Form: 1000A

SOP Title:	Bloodborne Pathogens Exposure Control Plan
Number:	2006
Version Number	0
Adoption Date:	02/28/2017
Author:	Howard L. Martin, MD
Applicable Department(s):	Laboratory
Replaces Document, of Date:	Portions of 0000
Retired Date:	N/A

Effective Date:

*The effective date is the date training of relevant personnel is completed.

Version Tracking*

Version Number:	N/A
Adoption Date:	N/A
Effective Date:	N/A
Author:	N/A

Sections of Protocol Affected: N/A

*Applies if this is a revision leading to a new version.

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Purpose:

The purpose of this policy is to inform all employees that they are at the risk of infection and subsequent illness as a consequence of exposure to human blood or other potentially infectious body fluids, but this plan minimizes exposure and risk of disease transmission. A copy of the plan is made available to all employees.

Background:

The Exposure Control Plan (ECP) has been developed to minimize employees' exposure to Bloodborne pathogens, such as Hepatitis B Virus (HBV) and Human Immunodeficiency Virus (HIV). The principle for establishing the ECP is for the implementation of procedures which relate to the control of bloodborne infectious diseases. The ECP is in compliance with the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Standard (29CFR 1910.1030) and serves as both the written program, for compliance purposes and as a training document.

Scope:

Applies to all employees of Sagis.

Definitions:

1. Blood: means human blood, human blood components, and products made from human blood.
2. Bloodborne Pathogens: means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include but are not limited to, hepatitis B virus (HBV), and Human Immunodeficiency Virus (HIV).
3. Clinical Laboratory: means a workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious materials.
4. Contaminated: means the presence or the reasonably anticipated presence of blood or potentially infectious materials or may contain sharps
5. Contaminated Laundry: means laundry which has been soiled with blood or other potentially infectious materials or may contain sharps
6. Contaminated Sharps: means any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires.
7 Decontamination: means the use of physical or chemical means to remove, inactivate, or destroy Bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface of the item is rendered safe for handling, use or, disposal.

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8. Director: means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designated representative.

9. Engineering Controls: means controls (e.g., sharps disposal containers, self-sheathing needles, safer medical devices, such as sharps with engineered sharps injury protections and needleless systems) that isolate or remove the Bloodborne pathogens hazard form the workplace.

10.Exposure Incident; means a specific eye, mouth or other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that result from the performance of an employee's duties.

11. Hand washing facilities: means a facility providing an adequate supply of running potable water, soap, and single-use towels or air-drying machines.

12. Licensed Healthcare Professional: is a person whose legally permitted scope of practice allows him or her t independently perform the activities required by paragraph (f) Hepatitis B Vaccination and Post-Exposure evaluation and Follow Up.

13. HBV: means hepatitis B Virus

14: HIV: means Human Immunodeficiency Virus

15. Needleless System: means a device that does not use needles for

(a) the collection of bodily fluids or withdrawal of bodily fluids after initial venous or arterial access is established;

(b) the administration of medication or fluids; or

(c) Any procedure involving the potential for occupational exposure to Bloodborne pathogens due to percutaneous injuries from contaminated sharps.

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

17. Other Potentially Infectious Materials: means –

(a) The following 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;

(b) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and

(c) HIV-containing cell or tissue cultures, organ cultures, and HIV-or HBV-containing culture medium or other solutions; and blood, organs, and other tissues from experimental animals infected with HIV or HBV.

18. Parenteral: means piercing mucous membranes or the skin barrier through such events as needle sticks, human bites, cuts, and abrasions.

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19. Personal Protective Equipment: is specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts, blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment.
20. Production Facility: means a facility engaged in industrial-scale, large volume, or high concentration, production of HIV or HBV
21. Regulated Waste: means liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials
22. Research Laboratory: means a laboratory producing or using research-laboratory-scale amounts of HIV or HBV. Research laboratories may produce high concentrations of HIV or HBV but not in volume found in production facilities.
23 Sharps with engineered sharps injury protection: means a no needle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident
24. Source Individual: means any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee. Examples include, but are not limited to, hospital and clinic patients; clients in institutions for the developmentally disabled; trauma victims; clients of drug and alcohol treatment facilities; residents of hospices and nursing homes; human remains; and individuals who donate or sell blood or blood components.
25. Sterilize: means the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores
26. Universal Precautions: is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain body fluids are treated as if known to be infectious for HIV, HBV, and other Bloodborne Pathogens.
27. Work Place Controls: means controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique)

Responsibilities:

It is the responsibility of the Quality Management Committee, Supervisors and Managers to ensure compliance.

