TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	7/29/2015
Department:	All staff	**Due Date:**	8/19/2015
		Implementation:	**8/19/2015**

DESCRIPTION OF PROCEDURE

Name of procedure:

Clinical Specimens Suspected of High Virulence Organisms GEC/SGAH/WAHQDMI815 v2.1

Description:

This is a new SOP to describe the safe and proper handling of specimens from patients with suspected severe acute respiratory syndrome (SARS) coronavirus, avian influenza, novel influenza A (H1N1) virus, Middle East Respiratory Syndrome (MERS) coronavirus, or other emerging pathogens.
It is needed to meet CAP requirements.

This SOP will be implemented on August 19, 2015

Document your compliance with this training update by taking the quiz in the MTS system.

Approved draft for training (version 2.1)

Non-Technical SOP

Title	**Clinical Specimens Suspected of High Virulence Organisms**
Prepared by	Tom Heeley, Corporate EHS Manager **Date:** 06/2011

Laboratory Approval	**Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

Review		
Print Name and Title	**Signature**	**Date**

Corporate Approval	**Corporate Issue Date:** 9/8/2014	
Print Name and Title	**Signature**	**Date**
Janet Cromien **Owner**	*On file*	**9/5/14**
Gordon Love, M.D. **BPT Medical Advisor**	Gordon L. Love MD	**9/5/14**
William M. Miller, M.D. **Chief Laboratory Officer/Designee**	e-signature	**9/6/14**

Retirement Date:	*Refer to the SmartSolve EDCS.*
Reason for retirement/replacement:	

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1. PURPOSE

This policy is designed to ensure the safe and proper handling of clinical specimens received by Quest Diagnostics laboratories at from patients with suspected severe acute respiratory syndrome (SARS) coronavirus, avian influenza, novel influenza A (H1N1) virus, Middle East Respiratory Syndrome (MERS) coronavirus, or other emerging pathogens. This policy will be expanded as new emerging pathogens are encountered.

2. SCOPE

The policy applies to any clinical laboratory that knowingly or unknowingly accepts samples with the potential for SARS coronavirus, avian influenza, novel influenza A (H1N1) virus, Middle East Respiratory Syndrome (MERS) coronavirus, or other emerging pathogens. This guidance describes supplemental handling and/or disinfection procedures above and beyond the Standard Precautions outlined in the Quest Diagnostics Bloodborne Pathogens Exposure Control Plan and the Comprehensive Microbiology Safety Procedures document.

3. RESPONSIBILITY

Responsible Party	Task
Laboratory Director and Department Technical Supervisors/Managers	• Implement this policy and ensure that all lab personnel likely to encounter samples with suspected virulent organisms are trained in the special handling, decontamination and post-exposure steps. Retraining will be provided as needed to ensure competency in the process.

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4. DEFINITIONS

Avian influenza	A type A influenza virus that is responsible for a viral disease ranging from mild to fatal in chickens, turkeys and other bird species, but has on rare occasion crossed the species barrier to infect humans. May be distinguished as a "low pathogenic form" or "high pathogenic form". Recent outbreaks (2004-2006) involved the highly pathogenic strain H5N1.
MERS-CoV	MERS-CoV is the acronym for Middle East Respiratory Syndrome Coronavirus, the virus that causes MERS. The virus was first reported in 2012 in Saudi Arabia. MERS-CoV is not the same coronavirus that causes severe acute respiratory syndrome (SARS). MERS-CoV is suspected of being transmitted to humans from animal sources like camels and bats.
SARS	Severe acute respiratory syndrome - a viral respiratory illness caused by a previously undescribed coronavirus, called SARS-associated coronavirus (SARS-CoV). SARS was first reported in Asia in Feb. 2003 and quickly spread to more than 24 countries affecting 8,100 people before the global outbreak was contained.

5. PROCEDURE

5.1 General

5.1.0 All employees are required to use "Standard Precautions" for handling any sample as outlined in the Quest Diagnostics ***Bloodborne Pathogens Exposure Control Plan***. This typically includes a buttoned lab coat, latex or non-latex gloves, and a face shield (when handling open samples).

5.1.1 Quest Diagnostics will rely on guidance from the CDC and local public health departments when working with any new emerging pathogen. This policy will be updated when guidance for new emerging pathogens are developed.

5.2 Avian Influenza Virus (H5N1)

5.2.1 **Background**

The influenza viruses are enveloped RNA viruses belonging to the Orthomyxoviridae. There are three serotypes of influenza viruses, A, B and C. Influenza A is further classified into subtypes by the surface glycoproteins that possess either hemagglutinin (H) or neuraminidase (N) activity. Emergence of completely new subtypes (antigenic shift) occurs at irregular intervals with Type A viruses. New subtypes are responsible for pandemics and can result from re-assortment of human and avian influenza virus genes. The Avian influenza, or "bird flu", normally infects bird species and less commonly pigs, but has rarely crossed the species barrier to infect humans.

