TRAINING UPDATE

Lab Location:	SGMC, WAH & GEC	**Date Distributed:**	3/5/2019
Department:	All staff	**Due Date:**	3/31/2019
		Implementation:	**3/13/2019**

DESCRIPTION OF REVISION

Name of procedure:

Bloodborne Pathogens Exposure Control Plan SGMC.SA931 v1

Description of change(s):

This is a 'new' SOP that replaces our previous EHS corporate version. It is very similar to the old SOP but has been converted to our local SOP format. A few minor changes were made:

- Update responsibility section to match our job titles
- Removed work practices that do not apply to our sites and added our policies
- Added 2018 needle stick initiatives (from corporate SOP)

Note: This new version is processed thru Media Lab (the new electronic document control system). SOP numbers for new shared documents are prefixed with SGMC (not SGAH) and initial version is 1 (not 0).

This SOP will be implemented on March 13, 2019

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	Leslie Barrett Date: 2/15/2019
Owner	Robert SanLuis Date: 2/15/2019

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

Review:		
Print Name	**Signature**	**Date**

TABLE OF CONTENTS

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
Quest Diagnostics Corporate Environment, Health and Safety (EHS)	• 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.
Local EHS Manager, Laboratory Services Director, Managers, Supervisors or designee.	• Review, train, document training and implement the SOP and any updates that are distributed • Establish local safety practices, as appropriate, and reflect those actions in the local version of this SOP. • Ensure the SOP is 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.

Responsible Party	Task
	• Work with Corporate EHS and Adventist HealthCare to establish and document any local safety practices.
Managers and supervisors of job classifications with occupational exposure risk to blood or OPIM	• Comply with the policies outlined in this SOP within their area of responsibility and ensure their staff complies in order to minimize exposure potential.
Employees in job classifications that may have occupational exposure risk to blood or OPIM.	• 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.

EHS COE – the Environment, Health and Safety Center of Excellence; which is a centralized resource for safety and injury prevention or reporting assistance. The EHS COE can be reached at 844-373-3910 or by email at EHSCOE@questdiagnostics.com .

Employee in this document means those employees who work in job classifications in which all or some have or may have occupational exposure risk. 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.

Human Resources Service Center (HRSC) – the centralized service center responsible for employee assistance including the management of the Hepatitis B vaccination program.

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 Risk 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, HCV, 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 – refer to Appendix 1

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 will review this SOP 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. Staff may also refer to the Quest corporate EHS Policies and Procedures page of the Quest intranet site.

The SOP is updated whenever necessary:

- to reflect new or modified tasks and procedures which affect occupational exposure risk
- to reflect new or revised employee job categories with occupational exposure risk
- 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.

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. Documentation of these efforts is found in section 5.12. 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, 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.
   - Plastic specimen tubes are routinely used instead of glass tube whenever available and/or feasible; unless there are quality issues with the plastic tubes.
   - 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 are available in case of a blood or OPIM exposure to the eyes or other mucous membranes.

b. Work Practice Controls:

- 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.
- Gloves are required when handling any specimens and face protection (covering eyes, nose, and mouth) is required when handling open specimens or when there is a chance of splash or spray.
- Communicate clearly with the patient to minimize 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. Conventional (non-safety) needles and syringes are not to be used to sub-culture blood culture bottles.
- Employees must wash their hands using an effective antimicrobial method (e.g. with antimicrobial soap or an antiseptic hand cleaner) every time gloves are changed or when leaving the laboratory.
- Employees must wash hands and other exposed skin with an antimicrobial cleaner and 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 found outside of a sharps container, even if covered by a safety device, are to be picked up using mechanical device such as forceps in order to discard.
- 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
  Adventist Hospital laboratories prohibit the use of personal electronic devices within the laboratory work areas.

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 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 Mangers / 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 5.12.
- 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 Report*s, 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 in the appropriate size, cleaned, maintained, and disposed of at no cost to the employee. PPE is obtained from the department supervisor or designee. 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:

- Lab coats or gowns:
  - 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.
  - 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.
  - Vendors or instrument personnel are required to wear a laboratory coat when performing maintenance tasks on instruments within the lab environment.

