comments
Does the laboratory maintain this documentation as long as the method is in use and for **at least five years** past the date of last use?				5123 51215	5.4.12 [M2, 4.13.3(a)]; 5.4.12.2.4.b [M2, 4.13.3(b)] 5.4.12.2.4.b [M2, 4.13.3(b)]
3. PHYSICAL FACILITIES					
GENERAL - Biosafety Level Facilities *CA00013*					
Are facilities that house restricted agents locked?				CA00036	
Does the laboratory have a ducted exhaust air ventilation system that creates directional airflow that draws air into the laboratory from “clean” areas and toward “contaminated” areas?				CA00015	
Is the exhaust air from the laboratory room discharged to the outdoors away from occupied areas and air intakes and through HEPA filtration (recommended) or other acceptable system?				CA00016	
When Class II biological safety (bio-safety) cabinets (BSCs) are used: CA00017					
a ___ Are they decontaminated at the start and end of each application and immediately following a spill or accident?				CA00018	
b ___ Is the air flow monitored and maintained at required levels while in use?				CA00019	
c ___ Are they tested and certified according to the National Sanitation Foundation **at the time of installation**, when they are moved, or at least **annually** thereafter?				CA00020	
d ___ Are they installed in such a manner that fluctuations of the room supply and exhaust air does not cause them to operate outside their parameters for containment?				CA00021	
e ___ Do the on-site measurements indicate they are working correctly?				CA00022	
When HEPA-filtered exhaust air from a Class II BSC is recirculated into the laboratory, is it tested and certified at least **annually**?				CA00023	
When exhaust air from Class II BSC is to be discharged to the outside through the building exhaust air system, is it connected in a manner that avoids any interference with the air balance of the cabinet or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct)?				CA00024	
Are Class III BSC connected directly to the exhaust system?				CA00025	
When using Class III BSC,					
a. ___ Is exhausted air not re-circulated to other areas of the building?				CA00026	

Question	Y	N	NA	Codes	Comments
b. ___ Is the ventilation to the laboratory balanced to provide directional airflow into the laboratory room so that negative pressure is maintained in the laboratory?				CA00027	
Are bench tops impervious to water and resistant to moderate heat and chemicals?				CA00028	
Are lab furniture and chairs covered with a non-permeable material that can easily be decontaminated?				CA00029	
Is a sink (hand free or automatically operated is recommended) readily available to laboratory employees?				CA00030	
Is an eye wash station readily available?				CA00031	
Are warning labels with the universal biohazard symbol or with the legend "Biohazard" affixed to cabinets and refrigerators?				CA00032	
Are biohazard warning signs posted on all laboratory access doors when infectious agents or toxins are in use?				CA00033	
Are measures taken to avoid accumulation of dust by _a__ Providing sufficient storage space, _b__ Having minimal paperwork in the laboratory, and _c__ Prohibiting plants and personal possessions in the laboratory work area?				0d355a 0d355b 0d355c	D.3.8.a [M5,1.7.3.7(a)]
Do the temperature measurement devices have the appropriate quality needed to achieve the specification in the test method?				00d356	D.3.8.b.1 [M5,1.7.3.7(b)(i)]
Are the devices temperature calibration traceable to national or international standards at least **annually**?				00d357	D.3.8.b.1 [M5,1.7.3.7(b)(i)]
Are the graduations of the temperature measuring devices appropriate for the required accuracy of measurement?				00d358	D.3.8.b.1 [M5,1.7.3.7(b)(i)]
Is the stability of temperature, uniformity of temperature distribution and time required to achieve equilibrium conditions in incubators, water baths, ovens and temperature-controlled rooms established? (Note: for example, position, space between and height of stacks of Petri dishes)				00d359	D.3.8.b.6.i [M5,1.7.3.7(b)(v)(1)]
Is a method for decontaminating all laboratory wastes available in the facility and utilized (preferably within the laboratory) (i.e., autoclave, alternative technology, etc)?				CA00034	
Is the system used to decontaminate waste (i.e. autoclaving) in or adjacent to the laboratory?				CA00035	
Is the performance of each autoclave **initially** evaluated by establishing its functional properties? (Note: for example heat distribution characteristics with respect to typical uses)				00d360	D.3.8.b.2.i [M5,1.7.3.7(b)(ii)]