Safety:

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Personal Protective Equipment and Clothing:
Personal protective equipment and clothing may act as a barrier to help minimize the risk of exposure to aerosols, splashes, and accidental, inoculation. The clothing and equipment selected is dependent on the nature of the work performed. Protective clothing should be worn when working in the laboratory. Before leaving the laboratory, protective clothing should be removed.

Specimen Requirements:
N/A

Materials and Equipment:
Personal protective equipment also known as PPE defined as the following:

1. Laboratory coats, gowns, coveralls, and aprons
2. Goggles, safety spectacles, and face shields.
3. Respirators where applicable
4. Gloves

Reagents:
N/A

Controls and Calibrations:
N/A

Validation:
N/A

Procedure:

1) To minimize exposure to blood borne pathogens, four prevention strategies are used:
   a) Universal precautions: employees shall observe universal precautions when working with blood or other potential infectious materials (OPIM) to prevent contact with such materials. The concept of universal precautions is to treat all human fluids and tissues as if it were known to be infectious for blood borne pathogens such as HIV, HBV among others.
   b) Work practice controls:
      i) Never mouth pipette. Use mechanical devices only. Refer to SOP 2008 prohibition of mouth pipetting.

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ii) Never eat, drink, take medications, apply cosmetics/lip balm, or handle contact lenses in the laboratory. Refer to SOP 2009 Prohibition of eating/drinking in the laboratory.

iii) Food or beverages storage is prohibited in lab refrigerators, freezers, shelves, cabinets, countertops, benchtops in the laboratory.

iv) Use the aseptic technique. Hand washing facilities are provided. Thorough hand washing is essential after handling tissue, body fluids, or cells and before exiting the laboratory. Wash hands after removing gloves.

v) The laboratory is equipped with eyewash stations and an emergency shower. Employees that come in contact with a potential infectious material should wash skin with soap and water or flush mucous membrane (eyes, nose, mouth) immediately after exposure.

vi) Appropriate PPE is provided and ready accessible such as gloves, laboratory coats, and eye protection.

vii) Remove laboratory coats and gloves when leaving the laboratory area. Replace PPE when It becomes ineffective or contaminated.

viii) Use precaution when handling sharps or glassware. Never attempt to re-cap a needle. Refer to SOP 2010 2010 Prohibition of Manual Manipulation of Needles. Never re-use a disposable sharp

ix) Contaminated sharps shall not be stored in a manner that requires reach by hand into containers where the sharps are placed. Contaminated sharps shall not be picked up directly with the hands. Mechanical means such as forceps, or a brush and a dust pan should be used.

x) Sharp containers should be easily accessible and located close to where the sharps are used. Do not overfill sharp containers. Sharp containers should not be opened or emptied. Sharp containers contents should not be accessed.

xi) Never leave potentially infectious material open to the environment outside biosafety cabinets.

xii) Access to the laboratory is limited to authorized personnel only

xiii) A hazard warning sign should be posted on all access doors to the lab.

xiv) Use the most suitable disinfectant for decontaminating work surfaces and Equipment. Understand the laboratory plan for managing spills. Refer to SOP 2011 spill handling.

xv) Clean up the laboratory areas thoroughly with disinfectant after handling pathogenic materials and at the end of every work shift.

xvi) Methods of cleaning shall be effective and appropriate for the location within the facility, type of surface and equipment, type of contamination and tasks and procedures performed in the area.

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xvii) Remove and replace protective coverings, such as absorbent paper, when they become contaminated or at the end of the work shift.

xviii) Personnel working in the laboratory shall be advice of potential hazards, read and acknowledge procedures and protocols.

xix) Report all spills ad accidents that resulted in an exposure incident. Refer to SOP 2013 General Standards of Laboratory Safety Practice.

xx) For exposure incidents procedure refer to SOP 2013 General Standards of Laboratory Safety Practice

xxi) Handling, storage, treatment and disposal of all regulated waste must be in accordance with the health and safety code of the united states. For Waste handling and disposal procedures refer to SOP 2014

c) Engineering controls:

i) Engineering controls refers to controls that isolate or remove the hazard from the work place, thereby reducing the potential for employee exposure.

ii) Protector work stations and biosafety cabinets are used to provide containment of infectious splashes and aerosols. The work stations are Equipped with an exhaust system that take air from the work station and directed outside the laboratory.

d) PPE:All employees working with biohazards are provided with gloves, lab coats and safety glasses. Refer to SOP 2007 PPE.