Laboratory acquired infections (LAI) have not been documented routinely, but informal accounts and published reports indicate that such infections are known

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to have occurred, particularly when new strains showing antigenic shift or drift are introduced into a laboratory for diagnostic or research purposes.

5.2.2 **Specimens and Tests Offered**

Specimens – the virus may be present in respiratory tissues or secretions. The primary laboratory hazard is inhalation of virus from aerosols generated by aspirating, dispensing, mixing, centrifuging or otherwise manipulating virus-infected samples.

Tests offered - Quest Diagnostics currently offers only a RT-PCR assay on a nasopharyngeal aspirate/swab, bronchial alveolar lavage (BAL), sputum or throat/nasal swab. Viral cultures ordered for H5N1 (or other highly pathogenic avian influenza - HPAI) should only be performed by the CDC's Influenza Division under BSL-3 conditions.

5.2.3 **Laboratory Safety**

Lab workers are required to participate in the seasonal flu vaccine program which will prevent co-infections of normal seasonal flu with avian strains where genetic re-arrangement could take place, leading to the emergence of potential pandemic strain

Standard precautions are used in a BSL-2 environment for diagnostic testing activities for contemporary, circulating human influenza strains (e.g., H1/H3/B) and low pathogenicity avian influenza (LPAI) strains (e.g., H1-4, H6, H8-16), and equine and swine influenza viruses. Activities that generate aerosols should be conducted in a BSC.

Work surfaces must be decontaminated with an appropriate EPA registered disinfectant (e.g.10% bleach) upon completion of work. Follow the manufacturer's recommendations for use, including dilution, contact time and care in handling.

All waste must be handled as regulated medical waste and decontaminated prior to disposal.

Packaging, shipping, and transport of specimens from possible and known cases of avian influenza disease must follow the current procedures for Category B infectious agents found in the Safe Transportation of Diagnostic Specimens and Other Hazardous Materials procedures on the Quest Diagnostics intranet.

CDC must be notified immediately of any positive test for H5N1, and clinical specimens should be sent to the CDC for confirmation.

5.3 Severe Acute Respiratory Syndrome (SARS) Coronavirus

5.3.1 **Background**

SARS is a viral respiratory illness caused by a previously undescribed coronavirus, SARS-associated coronavirus (SARS-CoV) within the family

Coronaviridae. SARS was retrospectively recognized in China in November 2002. Laboratory-acquired infections of SARS from processing of diagnostics specimens has not been documented, however the virus represents an emerging infectious disease for which the risk to medical and lab personnel is not fully understood.

5.3.2 **Specimens and Tests Offered**

Specimens - SARS-CoV may be detected in respiratory, blood, or stool specimens. The exact mode of transmission of SARS-CoV as a potential laboratory-acquired infection has not been established, however in clinical settings the primary mode of transmission appears through direct or indirect contact of mucous membranes with infectious respiratory droplets.

Tests offered - Quest Diagnostics currently offers only a RT-PCR assay on a nasopharyngeal aspirate/swab, bronchial alveolar lavage (BAL), sputum or rectal swab.

5.3.3 **Laboratory Safety**

In clinical laboratories, whole blood, serum, plasma and urine specimens should be handled using Standard Precautions, which includes use of gloves, lab coat or gown, and face protection (e.g. full face shield, or eye protection with a surgical mask).

Any procedure with the potential to generate aerosols (e.g., vortexing of specimens in an open tube) should be performed in a Class II biological safety cabinet (BSC). Use sealed centrifuge rotors or gasketed safety carriers for centrifugation. Rotors and safety carriers should be loaded and unloaded in a BSC. Procedures conducted outside a BSC must be performed in a manner that minimizes the risk of personnel exposure and environmental release.

The following procedures may be conducted in the BSL-2 setting:

- routine staining and microscopic analysis of fixed smears,
- routine examination of bacterial and fungal cultures,
- and final packaging of specimens for transport to diagnostic laboratories for additional testing (specimens should already be in a sealed primary container).

Activities involving manipulation of untreated specimens should be performed in BSL-2 facilities with a BSC and following BSL-3 practices (listed in Addendum A).

NOTE: In the rare event that a procedure or process involving untreated specimens cannot be conducted in a BSC, then gloves, gown, eye protection, and respiratory protection [e.g. a properly fit-tested, NIOSH-approved filter respirator (N-95 or higher)] should be used. All personnel who use respiratory protective devices should be enrolled in a respiratory protection program. Contact your EHS representative for more information.

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Work surfaces must be decontaminated with an appropriate EPA registered disinfectant (e.g.10% bleach) upon completion of work. Follow the manufacturer's recommendations for use, including dilution, contact time and care in handling.