Question	Y	N	NA	Codes	Comments
Is sterilization demonstrated by continuous temperature recording devices or through the use of a maximum registering thermometer with every cycle?				0d361a	NELAC D.3.8.b.2.ii
Are appropriate biological indicators used **at least each month** of use to determine effectiveness of sterilization?				0d361b	NELAC D.3.8.b.2.ii
Is temperature sensitive tape used with the contents of each autoclave run to indicate that the autoclave contents have been processed?				0d361c	NELAC D.3.8.b.2.ii
Do the records of autoclave operations include the following: a.__ Date, b.__ Contents, c.__ Maximum temperature reached, d.__ Time in sterilization mode, e.__ Total run time (may be recorded as time in and time out), and f.__ Analyst's initials?				 0d362a 0d362b 0d362c 0d362d 0d362e 0d362f	NELAC D.3.8.b.2.iii
Is autoclave maintenance performed either internally or by service contract, **annually**?				00d363z	NELAC D.3.8.b.2.iv
Does the **annual** maintenance of the autoclave include a pressure check and calibration of the temperature device?				0d363a	NELAC D.3.8.b.2.iv Ignore the part about pressure PV=nRT
Is the autoclave <u>mechanical</u> timing device checked **quarterly** against a stopwatch and is the actual time elapsed recorded?				0d363b	NELAC D.3.8.b.2.v
Biosafety Level 3 Facilities (Powders, Fluids and Bulk Material only) CA00037					
Is the laboratory separated from areas that are open to unrestricted traffic flow within the building? Is access to the laboratory restricted?				CA00038 CA00038A	
Is there a passage through a series of two self-closing doors for entry into the laboratory from access corridors (double door airlock passageway that may include a clothes change room)?				CA00039	
Are passageway doors lockable?				CA00040	
If the laboratory is situated in the same building as a patient-care facility, does the laboratory have separate access only from outside of the building?				CA00041	
Are interior surfaces sealed and impermeable to liquids, resistant to disinfectants, and easily cleanable?				CA00042	
Is the sink for hand washing "hand-free" and adjacent to the exit door?				CA00043	
Are vacuum lines protected with liquid disinfectant traps and HEPA filters, or their equivalent?				CA00044	

Question	Y	N	NA	Codes	Comments
Are outside windows removed or covered to render them unbreakable? Is the area sealed?				CA00045 CA00045A	
Is there verification that the direction of the airflow (into the laboratory) is proper? It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry.				CA00046	
Is there an HVAC control system to prevent sustained positive pressurization of the laboratory that is monitored by audible alarms to notify personnel of HVAC system failure? (recommendation)				CA00047	
BSL3 PRACTICES *CA00048*					
Does the laboratory Technical Director have final responsibility for assessing who may enter or work in the laboratory?				CA00049	
Is access to the laboratory limited or restricted by the laboratory Technical Director to protect the public and/or employees when work with infectious agents or toxins is in progress?				CA00050	
Are minors precluded from the laboratory entry?				CA00051	
Has the laboratory director established policies and procedures whereby only persons, who have been advised of the potential hazards and meet specific entry requirements, (e.g. appropriate immunizations) may enter the laboratory?				CA00052	
Are persons known to be at risk of acquiring infection or for whom infection may have serious consequences precluded from the laboratory?				CA00053	
Does the laboratory prohibit eating, drinking, smoking, handling contact lenses, and applying cosmetics and lip balm in work areas?				CA00054	
Is a biosafety manual specific to the laboratory prepared or adopted by the laboratory Technical Director? Are biosafety precautions incorporated into standard operating procedures?				CA00055 CA00055A	
Are personnel advised of special hazards? Do personnel read and follow instructions on practices and procedures referenced in the biosafety manual?				CA00056 CA00056A	
Does the laboratory and program specific BSL 3 manual detail: CA00057					
a. ____ specific agent risks?				CA00058	
b. ____ personnel training protocol?				CA00059	
c. ____ personal protective equipment?				CA00060	