Equipment	**Hazard Corrected**	**Safety Features**
Laboratory Coats, gowns, coveralls	Contamination of clothing	• Cover Street Clothing
Plastic Aprons	Contamination of Clothing	• Waterproof
Goggles	Impact and Splash	• Splash
Safety Goggles	Impact and Splash	• Impact-resistant lenses (must optically correct or worn over

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		corrective eye glasses) • Side shields
Safety Glasses	Impact	• Impact-resistant lenses (must be optically correct) • Side shields
Face Shields	Impact and Splash	• Shield entire face • Easily removable in case of an accident
Respirators	Inhalation of aerosols	• Designs include single use disposable; full face or hooded powered air purifying (PAPR); and supplied air respirators
Gloves	Direct contact with microorganisms	• Disposable microbiologically approved latex, vinyl, or nitrile • Hand protection

2) Employees who have been identified as having occupational exposure to blood or other OPIM will be offered the Hepatitis B vaccine series. Refer to SOP 2012 Hepatitis B vaccination.
3) The safety officer shall ensure biohazard signs are posted at entrances to work areas in with blood or OPIM work is taking place.

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4) All employees should receive blood borne pathogens training either online or classroom. Documentation of training should be file with the personnel files.

Forms:
N/A

Quality Management:
Review of the Exposure Control Plan will be maintained under SOP 2006.

Reference Intervals Defined:
N/A

Interpretation of Results:
N/A

Reporting:
N/A

Limitations of procedure/results:
N/A

Troubleshooting:
N/A

Manufacturer:
N/A

Service:
N/A

Maintenance:
N/A

References:
US Dept of Labor: Occupational Safety & Health Administration. Regulations – Standards 29 CFR, retrieved from http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARD&p_id=10051

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World Health Organization (2004). Laboratory Biosafety Manual (3rd. edition). Retrieved from http://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf

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Signature for original Adoption:

Signature of Laboratory Director: _____ Date: 3/28/17

Print name: Hal Mnks. MD.

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Signature for Adoption of Revision(s) if Applicable

Revision number: [Revision number]

Signature of Laboratory Director or by Technical Supervisor if appropriate:

_____ Date: _____

Print name:

Revision number: [Revision number]

Signature of Laboratory Director or by Technical Supervisor if appropriate:

_____ Date: _____

Print name:

Revision number: [Revision number]

Signature of Laboratory Director or by Technical Supervisor if appropriate:

_____ Date: _____

Print name:

Revision number: [Revision number]

Signature of Laboratory Director or by Technical Supervisor if appropriate:

_____ Date: _____

Print name:

Revision number: [Revision number]

Signature of Laboratory Director or by Technical Supervisor if appropriate:

_____ Date: _____

Print name:

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Signatures for/indicating Periodic Review

Signature of Laboratory Director or Technical Supervisor:

_____ Date: _____

Print name:

Signature of Laboratory Director or Technical Supervisor:

_____ Date: _____

Print name:

Signature of Laboratory Director or Technical Supervisor:

_____ Date: _____

Print name:

Signature of Laboratory Director or Technical Supervisor:

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_____ Date: _____

Print name:

Signature of Laboratory Director or Technical Supervisor:

_____ Date: _____

Print name:

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Single Subject Training Acknowledgement Form

Form 1001B

Sagis® Patient-Focused Diagnostics

Training Subject:	2006 Bloodborne Pathogens Exposure Control Plan

Name of Trainer	Signature	Date
Howard L. Martin, MD		2/28/17

Trainer Acknowledgement: My signature above acknowledges that I have appropriately trained all relevant personnel on the above subject and/or SOP.

Trainee Acknowledgement: My signature below acknowledges that I understand and will compy with the above subject and/or SOP.

Trainee Name Printed	Signature	Date

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Document Control

Form 1000B

*Record for New or Revised Documents

1) Document Title and Number: 2006 Bloodborne Pathogens Exposure Control Plan

2) New Document or Revised Document

3) Original Adoption Date or N/A: N/A

4) Previous Revision Date or N/A: N/A

5) Current Revision Date or N/A: N/A

6) If this is a revision, reason for revision:
N/A

7) If this is a new document replacing any other documents, please list those documents:
N/A

8) List all existing hard copy locations of any previous document to be replaced by the current revision:
N/A

9) List all Departments and/or Supervisors that require training on the new or revised document: All

Signature of Laboratory Director:

_____ Date: 2/28/17

Print name: Howard L. Martin, MD

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