

TRAINING UPDATE

Lab Location: GEC, SGAH & WAH
Department: All staff

Date Distributed: 5/22/2014
Due Date: 6/30/2014

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
Bloodborne Pathogens Exposure Control Plan GEC/SGAH/WAH. QDEHS701v10.1
Description of change(s):
<p>Our labs adopted this corporate SOP in February. The training update and quiz are required by all employees in the East Region business units.</p> <p>Expectation for staff:</p> <ul style="list-style-type: none">• Understands the meaning of a “bloodborne pathogen”.• Understands the meaning of universal precautions.• Can describe an example of an engineering control and a work practice control used in the department.• Can describe the appropriate personal protective equipment (PPE) to use when handling open specimens.• Understands where PPE is not to be worn.• Can identify where to get PPE in the department and where to discard used PPE.• Can differentiate between waste that is biohazardous and waste that is not. <p>This revised SOP has already been implemented</p>

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

Non-Technical SOP

Title	Bloodborne Pathogens Exposure Control Plan	
Prepared by	Tom Heeley, Corp. EHS Manager	Date: 10/03/2013

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

Review		
Print Name and Title	Signature	Date

Corporate Approval	Corporate Issue Date:	
Print Name and Title	Signature	Date
Clete Lewis, Director, Environment, Health and Safety Owner	<i>On file</i>	10/04/2013
Chief Laboratory Officer/Designee		

Retirement Date:	
Reason for retirement/replacement:	

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1. PURPOSE

This document sets forth the policy to minimize or eliminate occupational exposure to bloodborne pathogens in accordance with OSHA Standard 29 CFR 1910.1030 *Bloodborne Pathogens*.

2. SCOPE

This policy is applicable to all job classifications where there is direct or reasonably anticipated exposure to blood or other potentially infectious materials (OPIM) at company-owned or managed facilities.

3. RESPONSIBILITY

Responsible Party	Task
Corporate Environment, Health and Safety (EHS)	<ul style="list-style-type: none"> • Maintain, review and update the elements of the Bloodborne Pathogens Exposure Control Plan (ECP) • Review exposure incidents and other relevant information for opportunities to improve the ECP or training materials to reduce risk. • Establish other safety and health-related work policies and procedures.
Location EHS Manager, Specialist or contact.	<ul style="list-style-type: none"> • Review, train, document training and implement the ECP and any updates that are distributed • Make the written ECP available to employees and regulatory agencies • Review local exposure incidents to ensure corrective action is implemented where appropriate and opportunities for improved processes or training are initiated. • Ensure that all post-exposure management activities are performed and that appropriate employee medical and OSHA records are maintained • Work with Corporate EHS to establish and document any local safety practices

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Responsible Party	Task
Corporate and/or local Patient Service Management	<ul style="list-style-type: none"> Establish policies, procedures and other practices for blood and specimen collection in company-owned and managed Patient Service Centers (PSCs), In-Office Phlebotomy (IOP) arrangements, and Rapid Response Labs consistent with this ECP.
Location managers or supervisors of job classifications with potential for occupational exposure to blood or OPIM	<ul style="list-style-type: none"> Comply with the policies outlined in this ECP within their area of responsibility and ensure their staff complies in order to minimize exposure potential. Establish local safety practices, as appropriate, and reflect those actions in the local version of this ECP.
Employees in job classifications that may have occupational exposure to blood or OPIM.	<ul style="list-style-type: none"> Comply with the policies outlined in this ECP.

4. DEFINITIONS

Bloodborne Pathogens are pathogenic microorganisms that are present in human blood or other potentially infectious material and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).

Contaminated means the presence of visible blood or other potentially infectious materials on an item or surface.

Contaminated Sharps means any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and pipettes.

Employee means those employees who work in job classifications in which all or some have or may have occupational exposure. This includes those hired by Quest Diagnostics on a full-time or part-time basis. For any temporary or contract worker, Quest Diagnostics will make safety arrangements with the agency who provides those workers, recognizing that Quest Diagnostics will control and provide training for on-site conditions.

Infectious Substance means a specimen or culture, isolate or other derivative of a specimen that contains a viable infectious virus, prion, or a viable microorganism, including bacteria, rickettsia, parasites, fungi, or recombinant microorganisms (hybrid or mutant), that causes or may cause disease in humans. Toxins known to be pathogenic are included in this definition. This also includes any etiologic agent specifically listed by the CDC in its regulations.

Parenteral contact means piercing mucous membranes or the skin barrier by needlesticks, broken tubes, human bites, cuts, and abrasions.

Personal Electronic Device pertains to a personal entertainment or communication device including but not limited to a cell phone, smart phone (e.g. Blackberry, iPhone), iPod, MP3 player, personal AM/FM/HDFM radio.

Personal Protective Equipment (PPE) is specialized clothing or equipment worn by an employee for protection against a hazard. PPE may include lab coats, face shields, and gloves. General work clothes (e.g., uniforms, scrubs, pants, shirts or blouses), not intended to function as protection against hazards, are not considered to be personal protective equipment.

Occupational Exposure means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious material that may result from the performance of an employee's duties.

Other Potentially Infectious Material (OPIM) means (1) the following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; (2) any unfixed tissue or organ (other than intact skin) from a human (living or dead); and (3) HIV-containing cell or tissue cultures, organ cultures, and HIV, HBC, or HBV-containing culture medium or other solutions; and blood, organs or other tissues from experimental animals infected with HIV, HCV, or HBV.

Sharps container means a container that is closable, puncture resistant, leak-proof on sides and bottom, and labeled in fluorescent orange or orange-red, and bearing the Biohazard legend.

Solid Waste is any material to be discarded or that is no longer fit for its intended purpose. A solid waste may be liquid, solid, semisolid or gas.

Universal Precautions is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, HCV, and other bloodborne pathogens.