- Gloves
  - 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. **Note**: Only latex-free gloves and tourniquets are utilized by the Adventist Hospital laboratories. Refer to appendix 4 for Latex Management protocol.
  - Stretch glove over knit cuff of lab coat or gown (if present) for optimum protection.
  - Wear appropriate gloves when handling specimens, contaminated items or surfaces or anytime it can be reasonably anticipated that there may be hand contact with blood or OPIM.
  - Replace gloves if torn, punctured, contaminated, or if their ability to function as a barrier is compromised.
  - Never wash or decontaminate disposable gloves for reuse.
  - 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.

- Face Protection
  - Face protection covering the eyes, nose, and mouth are required when handling open specimens* and anytime there is the potential for splashes, sprays, splatters, or droplets of blood or OPIM. Face protection includes face shields, surgical masks with eye protection, and safety bench shields.
- All employees using PPE must observe the following precautions:
  - Wash hands with antimicrobial cleaner 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.
  - Use PPE according to manufacturer's instructions.

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

5.3 Visitors and Contactors

Visitors and contractors must be informed of the potential risk for bloodborne pathogens exposure associated with work in the laboratory. This may be done via informational handouts or content built into the visitor signature page, or other methods. Visitors and contractors will be provided with appropriate PPE as outlined in section 5.2.D when exposure potential exists and the contractor does not bring their own PPE (e.g. instrument vendors).

5.4 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, specimen racks, 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.

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.

5.5 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.

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 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 than 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 reasonable 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 florescent 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.
- There should be sufficient absorbent in bags of mixed biohazardous waste to prevent seepage of free liquid out of the red bag and the outer container. Double or triple bagging may be required to avoid rupture or puncture of the bag if using a fiberboard outer container. 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.

5.6 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 of 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.

5.7 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.

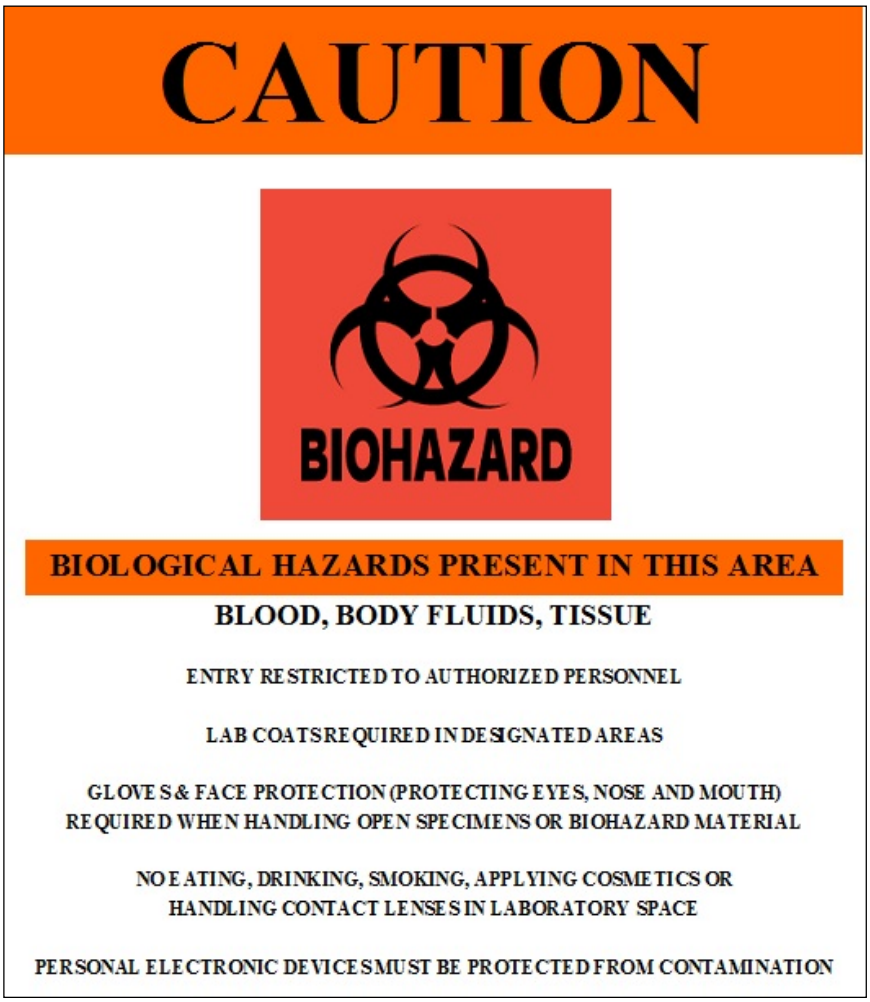
Labels shall be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.
Red bags or red containers may be substituted for labels.

