### Quality Control Material

1. Quality Control material as provided within test kits/systems is used as applicable. Where QC is not available within the kit, 3rd party Quality Control material is used.
2. ATCC Quality Control organisms prepared slides are used to check stains.
3. Reference QC organism stock material for media and disk QC, as applicable, are maintained at the CORE Microbiology Labs and provided to the satellite labs as requested.

### Quality Control – Frequency of testing

1. Each day of use (positive and negative controls internal) and with each new lot/shipment
   1. Occult blood / Gastroccult - each use is recorded in log book
2. Each week of use (positive and negative controls) and with each new lot/shipment(IQCP Supersedes this if applicable)
   1. Gram stain
3. Each Lot Number and Shipment (positive and negative controls)
   1. Bacitracin Disk ( performed at Shoreline Microbiology)
   2. Optochin Disk (performed at Shoreline Microbiology)
4. External controls per lot/shipment and not to exceed 30 days. Internal controls are performed with each test cartridge and are documented in respective log books.
   1. Strep A direct
   2. Influenza A/B
   3. Leuko EZ Vue, as applicable
   4. Rotavirus, as applicable
   5. RSV Ag, as applicable
   6. Clostridium difficile, as applicable

### Quality Control – Media

1. Media Quality Control
   1. No media is prepared in-house.
   2. Prepared, purchased media is controlled as set out in guidelines of the CLSI Document M-22-A3, 2004. All media will be examined visually for breakage, contamination, hemolysis, appearance, and evidence of freezing or overheating. The date received, Lot #, and expiration date are documented/retained.
   3. All media should be in visibly satisfactory condition i.e. plates smooth, adequately hydrated, uncontaminated, appropriate color and thickness. Tubed media should not be dried or loose from sides of the tube.
   4. Those media failing quality control testing will be removed from service and recorded on the QC Corrective Action form as well as reported to the manufacturer for documentation and credit.
   5. All other media will be logged as manufacturer tested (Refer to Media Preparation Manuals for documentation of Q.C. BBL done) and checked only for appearance.
   6. Expired, unsuitable, or contaminated media is discarded and replaced with fresh media.

### Quality Control – Temperature and Instrument Checks

1. Temperatures of all incubators, heat blocks, refrigerators, and ambient room are recorded daily and are in ranges listed on the appropriate log. Any temperature that is outside of range must have corrective action including notifying the supervisor so that the failure can be evaluated for adverse reactions.
2. Countertops shall be cleaned with disinfectant before beginning work and at frequent intervals throughout the day. Countertop disinfection is recorded once daily.
3. Atmosphere
   1. In the absence of a CO2 incubator, CO2 conditions are maintained by use of a CO2-generating bag system. The QC organisms maintained for chocolate media QC are used to assess CO2 bag system acceptability.
   2. Anaerobe systems are checked and documented on each day of use for adequate anaerobic conditions via indicator strip/tablet.
4. Maintenance - Effort is made to adhere to maintenance schedules set up by Maintenance and BioMed.
   1. Biological Safety Cabinets are certified once per year by commercial company.
   2. Instrument function checks are maintained for each instrument as suggested by the manufacturer.

### Quality Control – Stains

1. Stains of proven quality are used.
2. Slides of good quality are used.
3. Sterile slides are used.
4. Quality control is performed with each new lot# and shipment and weekly thereafter.
5. Quality Control – Results

Results of tests involving the above are recorded in the appropriate Quality Control Book. Control specimens are tested in the same manner as patient samples and by the same personnel as patient samples. In the event of test failure, all components are examined and corrective action instituted, usually by substitution of fresh components for all testing. Definitive dependence upon such controls is withheld pending correction of problem. Patient results are not reported until discrepancy in Quality Control is verified. Corrective Action Form is filled out with each occurrence and signed by the Lead Technologist/Technical Supervisor.