5. PROCEDURE

5.1 Determine employee exposure job classification

A. Job classifications in which all employees have occupational exposure:

Job Title	Department/Location
Pathologist	Anatomic Pathology
Technical Manager/Supervisor	Operations
Technologist	Operations
Technician	Operations
Laboratory Aide	Operations
Logistics Driver/Courier	Logistics
Phlebotomist	Phlebotomy
Specimen Processor	Operations
Processor	Cytology and Histology
Emergency Responder	Operations
First-Aid Responder	Operations

Quality Assurance Personnel	Quality Assurance
EHS Manager/Specialist	EHS
Maintenance personnel	Maintenance
Housekeeping personnel	Housekeeping

B. Job classifications in which some employees have occupational exposure. Below is a list of tasks and procedures, or groups of closely related tasks and procedures, in which occupational exposure may occur for these individuals:

(Note: This is not meant to be an all-inclusive list. Each business location will have to develop a table locally.)

Job Title	Department/Location	Task/Procedure
Facilities/Maintenance	Lab areas	Maintenance in lab areas
Information Technology	Lab areas	Maintenance on PCs/printers
Client Services	Lab areas	Specimen problem resolution

5.2 Methods of Implementation and Control

A. Universal Precautions

All employees will utilize universal precautions to help prevent or eliminate contact with blood or OPIM. Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids will be considered potentially infectious.

B. Exposure Control Plan Management

Employees receive an explanation of this ECP during the new hire onboarding process. The ECP also will be reviewed in their annual Bloodborne Pathogens refresher training or when significant changes are made. All employees have an opportunity to review this plan at any time during their work shifts by referring to the EHS Safety Manual located in their department or on the company's intranet. If the employee requests a copy of the ECP, it will be provided free of charge within 15 days of the request.

The ECP is updated, at least annually, and whenever necessary:

- to reflect new or modified tasks and procedures which affect occupational exposure
- to reflect new or revised employee job categories with occupational exposure
- to reflect changes in technology that eliminate or reduce exposures to bloodborne pathogens
- to document, as appropriate, consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure and related employee evaluations.

Business locations are to follow the standard process when adding local information to the ECP. Any site making changes to its ECP (other than local additions); will do so in consultation with the Corporate EHS Department.

If periodic updates to the ECP are made between annual changes, they may be issued as addenda, to be integrated into the ECP at a later time.

C. Engineering Controls and Work Practices

Engineering controls and work practice controls will be used to prevent or minimize employee exposure to bloodborne pathogens. Engineering controls shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness. Quest Diagnostics has and will continue to evaluate and select safer medical devices designed to eliminate or minimize occupational exposure to bloodborne pathogens. See section 5.11. Quest Diagnostics shall monitor developments in the marketplace and monitor products that meet the criteria for evaluation.

a. Engineering Controls:

- Safety engineered needles and lancets with intrinsic safety features (Becton Dickinson Eclipse™ needles, BD one use needle holders (single use needle holders), Safety-Loc™ butterfly needles, Ultilet Safety Lancets, Microtainer® Contact Activated Lancet, and QuikHeel™ Lancet) will be used for phlebotomy.
- Safety engineered needles with intrinsic safety features (BD Safety-Lok™ or BD SafetyGlide™ syringes) will be used in the laboratories when possible.
- Mechanical pipetting devices will be used for manipulation of all liquids. No mouth pipetting is permitted under any circumstances.
- Specimens of blood or OPIM shall be placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.
- Sharps disposal containers of adequate capacity will be provided wherever sharps are used.
- Plumbed eyewash stations or commercially prepared squeeze bottles of saline or sterile irrigant must be available in case of a blood or OPIM exposure to the eyes or other mucous membranes.

b. Work Practice Controls:

- Gloves and face protection (covering eyes, nose, and mouth) are required when handling specimens.
- Fully buttoned lab coats are required in designated laboratory areas and while performing phlebotomy. The lab coats need to cover the employee's arms from shoulder to wrist and must hang down to the employee's mid-thigh at a minimum.
- Minimize patient movement during venipuncture procedure.
- Activate engineering controls or safety features of needles and other sharps immediately after use.
- Used needles or sharps are to be immediately placed in a sharps container. The container shall be placed as close as possible to the workstation.
- Needles are not to be bent, broken, reused, or recapped (the safety device is to be activated).
- Approved vent-subculture units will be used to subculture blood culture bottles in the Microbiology Department. Consult the Comprehensive Microbiology Safety Procedures SOP for currently approved devices. Conventional (non-

safety) needles and syringes are not to be used to sub-culture blood culture bottles.

- Employees must wash their hands every time gloves are changed or when leaving the laboratory.
- Where hand washing facilities are not available, the employee will be provided with an antiseptic hand cleaner. When antiseptic hand cleaners are used, hands shall be washed with soap and running water as soon as feasible.
- Employees must wash hands and other exposed skin with soap and water or flush mucous membranes with water immediately or as soon as possible following contact with blood or OPIM.
- Sharps disposal containers are to be inspected and maintained or replaced whenever necessary to prevent overfilling.
- All needles to be discarded, even if covered by a safety device, are to be picked up using mechanical means such as forceps if they are found outside of a sharps container.
- All procedures and manipulations involving blood or OPIM shall be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances.
- Centrifuges are not to be opened while rotors are moving.
- Eating (including chewing gum), drinking, smoking, applying cosmetics or lip balm, and handling contact lenses within work areas where an exposure could occur is strictly prohibited.
- Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets, or on counter tops or bench tops where blood or OPIM is used, present, or likely to be present.
- An insect and rodent control program shall be in effect as needed in the areas designated for handling, storing, or disposing of biohazardous materials.
- Managing Personal Electronic Devices in the Lab
Use of personal electronic device (cell phones, MP3 players, etc.) in the lab by employees and vendor service technicians must comply with local Department of Health regulations and site policies. The following guidelines must be followed to prevent contamination of the device, which in turn may contaminate the user, thereby presenting a health risk.
 - Any device carried by a lab tech working with specimens should be kept under the lab coat (e.g. in clothing pocket). Any accessory cords (e.g. to ear phones) must also be run under the lab coat.
 - The device/accessories should not be touched while wearing PPE or while performing tasks that may result in contamination of the device. Remove PPE (gloves, lab coat) and wash hands prior to handling the device.

c. Updates to Engineering and Work Practice Controls:

- On an ongoing basis, and at least annually, the business location's EHS Manager and Corporate EHS will independently and in concert, as appropriate, review any need to update or modify engineering and work practice controls. The sites will forward comments and/or engineering and work practice control

recommendations to Corporate EHS for inclusion in the ECP. Updates will be reflected in the ECP.