All waste must be handled as regulated medical waste and decontaminated prior to disposal.

Packaging, shipping, and transport of specimens from possible and known cases of SARS disease must follow the current procedures for Category B infectious agents found in the Safe Transportation of Diagnostic Specimens and Other Hazardous Materials procedures on the Quest Diagnostics intranet.

Public health and/or CDC must be notified immediately of any positive test for SARS.

5.4 Middle East Respiratory Syndrome Coronavirus (MERS-CoV)

5.4.1 Background

Symptoms of MERS often include severe acute respiratory illness with associated fever, cough and shortness of breath, but some infected people show only mild or no symptoms at all. The incubation period is 2-14 days. People with underlying health conditions or diseases are at a higher risk of getting MERS or having a severe case. Transmission is only through close contact (e.g. living or caring for someone with MERS). Currently, there is no vaccine or treatment for MERS, other than supportive care.

5.4.2 Specimens and Tests Offered

Specimens - MERS-CoV may be detected in respiratory, blood, or stool specimens. The exact mode of transmission of MERS-CoV as a potential laboratory-acquired infection has not been established, however in clinical settings the primary mode of transmission appears through direct or indirect contact of mucous membranes with infectious respiratory droplets.

Tests offered - Quest Diagnostics does not offer testing for MERS-CoV.

5.4.3 Laboratory Safety

MERS-CoV specimens sent for routine hematology, urinalysis, and clinical chemistry studies, or microbiology tests on serum, blood, or urine specimens may be processed following standard laboratory practices (e.g. Standard Precautions), which includes use of gloves, lab coat or gown, and face protection (e.g. full face shield, or eye protection with a surgical mask).

Any procedure with the potential to generate aerosols (e.g., vortexing of specimens in an open tube) should be performed in a Class II biological safety cabinet (BSC). Use sealed centrifuge rotors or gasketed safety carriers for centrifugation. Rotors and safety carriers should be loaded and unloaded in a

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BSC. Procedures conducted outside a BSC must be performed in a manner that minimizes the risk of personnel exposure and environmental release.

The following activities may be performed in BSL-2 facilities using standard BSL-2 work practices:

- Routine examination of bacterial and mycotic cultures
- Routine staining and microscopic analysis of fixed smears

The following activities involving manipulation of potentially infected specimens should be performed as above and in a Class II BSC:

- Aliquoting and/or diluting specimens
- Inoculating bacterial or mycological culture media
- Performing diagnostic tests that do not involve propagation of viral agents in vitro or in vivo
- Preparation and chemical- or heat-fixing of smears for microscopic analysis

NOTE: In the rare event that a procedure or process listed above cannot be conducted in a BSC, then gloves, gown, eye protection, and respiratory protection [e.g. a properly fit-tested, NIOSH-approved filter respirator (N-95 or higher)] should be used. All personnel who use respiratory protective devices should be enrolled in a respiratory protection program. Contact your EHS representative for more information.

Work surfaces must be decontaminated with an appropriate EPA registered disinfectant (e.g.10% bleach) upon completion of work. Follow the manufacturer's recommendations for use, including dilution, contact time and care in handling.

All waste must be handled as regulated medical waste and decontaminated prior to disposal.

Viral cultures for other respiratory pathogens when MERS-CoV is suspected should be sent to the local public health lab or CDC.

Packaging, shipping, and transport of specimens from possible and known cases of MERS disease must follow the current procedures for Category B infectious agents found in the Safe Transportation of Diagnostic Specimens and Other Hazardous Materials procedures on the Quest Diagnostics intranet.

Local or state public health laboratories and the CDC must be notified immediately when transporting a specimen suspected of MERS-CoV.

6. RECORDS MAINTENANCE

Not applicable

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7. RELATED DOCUMENTS

- Quest Diagnostics Bloodborne Pathogens Exposure Control Plan, (QDEHS701); http://questnet1.qdx.com/Employee_Center/environment_health_safety/ehs_toc.htm
- Quest Diagnostics Comprehensive Microbiology Safety Procedures, (QDMI726); http://questnet1.qdx.com/Business_Groups/test_the_specimen/national_testing_operations/microbiology/qdmi726.doc
- Quest Diagnostics Safe Transportation of Diagnostic Specimens and Other Hazardous Materials Procedures; http://questnet1.qdx.com/Business_Groups/acquire/logistics/ehs_hazmat/HazMat_toc.htm