**PRINCIPLE**

In order to ensure that all laboratory personnel report microscopic observation and interpretations with respect to morphologic identification on gram stains, slides consisting of stained organisms with defined characteristics will be issued to randomly selected laboratory personnel at least annually. The selected laboratory personnel document results on the gram stain proficiency testing form.

**PROCEDURE**

1. Follow universal precautions
2. Internal proficiency testing will be performed at least annually.
3. Proficiency testing will be performed using CAP Bacteriology specimens.
4. The employee will be given a gram stain proficiency document by the Lead Tech.
5. The employee test results must fall within the expected result range to attain good proficiency.
6. Recommendations will be based on observations and review of documentation.
7. A competency evaluation form is evaluated and signed by the Lab Director\ or Lead Technologist and employee.

# REVIEW OF PROCEDURE MANUAL

Each procedure in the Procedure Manual shall be reviewed initially by the Medical Director prior to being placed in use. The Manual will then be reviewed on a biennial basis by the Medical Director, Laboratory Manager or Lead Technologist as designated by the medical director.

Each technologist/technician working in the laboratory is required to review and demonstrate knowledge of the contents of the Procedure Manuals upon initial hiring and on an annual basis. Documentation of meeting this requirement of the annual competency test is placed in the technologist/technician’s file.

Evidence of review of the Procedure Manual by the Medical Director of the Laboratory, the Laboratory Manager or the Lead Technologist shall be documented in the procedure manual. This first page will show the date the policy went into effect and the date of the last revision. The first page of each procedure will show the date of initial review/approval by the Medical Director and the biennial review.

Should there be a change in Medical Director, all procedures will be promptly submitted to the new Medical Director for review.

All discontinued procedures will be saved for at least two years before they are discarded in the retired policy and procedure file.

**PARALLEL TESTING**

Parallel testing will be performed on all test kits to ensure that new lot numbers, kits or ship dates of reagents, are sensitive and accurate before being placed in service following best clinical practices. See this manual for specific procedure.

PROFICIENCY TESTING:

The Proficiency Survey will be performed as soon as possible after it is received in the laboratory. At the beginning of each year the Laboratory Manager, Lead Technologist or designee will assign all proficiency tests among testing personnel. This proficiency testing will be rotated among testing personnel. This schedule will ensure that all testing personnel participate in proficiency testing. Testing will occur on any and all shifts. All survey materials will be tested, when possible, in exactly the same manner as patient samples and as part of the regular workflow.

A copy of results and of the signed attestation statement by the Lead Technologist or Laboratory Manager will be kept on file. The results of the Proficiency Survey should be reviewed and signed by the Lead Technologist or Laboratory Manager upon receipt of results. If unacceptable results were submitted then results must be signed by the Lead Technologist or Laboratory Manager and reviewed by the Pathologist.

Inter-laboratory communication about proficiency testing samples prior to submission to CAP/API will not be permitted. Testing not performed at SAH will not be sent to referral lab for testing but recorded as “sent to referral lab for testing” on the CAP/API response form. Specimens will not be sent to any other lab for verification of results or comparison of results under any circumstances.

Any corrective action in response to “unacceptable” results on the survey report should be documented on the survey and in the appropriate instrument action log. Whenever possible, specimens suitable for re-testing at a future date will be stored in an appropriate place and re-testing at a future date will be performed whenever “unacceptable” results are obtained.

The results of the CAP/API Proficiency Survey should be reviewed and entered by the Lead Technologist or designee with the final submission approved by the Laboratory Manager or Lead Technologist .

The Lead Technologist or Laboratory Manager will print out the outstanding CAP/API Survey PT list from the online website and reviewed weekly to ensure that all CAP/API Survey’s are submitted in a timely manner. However, in the event that a proficiency test is not graded by the CAP/API, the survey was submitted late, the result form was erroneous, or the incorrect method code was submitted results will be reviewed and manually compared with the expected results from the participant summary and documentation on the report next to the results will reflect the findings. A Remedial Action form will be completed and signed according to the above criteria on all unacceptable CAP/API surveys.