- Corporate EHS will independently and in concert with the Needlestick Prevention Team and business locations, as appropriate, reviews the need to update or modify the engineering controls and work practices. This is accomplished through a review of exposure incidents information in the Human Resources Service Center case management system, the Workers Compensation claim records, employee interviews and input, Safety Committee activities and ideas, and previously completed *Needle and Lancet Injury Report or Incident and Injury Investigation Reports*. The information included in the review process may include:
 - Date, time, and location
 - Employee's job classification
 - Task or procedure being performed
 - Route of exposure
 - Type and brand of sharp or other device involved
 - Description of the exposure
 - Employee comments
- Through this review process the effectiveness of the Exposure Control Plan can be assessed; and changes or updates to training can be implemented as appropriate to reduce exposure incidents.
- Any new engineering or work practice controls should be evaluated by the local EHS Manager and/or Corporate EHS prior to the introduction of new products and procedures.
- Information regarding training topics, new product implementation, and other relevant information is distributed to the business location EHS Managers / Specialists or local contacts by the Corporate EHS Managers via conference calls, individual calls or email distribution, or on a company-wide 'All Hands Call' for urgent information.
- The process and history of needle products reviewed and selected is summarized in Section 5.11.
- Contracts with temporary employee agencies contain language describing how Quest Diagnostics and the agency will allocate safety responsibilities.

d. Employee Input in Engineering and Work Practice Controls:

- Once a product is selected for evaluation, it is submitted to groups of non-managerial employees who would use the product should it be selected. Employee evaluation forms are used to gather and summarize input.
- The completed documents for product and/or work practice evaluations are maintained at the evaluation site and/or at the corporate level.
- If a product is selected, employees are extensively trained on the new product and/or related work practices. Employee input is also gathered during this process and used as appropriate to further modify work practices.
- As part of the evaluation of incidents recorded on the *Needle and Lancet Injury Reports* and/or the *Incident and Injury Investigation Reports*, employees may provide input on the engineering control and/or work practice involved.

- Employees are able to use the company's open-door policy or CHEQline to provide comments at any time to Supervisors, Managers, or to others in the business locations relative to engineering and work practice controls.

D. Personal Protective Equipment (PPE)

PPE is provided, cleaned, maintained, and disposed of at no cost to the employee. The department supervisor, EHS Manager/Specialist or designee provides training in the use of the appropriate PPE for the tasks or procedures performed by the employees. Complete and document training prior to PPE use. The types of PPE available to employees are as follows:

- Protective clothing such as laboratory coats, aprons, gowns, or uniforms must be worn when working with biohazardous materials and removed before leaving the laboratory. Under no circumstances should employees go to the cafeteria, vending area, rest rooms, or lounge areas while wearing protective clothing used in handling biohazardous materials.
- Water impermeable gloves must be easily accessible and available at no cost to those employees.
- "Hypoallergenic" gloves, glove liners, powderless gloves, or other similar alternatives must be easily accessible and available at no cost to employees who are allergic to the gloves normally provided.
- Gloves are required when handling specimens.
- Face protection covering the eyes, nose, and mouth are required when handling open specimens*. Face protection includes face shields, surgical masks with eye protection, and fixed safety bench shields.
- PPE may be obtained through all department supervisors.
- All employees using PPE must observe the following precautions:
 - Wash hands immediately or as soon as feasible after removal of gloves or other PPE
 - Remove PPE immediately after it becomes contaminated and before leaving the work area.
 - Used disposable lab coats may be disposed of in regular trash unless visibly contaminated with blood or OPIM.
 - Used cloth lab coats are to be handled as directed by the laundry service
 - Wear appropriate gloves when it can be reasonably anticipated that there may be hand contact with blood or OPIM, and when handling or touching contaminated items or surfaces.
 - Replace gloves if torn, punctured, contaminated, or if their ability to function as a barrier is compromised.
 - Utility gloves may be decontaminated for reuse if their integrity is not compromised. Discard utility gloves if they show signs of cracking, peeling, tearing, puncturing, or deterioration.
 - Never wash or decontaminate disposable gloves for reuse.
 - Wear appropriate face and eye protection when splashes, sprays, splatters, or droplets of blood or OPIM pose a hazard to the eye, nose, or mouth. Appropriate face and eye protection includes masks in combination with eye protection

devices, such as goggles or glasses with solid side shields, or chin-length face shields.

- PPE is to be used according to manufacturer's instructions.

*Business locations may decide to use measures above and beyond this standard.

5.3 Housekeeping

The worksite will be maintained in a clean and sanitary condition. The written schedule for cleaning/disinfection in each department or location where biohazardous materials are present or likely to be present is stated below.

Contaminated work surfaces shall be decontaminated with an appropriate disinfectant:

- After completion of procedures
- Immediately or as soon as feasible when surfaces are overtly contaminated or after any splash or spill of blood or other potentially infectious materials
- At the end of the work shifts if the surface may have become contaminated since the last cleaning.

Protective coverings, such as plastic wrap, aluminum foil, or imperviously-backed absorbent paper used to cover equipment and environmental surfaces, shall be removed and replaced as soon as feasible when they become overtly contaminated or at the end of the work shift if they may have become contaminated during the shift.

All bins, pails, cans, and similar receptacles intended for reuse that have a reasonable likelihood of becoming contaminated with blood or other potentially infectious materials shall be inspected and decontaminated on a regularly scheduled basis and cleaned and decontaminated immediately or as soon as possible upon visible contamination.

Broken glassware and other sharp items that may be contaminated shall not be picked up directly with the hands. They must be cleaned up using mechanical means, such as a brush and dustpan, tongs, or forceps.

Reusable sharps that are contaminated with blood or other potentially infectious materials shall not be stored or processed in a manner that requires employees to reach by hand into the containers where these sharps have been placed. All material that is defined as sharps, whether contaminated or not, must be disposed of in a sharps container, which is then placed in a DOT approved biohazardous waste container.

All discarded needles, even if covered by a safety device, are to be picked up using mechanical means such as forceps if they are found outside of a sharps container.