Question	Y	N	NA	Codes	Comments
d. ____ standard protocols (including techniques)?				CA00061	
e. ____ sharps policy?				CA00062	
f. ____ emergency procedures?				CA00063	
g. ____ disinfection procedures?				CA00064	
h. ____ laboratory maintenance/cleaning procedures?				CA00065	
i. ____ spill procedures (inside and outside BSC)?				CA00066	
Are manipulations of suspect *B. anthracis* and other infectious materials and toxins conducted in a Class II or a Class III BSC?				CA00067	
Are manipulations of unknown samples or suspected Ricin toxin samples restricted to the BSC until a protein inactivation step is completed (e.g., chaotropic salt, heat, alcohol treatment)?				CA00068	
Are standard microbiological practices and special practices for BSL 3 rigorously followed?				CA00069	
When using a BSC, does the laboratory do the following:					
a. ____ maintain a clean and orderly work area?				CA00071	
b. ____ use techniques for minimization of aerosol generation?				CA00072	
c. ____ maintain open air vents for proper airflow?				CA00073	
d. ____ conduct work in center of the hood?				CA00074	
e. ____ remove of hands from hood only after disinfection?				CA00075	
f. ____ perform surface decontamination of all items before removal from it?				CA00076	
g. ____ employ use of an assistant outside it whenever powder samples are being manipulated/analyzed?				CA00077	
When a procedure or process cannot be conducted with a BSC, are appropriate combinations of personal protective equipment (e.g., respirators, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors) used?				CA00078	
Do laboratory personnel wash their hands following completion of laboratory activities and removal of protective clothing, before leaving the laboratory, and immediately upon contamination?				CA00079	
Are foods and drinks stored outside of the testing area in designated cabinets or refrigerators?				CA00080	
Is mouth pipetting prohibited? Are mechanical devices used for all pipetting procedures?				CA00081 CA00081A	

Question	Y	N	NA	Codes	Comments
Is there a policy for the safe handling of sharps? (See CA00062, too.)				CA00082	
Are contaminated sharp items always handled with a high degree of precaution?				CA00083	
Are sharp items minimally used?				CA00084	
Are procedures (involving the manipulation of potentially infectious or toxic agents) performed to minimize splashing, spraying, and creation of aerosols?				CA00085	
Are infectious or toxic substances and other regulated medical waste treated on-site using an approved method (such as autoclaving), or are they transported off-site in accordance with applicable local, state, and federal regulations?				CA00086	
Are materials to be decontaminated outside of the immediate laboratory placed in durable, leak-proof containers and closed for transport from the laboratory?				CA00087	
Are laboratory doors kept closed when work with infectious agents or toxins are in progress?				CA00088	
Are properly maintained BSCs (Class II) or other containment devices and appropriate personal protective equipment (PPE) used when: CA00089					
a. ___ procedures for creating infectious aerosols or splashes are done?				CA00090	
b. ___ high concentrations or large volumes of infectious agents or toxins are used?				CA00091	
Is equipment that may have been contaminated with infectious materials or toxins decontaminated and cleaned before removal from the laboratory?				CA00092	
Are protective laboratory clothing (such as solid-front or wrap around gowns, scrub suits, or coveralls) and PPE: CA00093					
a. ___ worn by analysts?				CA00094	
b. ___ not worn outside the laboratory?				CA00095	
c. ___ decontaminated, if reusable, before being laundered?				CA00096	
d. ___ changed when overtly contaminated?				CA00097	
Is appropriate respiratory protection (e.g., PAPR) worn whenever conducting procedures with a high potential for creating aerosols and powders?				CA00098	
Is protective laboratory clothing removed and left in the laboratory before leaving for non-laboratory areas?				CA00099	
Are double gloves worn when handling infectious materials or toxins and contaminated equipment?				CA00100	
Primary gloves:					