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.

5.8 Signs

The laboratory shall post signs indicating biohazard areas. These signs shall be fluorescent orange-red or predominantly so, with lettering and symbols in a contrasting color. One example of an appropriate sign is shown below.



5.9 Hepatitis B Vaccination

The Hepatitis B vaccination series will be offered to all employees with occupational exposure risk to blood or OPIM. Please refer to the Immunization Practices SOP for guidance on Hepatitis B Vaccination program. Contact the local EHS representative or the HRSC for more information.

5.10 Post Exposure Evaluations and Follow-Up

Employees using universal precautions and safe techniques outlined in this document will significantly reduce the risk of exposures and injuries. However, if an incident does occur notify your supervisor, follow the guidelines below and complete an *Incident and Injury Investigation Report Form.* Contact the local EHS contact or the EHS COE for more information.

If this happens:	**Then do this:**
Blood or other potentially infectious material (OPIM) contamination on lab coat or street clothes.	Remove contaminated clothing and decontaminate by soaking in an appropriate disinfectant solution. If contamination soaks through to the skin follow the next step.
Blood or OPIM contamination on intact skin.	Wash thoroughly with antimicrobial soap and water or antiseptic hand cleaner.
Blood or OPIM contamination in open wound (e.g cut) or on chapped or abraded skin.	Wash thoroughly with antimicrobial soap and water or antiseptic hand cleaner, immediately follow the *Post-Exposure Management Policy* found on the EHS webpage (see related documents).
Blood or OPIM contamination in mucus membranes.	Rinse with water for 5 minutes and immediately follow the *Post-Exposure Management Policy* found on the EHS webpage (see related documents).
Blood or OPIM contamination on workbench or floor.	Remove any glass or plastic with a mechanical device (e.g. forceps, cardboard or scoop) and discard in sharps container. Reduce the organic matter by removing or absorbing most of the sample with paper towel or cardboard. Cover the spill area with paper towels, soak the area with an appropriate EPA approved disinfectant and let sit for recommended contact time of the manufacturer. Discard all cleaning material in the biohazardous waste. Clean the area again with disinfectant and allow to air dry. **Note**: 10% bleach may not be optimal as it is inactivated by substances with high protein content.

Contact the local EHS contact or the EHS COE for more information.

5.11 Employee Training

All employees with occupational exposure risk 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 risk. 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

5.12 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 contact to demonstrate product or provide product use information for the 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/or inside a hospital).
- Product evaluations will include a wide variety of applications when possible (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
- Provide initial product evaluation
- 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 ¾ inch); the BD Vacutainer Passive Shielding Blood Collection system (22G 1inch), and the Vacuette Butterfly without Holder (21G ¾ 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.
- In March-June 2014, a Safety team comprised of EHS staff and Oregon Patient Services phlebotomists evaluated butterfly needles products at sites throughout Oregon. The medical devices included: The Greiner Bio-One Vacuette Butterfly with Holder (23G ¾ inch with 7.5"tubing); the Smith Medical Saf-T-Wing Blood Collection System (23G ¾ inch with 12" tubing), and the Greiner Bio-One Vacuette Quickshield Tube Holder with built-in shield and their Multiple Sample Blood Collection Needle (21G 1 inch). The evaluation determined that the devices evaluated were not safer to use than the BD Safety Lok and BD Eclipse straight safety needle currently in use.