5.4 Biohazardous Waste Management

Waste is biohazardous if any of the following apply:

- It contains an infectious substance and was generated in the diagnosis, treatment, or immunization of human beings or animals.

- It is saturated or caked with blood or OPIM (e.g. disposable lab coats, gloves, paper, glass, plastics).
- It is a diagnostic kit containing biological products.
- It is a cytology or histology specimen (with preservative decanted off)

Waste is not biohazardous if:

- It is material that previously contained an infectious substance and has been treated by steam sterilization, chemical disinfection, or other appropriate method, so that it no longer poses the hazard of an infectious substance.
- It is billing requisitions, gloves, or disposable lab coats that are not saturated or caked with blood or OPIM*.
- It contains chemicals, solvents, or other hazardous wastes.

*Business locations may decide to use measures above and beyond this standard.

Biohazardous waste collection:

Some biohazardous waste in liquid form may be disposed into the sewer. Please refer to local regulations for waste that can be put into the sewer. All other waste must be properly contained.

Biohazardous Waste Containers:

A. Sharps container

A sharps container is:

- Rigid
- Leak resistant
- Impervious to moisture
- Closable
- Puncture resistant
- Leak-proof on sides and bottom
- Labeled in fluorescent orange or orange-red and bearing the Biohazard legend.
- Easily accessible to personnel
- Located as close as feasible to the immediate area where sharps are used or can be reasonably anticipated to be found
- Maintained upright throughout use
- Replaced routinely and not be allowed to overfill.
- Sharps containers shall not be opened, emptied, or cleaned manually or in any other manner. Re-usable sharps containers must be handled according to manufacturer's instructions.

B. Other Biohazardous Waste Containers:

- Biohazardous waste other than sharps must be put in a container that is closable, constructed to contain all contents, and prevents leakage of fluids during handling, storage, transport, or shipping.
- The container must have a fluorescent orange or orange-red label that bears the biohazard legend and biohazard symbol.

- If the outer surfaces of the container become contaminated with a biohazardous material, it must be decontaminated or placed in a secondary container meeting the same requirements.
- Containers designed to hold liquids must be closed or sealed in a way that prevents leaks or spills and then placed upright inside a red bag that lines an exterior container. If this is not possible, then liquids must not be placed in containers.
- Close the red bag with a knot or with tape.
- The container must be closed prior to removal.
- Prior to use, reusable containers must be inspected for residue or damage that reduces the structural integrity of the container.

5.5 Laundry

Contaminated laundry shall be handled as little as possible with a minimum of agitation.

Contaminated laundry shall be bagged or containerized at the location where it was used and shall not be sorted or rinsed in the location of use.

Contaminated laundry shall be placed and transported in bags or containers labeled or color-coded as stated above. When a facility utilizes Universal Precautions in the handling of all soiled laundry, alternative labeling or color-coding is sufficient if it permits all employees to recognize the containers as requiring compliance with Universal Precautions.

Whenever contaminated laundry is wet and presents a reasonable likelihood of soak-through or leakage from the bag or container, the laundry shall be placed and transported in bags or containers that prevent soak-through and/or leakage of fluids to the exterior.

The employer shall ensure that employees who have contact with contaminated laundry wear protective gloves and other appropriate personal protective equipment. Employees cannot launder lab coats at their home or any other place outside of Quest Diagnostics.

When a facility ships contaminated laundry off-site to a second facility which does not utilize Universal Precautions in the handling of all laundry, the facility generating the contaminated laundry must place such laundry in bags or containers which are labeled or color-coded.

5.6 Labels

Warning labels shall be affixed to containers of regulated waste, refrigerators, and freezers containing blood or other potentially infectious material; and other containers used to store, transport, or ship blood or other potentially infectious materials.

Labels required by this section shall include the BIOHAZARD legend and symbol indicated in Signs, Section 5.7.

These labels shall be fluorescent orange or orange-red or predominantly so, with lettering and symbols in a contrasting color.

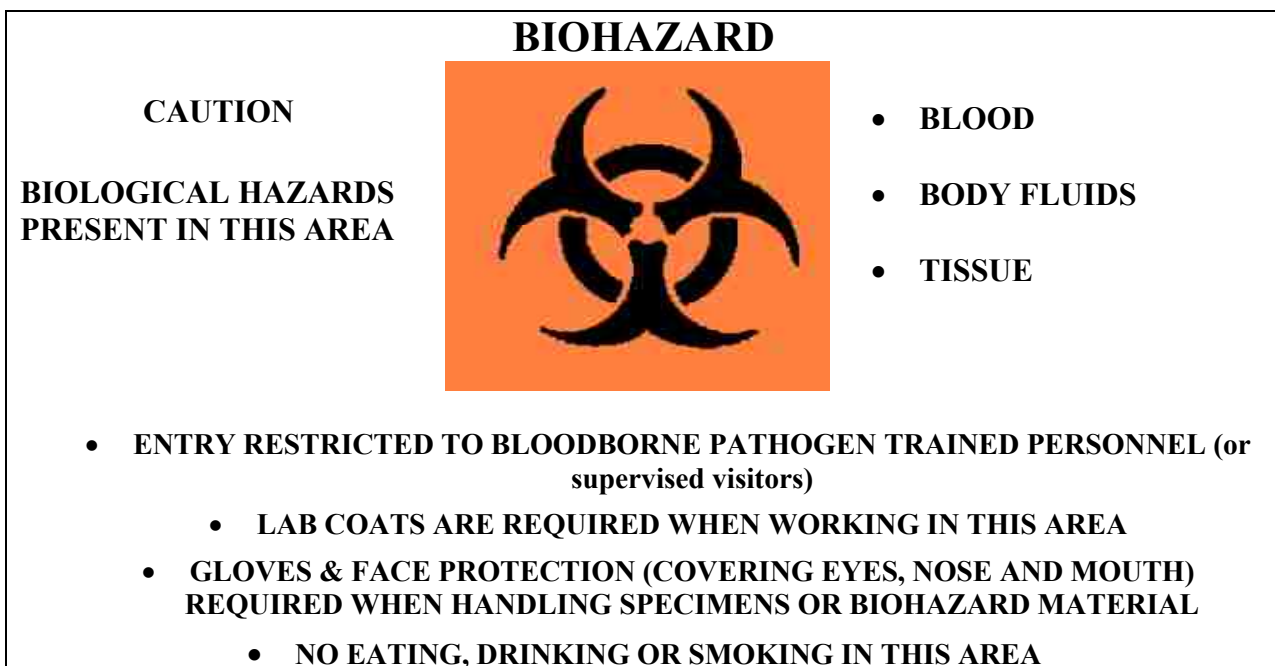
Labels shall be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.
Red bags or red containers may be substituted for labels.