Question	Y	N	NA	Codes	Comments
a. ___ Are they worn?				CA00101	
b. ___ Are they donned prior to, or immediately upon, entrance to the BSL?				CA00102	
c. ___ Are hands washed following removal of them?				CA00103	
Secondary gloves:					
a. ___ Are they worn?				CA00104	
b. ___ Are they donned prior to initiation of BSC work?				CA00105	
c. ___ Are they decontaminated or changed between samples?				CA00106	
d. ___ Are they decontaminated, removed, and disposed of within the BSC?				CA00107	
Are potentially contaminated waste materials (e.g., gloves, lab coats, etc.) from laboratories decontaminated before disposal or reuse?				CA00108	
Are laboratory equipment and work surfaces decontaminated routinely with an effective disinfectant after work with infectious materials or toxins is finished and after overt spills, splashes, or other contamination with infectious materials?				CA00109	
Are all spills and accidents that result in overt or potential exposures to infectious or toxic materials:					
a. ____ Properly handled?				CA00110	
b. ____ Immediately reported to the laboratory Technical Director?				CA00111	
c. ____ Documented and investigated?				CA00112	
d ____ Subjected to immediate remedial action, and the action documented?				CA00113	
Is medical evaluation, surveillance, and treatment provided as appropriate, and written records maintained for overt or potential exposures to infectious or toxic materials?				CA00114	
Are laboratory equipment and work surfaces decontaminated with an effective disinfectant on a routine basis, after work with infectious material is finished, and following spills, splashes, or other contamination by infectious materials? (Use of 1:10 (1 part N NaOH + 9 parts H_20) dilution of a 5.25% solution of NaOH prepared daily or 1:5 dilutions for solutions prepared weekly is recommended)				CA00115	
If waste is transported out of the lab, is it properly sealed and not transported in public corridors?				CA00116	
Are secondary containers used for containment of all infectious materials and toxins transported outside of the BSC to prevent leakage during handling, processing, and storage?				CA00117	

Question	Y	N	NA	Codes	Comments
4. TEST METHODS AND SOPS CA00118					
Does the laboratory only use the following approved by the Department:					
a ____ Methods?				CA00119	
b ____ Sample analyses?				CA00120	
c ____ Sample collection procedures (when the laboratory collects its own samples or provides training to others)?				CA00121	
Are analytical test method SOPs implemented as written?				CA00122	
Is there validation data available for review for each SOP utilized for testing of critical agents?				CA00122A	
Does the laboratory have a system of archiving earlier editions of Standard Operating Procedure Manual (SOPM) entries which documents dates of implementation and discontinuance?				CA00123	
Does the Standard Operating Procedure Manual (SOPM) include the following for environmental samples and any derivatives:					
a. ___ Policy?				CA00124	
b. ___ Collection method?				CA00125	
c. ___ Labeling procedures?				CA00126	
d. ___ Accession and preparation procedures?				CA00127	
e. ___ Sample acceptance criteria (including conditions of sample rejection, conditions under which a sample should be tested, and reporting of results)?				CA00128	
f. ___ Sample analysis?				CA00129	
g. ___ Reporting procedures consistent with PHL 55-2.13?				CA00130	
h. ___ Storage procedures?				CA00131	
i. ___ Transportation and packaging procedures consistent with Federal and State Regulations?				CA00132	
j. ___ Decontamination and disposal procedures?				CA00133	
k. ___ Biosafety procedures (if not covered in the bio-safety manual)?				CA00134	
l. ___ Biosecurity procedures?				CA00135	
Does the SOP for biothreat analysis contain the following, in sufficient detail:					
a. ___ Instructions for plating, incubating and observing cultures (e.g., hemolysis on blood agar plates)?				CA00137	
b. ___ Quality control for culture media (including the analysis and				CA00138	

Question	Y	N	NA	Codes	Comments
documentation of a sterility blank and known negative and positive cultures for each lot of pre-prepared, ready-to-use medium and for each batch of medium prepared in the laboratory, prior to first use of medium of medium with samples)?				00d381, 00d311, and 00d312	D.3.1.a.1 [M5,1.7.3.1(b)(i)] D.3.1.c [M5,1.7.3.6(d)(ii)] D.3.1.b.1 [M5,1.7.3.6(d)(i)]
c. ___ Performance, reading and QC of a Gram stain?				CA00139	
d,. ___ Performance and QC of motility testing?				CA00140	
e. ___ Instructions, QC, and interpretation of validated specific methods of analysis?				CA00141	
Does the SOP for Ricin Toxin analysis (and other PCR-based methods) contain the following, in sufficient detail:					
a.___ Instructions for PCR-based methods including specificity data, negative, positive, and inhibition controls?				CA00143	
b.___ Instructions for antibody-based methods (such as ELISA, time-resolved fluorescence, or microsphere arrays, including specificity data, negative controls, positive controls, inhibition controls, and antibody vendor information)?				CA00144	
b.___ Sample size and shape to allow removal from containers in the confines of an approved biosafety facility?				CA00171	
c.___ Sample evaluation for other hazardous material (e.g., explosives)?				CA00172	
d.___ Work-flow and safeguards against amplicon contamination?				CA00173	
e.___ Acceptable validation data including sensitivity, specificity and blind studies?				CA00174	
Are the quality control protocols specified by the laboratory's method manual followed by all analysts?				000d12	D [M2,5.9.3(d)]
Are all essential quality control measures incorporated in the lab's method manual?				000d13	D [M2,5.9.3(c)]
Are all quality control measures assessed and evaluated on an on-going basis and is quality control acceptance criteria used to determine the validity of the data?				000d14	D [M2,5.9.3(b)]
Is volumetric equipment with movable parts such as automatic dispensers, dispensers/diluters, and mechanical hand pipettes calibrated **quarterly** and documented?				00d364	D.3.8.b.3.i [M5,1.7.3.7(b)(iii)(1)]
Is the volume of disposable volumetric equipment such as sample bottles, disposable pipettes, and micropipette tips checked **once per lot**?				0d365a	D.3.8.b.3.iii [M5,1.7.3.7(b)(iii)(3)]