**PIPETTES:**

Delivery of pipettes must be accurate to within +/- 1% of the volume. Automatic pipette accuracy is verified every 12 months. Pipettes out of tolerance are removed from service and recalibrated. Pipette check, calibration and verification should be documented in the Automatic Pipette Calibration Log.

**CENTRIGUGES**

Operating speeds of centrifuges are checked annually by Biomed. A

Certified label placed on centrifuge and records are kept maintenance

Field service logbook.

**TEMPERATURES**

Refrigerators and freezers temperatures are checked daily using calibrated thermometer

**Laboratory Bioterrorism Contact Protocol**

If a possible BT agent is grown in the laboratory or detected by other laboratory means, place phone calls to the responsible physician and the following individuals noted below immediately. Contacting these individuals and the procedures required in laboratory or not a one person task. Additional assistance from other technologists or laboratory personnel is essential.

Or

If a specimen is submitted for detection of a BT agent as the result of a possible BT event, place calls to the individuals noted below immediately (See laboratory phone lists for individual telephone or cell phone numbers):

Laboratory Manager, Lead Technologist, Laboratory Medical Director

Infection Control: (361) 661-8123

Texas Department of State Health Services: (512) 458-7318

1. **The laboratory response network for bioterrorism:**

The Laboratory Response Network (LRN) National network of local, state and federal public health, hospital-based, food testing, veterinary and environmental testing laboratories that provide laboratory diagnostics and the capacity to respond to biological and chemical terrorism and other public health emergencies.

The LRN is a partnership involving key stakeholders in the preparation and response to biological and chemical terrorism. The Centers for Disease Control and Prevention (CDC), the Federal Bureau of Investigation (FBI), and the Association of Public Health Laboratories are its founding partners.

More than 140 federal, state and local labs in 50 states and abroad are part of the LRN:

* National labs –CDC, military –perform definitive testing.
* Reference labs –BSL-3 labs capable of confirmatory testing for agents such as *B. anthracis*, and *C. botulinum* toxin.

The goals of the LRN are to:

* Ensure that the nation’s public health, clinical, and other selected laboratories are prepared to detect and respond to a bioterrorism or chemical event in an appropriate and integrated manner.
* Ensure that all member reference laboratories collectively maintain state-of-the-art bio-detection and diagnostic capabilities and surge capacity as well as secure electronic communication of test results for the biological and chemical agents likely to be used in the commission of a bioterrorism event.
* Work with other department and agencies to ensure a successful federal response to an act of bioterrorism and to facilitate and optimize the ability of states to competently respond independently to public health emergencies in the state.
* Enlist an optimal number of registered participating LRN laboratories throughout the U.S. as determined by the LRN working group.

The LRN maintains the following:

* A registry and linkage of clinical and private laboratories in the U.S. that would include Sentinel and Reference laboratories.
* Complete, accurate, and standardized protocols for all levels of testing for agents deemed critical and likely to be used in the commission of acts of bio terrorism.
* Secure but accessible supply of standardized reagents and diagnostic technologies produced and maintained by CDC.
* Secure electronic laboratory reporting that integrated with key epidemiologic, surveillance, and emergency response components.
* Training and proficiency testing essential to the diagnostic process. Clinical laboratories play a critical role in the LRN. Their heightened awareness to the possibility of recovering the agents of bioterrorism from patient samples and referral of suspect isolates to the appropriate public health department is crucial.

**Definition of Bioterrorism:**

A *bioterrorism attack* is the deliberate release of viruses, bacteria, or other germs (agents) used to cause illness or death in people, animals, or plants

**Classification of LRN laboratories:**

1. **Sentinel (formerly Level A)**

Sentinel laboratories are clinical laboratories that follow Biosafety Level 2 (BSL-2) guidelines. Their primary responsibility is to recognize and rule out or refer suspicious agents by following standardized Sentinel Laboratory. Even though many Sentinel laboratories are capable of providing a “presumptive identification” of some of the targeted organisms, they must refer isolates to an LRN Reference laboratory.