Contaminated equipment shall be labeled with the BIOHAZARD legend and symbol until it is decontaminated.

Regulated waste that has been decontaminated need not be labeled.

5.7 Signs

The laboratory shall post signs indicating biohazard areas. One example of an appropriate sign is shown below.



These signs shall be fluorescent orange-red or predominantly so, with lettering and symbols in a contrasting color.

5.8 Hepatitis B Vaccination

Each business location will make available to all employees free Hepatitis B vaccinations, Hepatitis B antibody testing, and post-exposure medical counseling and treatment through occupational medical clinics. Please refer to the Immunization Practices SOP for guidance on Hepatitis B Vaccination program. Contact the local EHS contact or the Human Resources Service Center for more information.

5.9 Post Exposure Evaluations and Follow-Up

Please refer to the Post-Exposure Management SOP for guidance on post-exposure evaluation and follow-up. Contact the local EHS contact or the Human Resources Service Center for more information.

5.10 Employee Training

All employees with occupational exposure must participate in a training program at no cost to the employee and during working hours.

General training shall be provided at the time of initial assignment to tasks where occupational exposure may take place. Additionally, department specific training will be provided prior to initial assignment to tasks where occupational exposure may take place and at least annually thereafter.

Employers shall provide additional training when changes are made to current tasks or procedures, or institution of new tasks or procedures affect the employee's occupational exposure. The additional training may be limited to addressing the new exposures created. This includes training for new products implemented by the Needlestick Prevention Team based on product evaluations, as described above.

Material appropriate in content and vocabulary to the educational level, literacy, and language of employees shall be used.

The training program shall contain at a minimum the following elements:

- An accessible copy of the regulatory text of this standard and an explanation of its contents
- A general explanation of the epidemiology and symptoms of bloodborne diseases
- An explanation of the modes of transmission of bloodborne pathogens
- An explanation of the employer's Exposure Control Plan and the means by which the employee can obtain a copy of the written plan
- An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials
- An explanation of the use and limitations of methods that will prevent or reduce exposure including appropriate engineering controls, work practices, and personal protective equipment
- Information on the types, proper use, location, removal, handling, decontamination, and disposal of personal protective equipment
- An explanation of the basis for selection of personal protective equipment
- Information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccinations will be offered free of charge
- Information on the appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials
- Information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident
- An explanation of the signs and labels and/or color coding

- An opportunity for interactive questions and answers with the manager or supervisor during the department-specific safety training session
- The person conducting the department-specific safety training shall be knowledgeable in the subject matter covered in the training program

5.11 Product Evaluations

Product evaluations are a collaborative effort between the Needlestick Prevention Team, Patient Services, EHS, Corporate Procurement, and front line employees. Quest Diagnostics has and will continue to evaluate and select safer medical devices designed to eliminate or minimize occupational exposure to bloodborne pathogens. Quest Diagnostics shall monitor developments in the marketplace and monitor products that meet the criteria for evaluation. The following is the more specific criteria and outcomes from product evaluations that have occurred since 2000, prior to the start of the federal safety needle program. Facilities may utilize this process for specific needs, as appropriate, with consultation from Corporate EHS.

- A. The Needlestick Prevention Team will be responsible for:
 - Identify new products for consideration and evaluation
 - Establishing initial supplier meeting to demonstrate product with evaluation group
 - Determining if the product is a potential candidate for evaluation at the sites
 - Documenting the findings from the above activities
 - Capturing/sending notes from all Evaluation Team meetings
 - Coordinating contact between the supplier and business locations if the product will be evaluated at the sites
 - Coalescing data from the Evaluation forms and producing an Evaluation report
- B. The Needlestick Prevention Team Leader is responsible for:
 - Coordinating evaluation team meetings (when product evaluations are in planning and underway)
 - Assisting Needlestick Prevention Team with supplier contacts and initial review of new products/features
 - Ensuring that evaluating locations stay on track with product evaluation deployment and evaluation submissions
 - Crafting the Executive Summary of the Evaluation Report(s)
- C. Each evaluation location contact will be responsible for:
 - Contacting local supplier representative and or working with Corporate Purchasing to secure product.
 - Coordinating product training (with the supplier, if necessary) and placement of product (between supplier/Corporate Procurement) in appropriate PSCs for the evaluation period
 - Adhering to the schedule (see below) for product evaluations
 - Ensuring the completion of product evaluation forms
(See example Blood Collection Set Evaluation Form (Addendum A))
 - Forwarding completed forms to the Needlestick Prevention Team Leader

D. Evaluation Method

- Select and gain agreement from representative business locations to conduct product evaluations. Evaluation locations should represent the Quest Diagnostics geography and business mix.
- Each evaluating location selects phlebotomists from a pool of requested participants at the facility. The Phlebotomists chosen should be representative of the business location's group (e.g. new employees and seasoned Phlebotomists). Some business locations may elect to perform needle evaluations at all patient service sites.
- Initial evaluation follows a review of the product information and training on the device. The initial evaluation of the involved handling of the device through hands-on assembly, activation, and non-patient use (may include prosthetic arms or foam blocks). The device must be assessed as an equal or better device in terms of safety and operation than the current product to warrant further testing on patients. If the product is deemed a viable product for further evaluation, then the following steps occur.
- The participating phlebotomy team will perform a predetermined amount of concurrent venipunctures (using the device when appropriate) over a predetermined period. The evaluation is complete when either criterion is met (i.e., number of draws or period of time, whichever comes first).
- Each product will be evaluated in its own discreet time period (see below); therefore multiple products will not be evaluated concurrently.
- A "Blood Collection Set Evaluation Form" will be completed by each evaluating Phlebotomist and turned in to the evaluation location contact for product evaluations.
- Product evaluations will include and document blood draws in typical settings (inside a PSC, Mobile/Long-term care, IOP and inside a hospital).
- Product evaluations will evaluate the product in a wide variety of applications (patient sitting/lying down, geriatric, pediatric, large/small individuals).
- Alternately, an evaluation location may choose to perform a visual and hand-held evaluation of a new safety needle without actually performing patient draws. The results of these evaluations will be captured on the "Blood Collection Set Evaluation Form".