- Additionally, in June 2014, members from the Needlestick Prevention Team, Corporate EHS, and Corporate Procurement met in Madison, NJ to perform a preliminary evaluation all currently available safety engineered blood collection needles. This effort was design to be a comprehensive side-by-side hands-on evaluation with picture and video documentation to identify those devices that were determined best for a broader field evaluation going forward. Using a standard scoring method the following devices scored best:
    - BD Push Button butterfly blood collection set. It is an automatic in-vein activated device.
    - Covidien Monoject Angel Wing butterfly blood collection set. It is a manual in-vein activated device. It score similarly to the Greiner Vaccuette butterfly set and the NiPro Diagnostics butterfly (which is exactly the same as the Greiner Vaccuette), but was chosen because the Greiner Vaccuette has been evaluated multiple times in recent years.
    - Sarstedt Safety MultiFly Set. This has the traditional out-of-vein activation. It is designed to be used with the S-Monovette blood tubes but the vendor does have a vacutainer tube adapter which we will investigate.
- Field evaluations took place mid-year 2015 for the BD Push Button butterfly and the Sarstedt Safety MultiFly needle. The Covidien Monoject Angel Wing butterfly was not evaluated. Scores from the field evaluations were recorded and compared to the current product (BD Safety-Lok butterfly).
  In Q4 2015 an additional field evaluation was initiated for the third generation VanishPoint butterfly device from Greiner. The results of our 2015 evaluations were reviewed with stakeholders to determine next steps.
  Additionally, the BD Vacutainer® One Use Holder (BD Catalog #364815) was redesigned in 2015 for a fresh new look with enhanced features. The new design has a ribbed exterior to enhance grip and a domed top which may assist in better needle entry.
- A close review of the 2015 field evaluations identified some inconsistencies in the evaluation process. A larger field evaluation was conducted in Q2 2016 comparing the BD Push-Button butterfly and the RTI (Greiner) VanishPoint butterfly. Results were tabulated and shared with stakeholders.
- A field evaluation took place in Q4 of 2017 in the North Region evaluating the Greiner Quickshield straight needle and the Greiner Safety Blood Collection butterfly needle. The results of our 2017 evaluations were tabulated and reviewed with stakeholders.
- For 2018 we investigated needlestick data for a business partner that uses the RTI (Greiner) VanishPoint butterfly blood collection device. Their needlestick rate with this device in 2017 and YTD 2018 were significantly higher than the Quest needlestick rate. The majority of the needlestick occurred during the collection phase of the procedure secondary to unexpected patient movement or inattention by the employee, neither of which would have been mitigated by the enhanced shielding technology offered by the 3rd generation needle.

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, the EHS COE or Corporate Patient Services.

5.13 Recordkeeping

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

The EHS contact, HRSC and/or EHS COE 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, HRSC and/or EHS COE representative.

B. Training Records
Training records are completed for each employee upon completion of training. The local EHS contact, department manager or EHS COE 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, (not applicable for computer-based learning)
- 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. Training records are available in the Learning Management System and can be accessed by the employee's supervisor, local EHS contact or EHS COE 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.

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 Safety Procedures are available here.

- Quest Diagnostics *Bloodborne Pathogens Exposure Control Plan* (QDEHS701)
- Adventist HealthCare, Inc. *Bloodborne Pathogens Exposure Control Plan* (AHC CP 98.0)
- New Employee Orientation and On-Boarding Process, Laboratory policy
- Biohazardous Waste Management, Safety SOP
- Incident Reporting and Post Exposure Prophylaxis, Safety SOP

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	Reason for Revision	Revised By	Approved By
		Supersedes SGAHQDEHS701v15.1		

10. ADDENDA

Addendum	Title
A	Blood Collection Set Evaluation Form

11. APPENDICES

Appendix 1 Job classifications (5.1)
Appendix 2 Engineering Controls (5.2.C)
Appendix 3 Biohazard Waste Management (5.4)
Appendix 4 Latex Management (5.2D)