1. **LRN Reference (formerly Level B and C)**

LRN reference laboratories are local and state public health laboratories, selected academic- or university-based laboratories, designated specialty laboratories (veterinary, water, food, chemical, military, agricultural) that possess the reagents and technology for definitive confirmation of organisms including toxin testing, referred by Sentinel laboratories. LRN Reference laboratories follow BSL-3 containment and practice guidelines. Contact your nearest LRN Reference laboratory for instructions and guidance regarding the submission of suspicious agents for confirmatory testing.

1. **LRN National Laboratories (formerly Level D)**

LRN National Laboratories are Federal laboratories that have BSL-4 containment facilities and practice guidelines. The primary laboratory at this level is located at the CDC and specializes in the isolation and identification of BSL-4 agents such as Ebola, Marburg, and Smallpox virus. This laboratory also possesses the capability of advanced genetic characterization and archiving of all bioterrorism agents.

1. **Clinical laboratory responsibilities:**

As members of the LRN, Sentinel laboratories have access to the network and serve as “sentinels” for the early detection of and raising suspicion regarding a suspicious agent that cannot be ruled out as a possible bioterrorism-associated organism. Sentinel laboratories do not have access to the CDC secure website for *Reference Laboratory Testing Protocols* or reagents. Instead, Sentinel laboratories must utilize standardized testing protocols (ASM Sentinel Laboratory Guidelines) that have been designed to utilize conventional tests to facilitate the “rule-out” or “referral” of a suspicious isolate to an LRN Reference laboratory. The Sentinel laboratory is NOT responsible for and SHOULD NOT make the decision that a bioterrorism event has occurred; that responsibility rests with local, state, and federal health and law enforcement officials.

*\*\*A designated individual within your facility (Infection Control Officer) should be notified of a suspicious agent, who in turns notifies the local public health officials. Under no circumstances should the laboratory contact law enforcement or public health officials. The exception is the need to contact the LRN Reference Laboratory for guidance in the disposition of the suspicious agent prior to referral for confirmatory testing.*

**\*\*\*NOTE:** In no case should the Sentinel laboratory accept environmental (powders, letters, packages), animal, food, or water specimens for examination, culture, or transport for bioterrorism-associated agents. Such specimens should be submitted directly to the nearest LRN Reference laboratory**.**

1. **Organisms considered to be agents of bioterrorism:**

* Anthrax (*Bacillus anthracis*)
* Plague (*Yersinia pestis*)
* Botulism toxin
* Tularemia (*Francisella tularensis*)
* Q fever (*Coxiella burnetii*)
* Brucellosis (*Brucella* species)
* *Burkholderia mallei* and *B. pseudomallei*
* Staphylococcal enterotoxin B

1. **Resource Links:**

The local health department will be contacted to send someone trained on proper shipping and handling or call the following telephone number for instructions:

**CC Nueces County Public Health District**

1702 Horne Rd., PO Box 9727

Corpus Christi, TX 78416

(361) 851-7213; [(361)851-7202](http://www.dshs.state.tx.us/regions/)

(361) 533-3500 (after hours)

See attached copy of **Nueces County Public Health District Laboratory Submission** form in the next page.

**FBI – Corpus Christi Resident Agency**

(361) 883-8671

Centers for Disease Control and Prevention

[**http://www.bt.cdc.gov/bioterrorism/**](http://www.bt.cdc.gov/bioterrorism/)

Texas Department of State Health Services

[**http://www.dshs.state.tx.us/preparedness/bt\_pros.shtm**](http://www.dshs.state.tx.us/preparedness/bt_pros.shtm)