E. Evaluation Timetable

- Conduct training and move product into PSCs
- Begin evaluation of product
- Continue/conclude evaluation of product
- Complete evaluation form, submit to the local contact and mail the completed forms to the Needlestick Prevention Team Leader
- Coalesce data from the evaluation forms
- Produce report and a craft Executive summary

F. Results (This section documents those products selected that are now or were listed in Section 5.2.C. This list is a running, very general summary and historic record of the selection process.)

- In 2000 the BD Eclipse Blood Collection Needle, the BD Safety-Guard Phlebotomy System, the Bio-Plexus Punctur-Guard, the SIMS Portex Venipuncture Needle Pro, the

BD Safety-Lok Blood Collection Set, and the Retractable Technologies, Inc. VanishPoint Blood Collection Tube Holder were evaluated. The BD Eclipse and SIMS Needle Pro ranked the highest in phlebotomist evaluations, i.e., they were the safest medical devices evaluated. BD was chosen as a result of their product innovation and willingness to develop and assist in training, pricing, and our long-term relationship with BD.

- In June 2001, The BD Eclipse Blood Collection Needle and the SIMS Portex Needle Pro were re-evaluated and the results were consistent with the original evaluation.
- In November and December 2001, the BD Safety-Lok Blood Collection Set and the Bio-Plexus butterfly needle device. It was decided to stay with the BD Safety Lok Collection Set based on:
 - 1) Slower tube fill rate will affect patient and phlebotomist safety, especially during difficult draws when this device is typically used and when speed is a factor;
 - 2) Up to 1/3 of the phlebotomists also difficulty activating the device with one hand (an OSHA desired feature and evaluation criteria) which can also affect patient and phlebotomist safety as well;
 - 3) Too few phlebotomists ranked this product as “Better Than” the product they now use.
- In April 2002, the BD Single Use Holder, BD Pronto Holder, and Sims Portex were placed into an abbreviated evaluation in the event that OSHA forced employers to switch to single use holders regardless of safety experience. The BD Single Use Holder received a numerical rank just above the BD Pronto Holder; however, employee comments included highly negative comments on the product.
- In August 2002, the BD single use needle holder was evaluated again. It was the consensus of the team that the single use needle holder was not a safer medical device than the Pronto Quick Release Needle Holder already in use and would put our employees at a greater risk for a needlestick. The evaluation team was comprised of a mix of phlebotomists and included key supervisors and managers. Males with large hands had difficulty holding the smaller holder and females with small hands had difficulty securely holding the holder with a 10 ml tube.
- Throughout 2003, the BD Eclipse and Safety Lok were evaluated through employee feedback, information, and experience to determine if the products were effective. It was determined that they were the safest medical devices available.
- In 2003, sharps containers were evaluated in the Pittsburgh business location. Quest Diagnostics has determined that the design of the sharps container impacts the ability of the medical device to eliminate or minimize occupational exposure. Sharps containers were standardized to the safest sharps container for the task being performed.
- In April and May 2004, the ICU Medical Punctur-Guard and Portex butterfly needle devices were evaluated to determine if either was a safer medical device than the BD Safety Lok that was currently in use. The data from the two evaluations did not provide a clear direction on choice. Both products scored equally well and both products had drawbacks that have been corrected by the manufacturers. Phlebotomists had both highly positive and negative feedback on these products. The Portex butterfly is similar to the BD butterfly in that it requires the phlebotomist to activate the safety device after withdrawal from the vein. The safety device for the ICU Medical butterfly is activated in the vein and as a result, would require more training to learn a technique very different from the BD butterfly.

The two products received similar ratings and there were enough negative comments that neither product was determined to be a favored product by the phlebotomists over the existing BD Safety Lok.

- In March, April, and May 2005, the Portex butterfly underwent further evaluation. It was not rated easier to use and was ranked “worse than” the BD butterfly device currently in use. These results did not support a change from the BD Safety Lok device currently in use.
- A Corporate safety team comprised of EHS and Patient Services representatives evaluated various medical devices throughout 2007 and 2008 to determine whether they were safer than the devices currently in use. These medical devices included products from Terumo and VanishPoint. The evaluation team determined that the tested devices were not as safe as or safer than the devices currently in use, and therefore a more formal evaluation was determined not to be appropriate.
- The Needlestick Prevention Team evaluated various medical devices throughout 2009 to determine whether they were safer than the devices currently in use. The Greiner Vacuette underwent a formal evaluation in the Las Vegas, NY/NJ, TXGC, and Sonora Quest facilities. The phlebotomists did not evaluate the Greiner Vacuette Blood Collection Set as a safer or superior medical device than the one currently in use. The decision was made to continue using the product currently in use.
- The Needlestick Prevention Team felt there were enough additional attributes of the Greiner butterfly that it warranted a second evaluation in 2010 into 2011. The Needle evaluation team determined the device was not as safe as or safer than the BD Safety Lok device currently in use.
- In November and December of 2010, a Safety team comprised of EHS staff and Oregon Patient Services phlebotomists evaluated butterfly safety needles at sites throughout Oregon. The medical devices included: Sarstedt, Terumo, and Greiner butterfly safety needles. The evaluation determined that the devices evaluated were not safer to use than the current BD Safety Lok currently in use.
- In March 2012, a Safety team comprised of EHS staff and Oregon Patient Services phlebotomists evaluated butterfly safety needles at sites throughout Oregon. The medical devices included: The Jelco Needle Pro 21 safety needle Vacutainer system, the Jelco Saf-TW-Wing butterfly safety needle, and the Kendall Angle Wing butterfly safety needle. The evaluation determined that the devices evaluated were not safer to use than the current BD Safety Lok and BD Eclipse straight safety needle currently in use.
- In March-June 2013, a Safety team comprised of EHS staff and Oregon Patient Services phlebotomists evaluated butterfly safety needles at sites throughout Oregon. The medical devices included: The Vacuette Butterfly with Holder (21G $\frac{3}{4}$ inch); the BD Vacutainer Passive Shielding Blood Collection system (22G 1 inch), and the Vacuette Butterfly without Holder (21G $\frac{3}{4}$ inch). The evaluation determined that the devices evaluated were not safer to use than the current BD Safety Lok and BD Eclipse straight safety needle currently in use.