8. REFERENCES

- *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) 5th Edition; CDC, December 2009
- CDC's website *"Severe Acute Respiratory Syndrome (SARS)" Appendix F5 – Laboratory Biosafety Guidelines for the Handling and Processing Specimens Associated with SARS-CoV;* May 3, 2005 (http://www.cdc.gov/ncidod/sars/guidance/f/app5.htm)
- CDC's website *"Avian Influenza: Resources for Health Professionals"* (http://www.cdc.gov/flu/avian/professional/#ic)
- CDC's wesite *"Middle East Respiratory Syndrome (MERS)"* http://www.cdc.gov/coronavirus/mers/index.html

9. DOCUMENT HISTORY

Version	Date	Section	Revision	Revised By	Approved By
2	08/11/2014	1.0 2.0 4.0	Updated Purpose, Scope and Definitions to include information on MERS and Ebola.	Tom Heeley	
2	08/11/2014	5.4	Added section to cover MERS information.	Tom Heeley	
2	08/11/2014	5.5	Added section to cover Ebola virus information	Tom Heeley	
2	08/11/14	All	Updated document to current format	Tom Heeley	
2.1	4/22/15	Cover page	Adopting corporate issued version 2. Update Local Effective Date message	L. Barrett	R. Master
		5.2.3	Changed encouraged to required	R. Master	
		5.3.3, 5.4.3	Deleted activities not performed	R. Master	
		5.5	Deleted Ebola section as covered in separate procedure	R. Master	

10. ADDENDA

Addendum	Title
Addendum A	CDC's Biosafety in Microbiological and Biomedical Laboratories (BMBL) Biosafety Level 3 Practices

ADDENDUM A

CDC's Biosafety in Microbiological and Biomedical Laboratories (BMBL)

Biosafety Level 3 Practices

A. Standard Microbiological Practices

1. The laboratory supervisor must enforce the institutional policies that control access to the laboratory.
2. Persons must wash their hands after working with potentially hazardous materials and before leaving the laboratory.
3. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption must not be permitted in laboratory areas. Food must be stored outside the laboratory area in cabinets or refrigerators designated and used for this purpose.
4. Mouth pipetting is prohibited; mechanical pipetting devices must be used.
5. Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented. Whenever practical, laboratory supervisors should adopt improved engineering and work practice controls that reduce risk of sharps injuries.
6. Perform all procedures to minimize the creation of splashes and/or aerosols.
7. Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant.
8. Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method. A method for decontaminating all laboratory wastes should be available in the facility, preferably within the laboratory (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method). Depending on where the decontamination will be performed, the following methods should be used prior to transport:
    a. Materials to be decontaminated outside of the immediate laboratory must be placed in a durable, leak proof container and secured for transport.
    b. Materials to be removed from the facility for decontamination must be packed in accordance with applicable local, state, and federal regulations.
9. A sign incorporating the universal biohazard symbol must be posted at the entrance to the laboratory when infectious agents are present. Posted information must include the laboratory's biosafety level, the supervisor's name (or other responsible personnel), telephone number, and required procedures for entering and exiting the laboratory. Agent information should be posted in accordance with the institutional policy.
10. An effective integrated pest management program is required.
11. The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation

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procedures. Personnel must receive annual updates or additional training when procedural or policy changes occur. Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all laboratory personnel and particularly women of childbearing age should be provided with information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance.

B. Special Practices

1. All persons entering the laboratory must be advised of the potential hazards and meet specific entry/exit requirements.
2. Laboratory personnel must be provided medical surveillance and offered appropriate immunizations, when available, for agents handled or potentially present in the laboratory.
3. Each institution should consider the need for collection and storage of serum samples from at-risk personnel.
4. A laboratory-specific biosafety manual must be prepared and adopted as policy. The biosafety manual must be available and accessible.
5. The laboratory supervisor must ensure that laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with BSL-3 agents.
6. Potentially infectious materials must be placed in a durable, leak proof container during collection, handling, processing, storage, or transport within a facility.
7. Laboratory equipment should be routinely decontaminated, as well as, after spills, splashes, or other potential contamination.
    a. Spills involving infectious materials must be contained, decontaminated, and cleaned up by staff properly trained and equipped to work with infectious material.
    b. Equipment must be decontaminated before repair, maintenance, or removal from the laboratory.
8. Incidents that may result in exposure to infectious materials must be immediately evaluated and treated according to procedures described in the laboratory biosafety manual. All such incidents must be reported to the laboratory supervisor. Medical evaluation, surveillance, and treatment should be provided and appropriate records maintained.
9. Animals and plants not associated with the work being performed must not be permitted in the laboratory.
10. All procedures involving the manipulation of infectious materials must be conducted within a BSC, or other physical containment devices. No work with open vessels is conducted on the bench. When a procedure cannot be performed within a BSC, a combination of personal protective equipment and other containment devices, such as a centrifuge safety cup or sealed rotor must be used.

Source: http://www.cdc.gov/biosafety/publications/bmbl5/BMBL5_sect_IV.pdf

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