Question	Y	N	NA	Codes	Comments
Are temperatures of incubators and water baths recorded **twice daily** (morning & afternoon) separated by at least 4 hours as required by the methods?				000d32	D.3.8.b.6.i[M5,1.7.3.7(v)(1)]
Is the following support equipment associated with microbiological testing checked with NIST traceable materials (where possible): a.____ pH meter b.____ Balance(s) d.____ Refrigerator(s) and freezer(s) for sample storage and/or media storage e.____ Incubators f.____ Water baths				5916 00d34a 00d34b 00d34c 00d34d 00d34e 00d34f	5.5.5.2.1.d [M2, 5.5.13.1(d)] [M5,1.7.3.7(b)]
Does the laboratory demonstrate that the cultured samples have not been contaminated through sampling handling/preparation or environmental exposure?				000d37	
In order to demonstrate traceability and identity, does the laboratory use reference cultures of microorganisms obtained from a recognized national collection or an organization recognized by the NELAP Accrediting Authority?				00d341	D.3.7.a [M5,1.7.3.6(c)]
Are reference cultures [ ] revived (if freeze dried) or [ ] transferred from slants and sub-cultured once to provide reference stocks?				00d342	D.3.7.a.1 [M5,1.7.3.6(c)(i)]
Are microorganisms [ ] single use preparations or [ ] cultures maintained by documented procedures that demonstrate the continued purity and viability of the organism?				00d343	D.3.7.a [M5,1.7.3.6(c)]
Are the reference stocks preserved by a technique that maintains the desired characteristics of the strains? (Examples of such methods are freeze-drying, liquid nitrogen storage and deep-freezing methods.)				00d344	D.3.7.a.1 [M5,1.7.3.6(c)(i)]
Are reference stocks used to prepare working stocks for routine work?				00d345	D.3.7.a.1 [M5,1.7.3.6(c)(i)]
When reference stocks are thawed, are they not re-frozen and re-used?				00d346	D.3.7.a.1 [M5,1.7.3.6(c)(i)]
Are working stocks sub-cultured no more than 5 times?				00d348	D.3.7.a.2 [M5,1.7.3.6(c)(ii)]
Are working stocks not sub-cultured to replace reference stocks?				00d349	D.3.7.a.2 [M5,1.7.3.6(c)(ii)]
Media					
Is culture media [ ] prepared in the laboratory from different chemical ingredients if not commercially available or specified by the method,[ ] from commercial dehydrated powders, [ ] or purchased ready to use?				00d329	D.3.6.a [M5,1.7.3.5(a)]
Are reagents and commercial dehydrated powders used within the shelf life of the product and documented according to 5.10.5?				00d330	D.3.6.b M5,1.7.3.5(b)]
Is distilled water, deionized water or reverse osmosis produced water free from bactericidal and inhibitory substances used in the preparation of media solutions				00d332	D.3.6.c [M5,1.7.3.5(c)(i)]