Addendum A

BLOOD COLLECTION SET EVALUATION FORM

Needle Evaluation Form				
Evaluator:				
Date of Evaluation:				
Site Code:				
Supervisor:				
DEVICE NAME:				
MANUFACTURER:				
NUMBER OF TIMES USED:				
	YES	**NO**	**N/A**	**COMMENTS**
Training: have you received specific training on the device you are evaluating?				
Packaging: is it easy to unpack the needle and components?				
Assembly: is it easy to assemble the needle and tube holder prior to use?				
Butterfly needle assemblies: is the tubing coil relaxed and easy to control?				
Holding device: is the device a size that is comfortable and secure to hold?				
Use: can the draw be completed safely without interference from the safety shield?				
Use: can this device be easily operated by a left-handed person and a right-handed person?				
Use: can the device be used in a wide variety of situations - patient sitting/lying down, geriatric, pediatric, large or small				
Positioning the needle for the draw: Is it easy to position the needle (for entry into the vein) with the needle bevel up, without having to adjust the position of the safety shield?				
Flash: does the device provide a visible flash during insertion?				
Filling speed: did the tubes fill as designed?				
Safety activation: did your hands remain behind the needle until activation of the safety mechanism was complete?				
One hand activation of shield: can the safety shield be *easily* activated with one hand?				
Splatter potential: can the activation of the shield be accomplished without the risk of sprays, leakage and/or drips?				
Confirmation of needle protection: is there an unmistakable indicator, visually and/or audibly, that the needle shield has been engaged?				
Reliable: did the safety feature operate reliably with every draw?				
Potential for misuse: does the design of the safety feature prevent it from being disabled or removed prior to the draw?				
Disposal: is it easy to put the device into the sharps container?				
Training: is the device easy to use, and require little training?				
Overall: is this device acceptable for use?				

APPENDIX 1

Job Classifications for

Laboratories at Germantown Emergency Center, Shady Grove Medical Center and Washington Adventist Hospital

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
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 infections materials as part of normal job function.

APPENDIX 2

Engineering Controls

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

APPENDIX 3

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 Medical Center 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 Medical Center Safety Manual.

APPENDIX 4

Latex Management (5.2D)

The laboratory's latex program is designed to protect personnel from allergic reactions due to job-related exposures to natural rubber latex. Latex gloves are no longer available at Quest Diagnostics.

1. The latex program applies to all staff required to wear gloves or who may be exposed to latex protein at the job site.
2. Managers and Supervisors are responsible for supplying gloves according to this policy, and providing education and training materials regarding latex allergies.
3. Employees must participate in education and training regarding latex allergies, and report any occurrence of hypersensitivity to the Supervisor, Manager and Environmental Health and Safety Officer.
4. Latex products are manufactured from a milky fluid derived from the rubber tree. Several chemicals are added to this fluid during the processing and manufacturing of commercial latex.
5. Latex allergy – is a reaction to certain proteins in latex rubber. There may be over 200 latex proteins that may be potential allergens. The latex proteins may also enter the human system by attaching to the powder in powdered gloves.
6. The cornstarch powder is an effective allergen carrier. The cornstarch may promote both the contact (donning of gloves) and airborne inhalation (removal of powdered gloves) of latex proteins. The amount of latex exposure needed to produce sensitization or an allergic reaction is unknown. Increasing the exposure to latex proteins increases the risk of developing allergic symptoms. In sensitized persons, symptoms usually begin within minutes of exposure; however, they may occur hours later and vary in intensity.
7. The risk factors that may promote latex sensitization are:
    - Repeated exposure to latex
    - Allergies to the banana, tomato, potato, avocado, chestnut, papaya and kiwi fruit
    - Pre-existing contact dermatitis
    - Pre-existing allergies
    - Persons who have undergone multiple surgical procedures.
8. All employees must utilize preventive strategies and learn to recognize the symptoms associated with latex reactions. The employee will inform a supervisor and the facility EHS Manager if symptoms develop. Medical consultation is available. The employee will avoid contact with latex gloves and other latex containing products.
9. Products that contain latex may include bandages, bed protectors, computer mouse pads, envelope and stamp glue, IV tubing, oxygen cannulas, pencil erasers, rubber bands, stethoscope tubing, and tourniquets. Inform your supervisor and facility EHS Manager if you have a confirmed latex allergy and wear a medical alert tag or bracelet with this information.
10. Wash hands frequently.
11. Avoid oil-based hand creams or lotions, unless prescribed by a physician, as this may result in glove deterioration.
12. Gloves constructed of other materials such as vinyl, nitrile and neoprene for powdered of non-latex powdered latex gloves are to be used.