G. Additional Employee Input

Employees can provide comment and give input to engineering controls, including safe needle products, by contacting their manager or supervisor, their local EHS contact, Corporate EHS, or Corporate Patient Services.

5.12 Recordkeeping

A. Medical Records

Medical records are maintained for each employee with occupational exposure in accordance with 29 CFR 1910.20 "Access to Employee Exposure and Medical Records."

The EHS contact and/or Human Resource representative is responsible for maintenance of the required medical records. These confidential records are filed electronically in a secured document storage server according to the requirements published in the Quest Diagnostics *Records Management Program Reference Guide*, which meets or exceeds regulatory requirements. The privacy of exposed employees is strictly maintained.

Employee medical records are provided upon request of the employee or to anyone having written consent of the employee within 15 working days. Such requests should be sent to the EHS contact and/or Human Resource representative.

B. Training Records

Training records are completed for each employee upon completion of training. The local EHS contact, department manager or Human Resource Service Center maintains these documents for at least three years.

The training records include:

- Dates of the training sessions
- Contents or a summary of the training sessions
- Names and qualifications of persons conducting the training
- Names and job titles of all persons attending the training sessions

Employee training records are provided upon request to the employee or the employee's authorized representative within 15 working days. Such requests should be addressed to the local EHS contact or Human Resource Service Center representative.

C. OSHA Recordkeeping for Illness/Injury

Medical laboratories under SIC code 8071 (NAICS code 621511) are not subject to OSHA's recordkeeping and 300 Log requirements. This change became effective on January 1, 2002. Prior 200 logs are maintained according to OSHA recordkeeping regulations.

Any state requirements for records will be described in the local section of the ECP.

6. RECORDS MAINTENANCE

Records are maintained according to the requirements published in the Quest Diagnostics *Records Management Program Reference Guide*.

7. RELATED DOCUMENTS

- Quest Diagnostics *Immunization Practices* SOP (QDEHS703)
- Quest Diagnostics *Post-exposure Management* SOP(QDEHS702)
- Quest Diagnostics *Biohazardous Waste Management* SOP (QDEHS707)
- Quest Diagnostics *Comprehensive Microbiology Safety Procedure* (QDMI726)

8. REFERENCES

1. OSHA 29 CFR 1910.1030; Bloodborne Pathogens, Revision 7 FR 19934, April 3, 2012
https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051
2. OSHA Directives, CPL 2-2.69; Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens, including Appendix D (Model Exposure Control Plan); November 27, 2001;

9. DOCUMENT HISTORY

Version	Date	Section	Revision	Revised By	Approved By
1	9/22/2000	All	Corporate ECP issued in new format	Andrea Bellisario	Clete Lewis
1A	12/30/2000	Addenda	Addendum A implemented to update Engineering Controls	Andrea Bellisario	Clete Lewis
1B	2/27/2002	Addenda	Addendum B implemented to update status of Engineering Controls	Andrea Bellisario	Clete Lewis
1C	1/21/2003	Addenda	Addendum C implemented to update status of Engineering Controls	Andrea Bellisario	Clete Lewis
2	5/23/2003	Multiple	To incorporate additional elements of BBP program from other documents into ECP	Andrea Bellisario	Clete Lewis
3	8/2/2004	5.12	To update evaluation activity	Andrea Bellisario	Clete Lewis
4	8/6/2005	5.12	To update evaluation activity	Andrea Hernandez	Clete Lewis
5	2/20/2006	5.12	To update evaluation activity	Andrea Hernandez	Clete Lewis
6	11/30/2007	5.3.C.a	To update product information	Andrea Hernandez	Clete Lewis
7	12/11/2009	5.3.C.a 5.12	To update product information and evaluation activity	Andrea Hernandez	Clete Lewis
8	4/21/2011	5.3.C.a 5.3.C.b 5.12 Addenda	To update product information, policy on personal electronics, evaluation activity, incident reporting forms, and evaluation form.	Andrea Hernandez	Clete Lewis
9	4/25/2012	5.12 Addenda	To update evaluation activity and update Incident and Injury Investigation Report form.	Andrew Butterfield	Clete Lewis

10	10/03/2013	5.1 5.12 Addenda	Redistributed information in section 5.1 and renumbered subsequent sections. Added references to the HRSC 5.12 (now 5.11).H. Updated safe needle evaluation information Removed <i>Incident & Injury Investigation Report</i> and <i>Needle & Lancet Injury Report Form</i> . Revised the Blood Collection Set Evaluation form.	Tom Heeley	Clete Lewis
1/14/2014 Initial adoption of corporate SOP QDEHS701 v10					
10	1/14/2014	5.11 11	Supersedes GEC/SGAH/WAH. SA02.000 Correct numbering of items D-G Add local appendices	L Barrett	B Mason

10. ADDENDA

Addendum	Title
A	Blood Collection Set Evaluation Form

11. LOCAL APPENDICES

- Appendix 1 Job classifications (5.1)
- Appendix 2 Engineering Controls (5.2.C)
- Appendix 3 Biohazard Waste Management (5.4)
- Appendix 4 Post Exposure Evaluation and Follow-up (5.9)

Document:GEC.QDEHS701[10.1] Status:RELEASED,Effective:1/29/2014, Check Version Before Use

Form ID: QDNQA305 v1 issued 8/05/13

BLOOD COLLECTION SET EVALUATION FORM (example) Addendum A

Device: _____ Evaluation Date: _____

Name of Evaluator: _____

Location: _____ PSC IOP RRL

What did you like about this product? _____

What did you dislike about this product? _____

Does the device eliminate or reduce employee exposure to the contaminated needle? Yes No

Please explain: _____

Is the device reliable? Yes No Please explain: _____

Is it obvious to see or hear that the safety device has been activated? Yes No Please explain:

Document:GEC.QDEHS701[10.1] Status:RELEASED,Effective:1/29/2014, Check Version Before Use

Form ID: QDNQA305 v1 issued 8/05/13

APPENDIX 1

LOCAL APPENDIX

Job Classifications for

Laboratories at Germantown Emergency Center, Shady Grove Adventist and Washington Adventist Hospitals

Job Code	Exposure Category
Analyst, Implementation	3
Assistant, Admin	3
Assistant, Lab I	1
Assistant, Lab II	1
Dir, Hospital Lab	3
Group Lead, Field Ops	1
Group Lead, Med Technologist	1
Group Lead, Medical Lab Tech	1
Group Lead, Shipping & Receiving	2
Manager, Field Operations	2
Manager, Project-Lab	3
Manager, Technical	2
Rep, Field Operations I	1
Rep, Field Operations II	1
Rep, Field Ops Sr - Hospital	1
Specialist, Quality Assurance	2
Supervisor, Lab	2
Supervisor, Field Operations	2
Technician, Medical I	1
Technician, Medical II	1
Technologist, Medical I	1
Technologist, Medical II	1
Technologist, Medical Sr - NIE	1

Exposure Category:

- 1 - Routine, everyday exposure to blood or other potentially infectious materials as part of normal job function.
- 2 - Intermittent exposure to blood or other potentially infectious materials as part of normal job function.
- 3 - No exposure to blood or other potentially infectious materials as part of normal job function.

APPENDIX 2

LOCAL APPENDIX

Engineering Controls

Washington Adventist Hospital (WAH) Laboratory and Shady Grove Adventist Hospital (SGAH) Laboratory will use Becton-Dickinson (BD) single use needle holders.

APPENDIX 3

LOCAL APPENDIX

Biohazard Waste Management (5.4)

- 1.0 The Washington Adventist Hospital Laboratory will follow the Hazardous Materials Waste Definitions and Hazardous Materials and Waste Management Plan procedures as outlined in the Washington Adventist Hospital Safety Manual.
- 2.0 The Shady Grove Adventist Hospital Laboratory and the Germantown Emergency Center will follow the Hazardous Materials Management / Hazardous Communications Program and Waste Management Plan procedures as outlined in the Shady Grove Adventist Hospital Safety Manual.

APPENDIX 4

LOCAL APPENDIX

Post Exposure Evaluation/Follow-up (5.9)

The enclosed procedure is to be followed at Laboratories of Quest Diagnostics Nichols Institute Chantilly, at Germantown Emergency Center, Shady Grove Adventist and Washington Adventist Hospitals in the event of a bloodborne pathogen exposure to a Quest Diagnostics employee.

Biological Exposure Checklist – GEC, SGAH & WAH

Perform the following steps **IN ORDER**

- ___ If the exposure involves blood, serum or OPIM (see below) to INTACT SKIN, wash the area with soap and running water for 15 minutes. Complete the enclosed incident report with your Supervisor or the Manager on Duty, and FAX a copy to 703-802-7294. Send the original to Employee Health via interdepartment mail. STOP AT THIS POINT.

- ___ If the exposure involves a cut or puncture with a sharp item contaminated with blood, serum, OPIM (see below), wash the site of injury with soap and running water for a minimum of 15 minutes. If blood, serum or OPIM are splashed into the eyes, wash the eyes with the eyewash for 15 minutes. CONTINUE...

- ___ If the injury site is bleeding, apply a bandage to the site of injury (if bleeding is uncontrollable, report immediately to the Emergency Room or dial 4444). CONTINUE...

- ___ Contact your immediate Supervisor, or if unavailable, the Supervisor in the lab area. CONTINUE. If no Supervisor is available, CONTINUE

- ___ Find the source specimen(s). Include all the Identification number(s) for the sources with the report to EHS. CONTINUE...

- ___ If the exposure occurs during the time when the Occupational Health Department is operating, take the enclosed authorization note and requisition form with you and report to the Occupational Health Department. At all other times, take the enclosed authorization note and requisition form with you and report to the Emergency Room. CONTINUE...

- ___ Complete the enclosed incident report with your Supervisor, and FAX a copy to 703-802-7294. Send the original to Employee Health via interdepartment mail. If the incident involved a needlestick, complete the needlestick incident report IN ADDITION TO the incident report and FAX a copy to 703-802-7294. Send the original to Employee Health via interdepartment mail. INCIDENT REPORTS MUST BE RECEIVED BY EHS WITHIN 24 HOURS OF AN INCIDENT.

- ___ Questions? Call 703-802-6900, extension 2500 and request the EHS on Call to be contacted via the cellphone.

OPIM or Other Potentially Infectious Materials are biological materials that have the possibility of passing along an infectious disease. OPIM includes:

Blood	Pleural Fluid	Cerebrospinal Fluid	Unfixed Tissue or Organ	Semen
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To: **Shady Grove Adventist Hospital or Washington Adventist Hospital Occupational Health Department or Hospital Emergency Services**

From: B. Mason, Manager, EHS Quest Diagnostics Nichols Institute, Chantilly

The employee bearing this note is a Quest Diagnostics Nichols Institute Chantilly employee and has had an alleged exposure to a biological material to the eyes, nose, mouth, non-intact skin or through a laceration or puncture. This note authorizes assessment, treatment/follow-up for the exposure incident for this employee.

All billing resulting from this treatment should be submitted for payment to:

**Employee Health
Quest Diagnostics Nichols Institute
14225 Newbrook Drive
Chantilly, VA 20151**

Please verify that this patient has been seen as soon as possible by either contacting the EHS department at 703-802-6900, extension 3372, or by e-mailing Linda.A.Pond@questdiagnostics.com. If you have questions, please contact the above number Monday through Friday between 8:00 am to 5:00 pm. Please contact the EHS on call through Security at 703-802-6900, extension 2500 at all other times.

We request you report the name of the employee, and the date and time the employee was seen by your group and the type of exposure reported. Additionally, the EHS office would like to know when follow-up is recommended or work limitations are placed on the employee at that time.

Thank you for your help.

**Take this form with you to the
Occupational Health Department or the
Emergency Services Department if a
biological exposure occurs.**