Question	Y	N	NA	Codes	Comments
and buffers?					
Are media, solutions and reagents prepared, used and stored according to a documented procedure following the manufacturer's instructions or the test method?				00d335	D.3.6.d [M5,1.7.3.5]
Is prepared media stored so that: Unused Membrane Filter broth refrigerated & used within 96 hours, Membrane Filter agar plates, tight-fitting covers, refrigerated & used within 2 weeks, Media in tubes/containers with loose-fitting closures refrigerated & used within 2 week, Broth media in tubes/containers with screw caps refrigerated & used within 3 months, Poured HPC agar in plates sealed in plastic bags, refrigerated, & used within 2 weeks, HPC agar stored in screw-cap flask or container refrigerated & used within 3 months, and Refrigerated media incubated overnight prior to use; cultures indicating growth not used?				0d336a 0d336b 0d336c 0d336d 0d336e 0d336f 0d336g	D.3.6.d [M5, 1.7.3.5] (SM9020B, 4.i.4, Table 9010:IV)
Does documentation for media prepared in the laboratory include: a. __ Date of preparation, b. __ Preparer's initials, c. __ Type and amount of media prepared, d. __ Manufacturer & Lot #, e. __ Final pH of the media, and f. __ Expiration date?				0d337a 0d337b 0d337c 0d337d 0d337e 0d337f	D.3.6.d [M5,1.7.3.5(d)]
Does documentation for media purchased pre-prepared, ready-to-use include: a. __ Manufacturer, b. __ Lot #, c. __ Type and amount of media received, d. __ Date of receipt e. __ Expiration date of the media, and f. __ pH of the media?				0d338a 0d338b 0d338c 0d338d 0d338e 0d338f	D.3.6.d [M5,1.7.3.5(d)]
5. SAMPLE HANDLING CA00145					
If the laboratory collects environmental samples, is the collection method approved by the Department and implemented as written?				CA00152	
Does the laboratory have a written chain-of-custody procedure to implement upon request by a law enforcement agency?				CA00153	

Question	Y	N	NA	Codes	Comments
Does the chain-of-custody protocol include a record of the physical possession, storage, and disposition of the sample and any derivatives?				CA00154	
Does the laboratory assure that samples and their derivatives are maintained in a secure manner (biosecurity) in accordance with any litigation requirements (chain-of-custody)?				CA00155	
6. RECORDS CA00156					
Are access records and records of analysis of confirmed positive samples maintained for **10 years**?				CA00157	
Does the laboratory have a CDC Select Agent inventory and tracking system?				CA00158	
Does the CDC Select Agent inventory and tracking system ensure the following:					
a. ___ All aliquots, derivatives, and cultures are tracked and accounted for while in the laboratory's possession?				CA00160	
b. ___ Records are kept of all persons having access to all samples, aliquots, derivatives, and cultures?				CA00161	
c. ___ All agents, when not in use, are contained in locked storage facilities?				CA00162	
7. REPORTS CA00163					
When a test result indicates that Gram-positive, non-hemolytic, non-motile *Bacillus* was recovered:					
a. ____ Is an isolate submitted to the Wadsworth Center (or other laboratory identified by the Department) for confirmation?				CA00165	
b. ____ Is the appropriate authority, as determined by the Department, notified within 24 hours?				CA00166	
c. ____ Is the client notified that a "Bacillus species was isolated and further identification is required. The specimen has been forwarded to ____ for further characterization. If there are questions regarding this specimen, please call (___) ___ - ____)"?				CA00167	
When a test result indicates that a biothreat agent, other than B. anthracis, cannot be ruled out:					
a. ___ Is an isolate submitted to the Wadsworth Center (or other laboratory identified by the Department) for confirmation?				CA00175	
b. ___ Is the appropriate authority, as determined by the Department, notified within 24 hours?				CA00176	
c. ___ Is the client notified that "A suspected biothreat agent (insert name as genus species) was isolated. Further identification is required.				CA00177	

Question	Y	N	NA	Codes	Comments
The specimen has been forwarded to ____ for further characterization. If there are questions regarding this specimen, please call (___) ___ - ____"?					
When a test result indicates Ricin toxin (or another potential biothreat toxin) is present:					
a. ___ Is a sample aliquot immediately submitted to the Wadsworth Center (or other laboratory identified by ELAP) for confirmation?				CA00169	
b. ___ Is the appropriate authority, as determined by the Department, so notified within 12 hours?				CA00170	

ADDITIONAL NOTES: