# 01.02 – Blood Borne Pathogens (BBP) - Occupational Post-Exposure Prophylaxis

Purpose

The purpose of this document is to establish UTMB policy for the initiation of prophylaxis after occupational exposure to the human immunodeficiency virus (HIV) and hepatitis B virus (HBV) and early treatment of infection with the hepatitis C virus (at time of seroconversion) to prevent chronic infection. This policy has been developed from the most current medical literature, clinical experience at UTMB, the September, 2013 recommendations from the US Public Health Service Guideline (1) and the CDC December 20, 2013 document on prevention of Hepatitis B infection in Health-Care Personnel (2). This prophylaxis protocol and regimen will be continuously updated with the most recent medical information.

Audience

All employees of UTMB hospitals, clinics, outpatient surgical center, contract workers, volunteers, and students.

Definitions

- Occupational exposures requiring the initiation of prophylaxis are defined as:
  - Percutaneous injury (e.g. needlestick, laceration with a sharp object)
  - Contact of mucous membranes or ocular membranes
  - Contact of non-intact skin (e.g. skin that is chapped, abraded)

    with

    Blood or other potentially infectious fluid (semen; vaginal secretions; and cerebrospinal, synovial, pleural, peritoneal, pericardial and amniotic fluids; bloody body fluids and unfixed tissue).

- Occupational exposures requiring monitoring include the three above requiring prophylaxis and:
  - Contact with intact skin that is prolonged or involves an extensive area

    with

    Blood or other potentially infectious fluid (semen; vaginal secretions; and cerebrospinal, synovial, pleural, peritoneal, pericardial and amniotic fluids; bloody body fluids and unfixed tissue).

Occupational Exposure Monitoring

All UTMB employees and students with a documented occupational exposure shall have the exposure evaluated and documented by a healthcare provider following the standard protocol.

- At the Employee Health/Student Health, the healthcare provider will recommend prophylaxis for percutaneous exposures, contact of mucous membranes or non-intact skin.

  with

- Blood or other potentially infectious fluid (semen; vaginal secretions; and cerebrospinal, synovial, pleural, peritoneal, pericardial and amniotic fluids; bloody body fluids and unfixed tissue).
- Healthcare providers in the Emergency Department or in outlying clinics will recommend initial prophylaxis and refer exposed persons to the Employee Health Center/Student Health Services at UTMB on the next business day for follow up.

Prophylaxis

Prophylaxis shall be recommended to all UTMB employees or students:

- HIV:
  - For percutaneous exposures, contact of mucous membranes or non-intact skin.

    with

  Blood or other potentially infectious fluid (semen; vaginal secretions; and cerebrospinal, synovial, pleural, peritoneal, pericardial and amniotic fluids; bloody body fluids and unfixed tissue).
  - Ideally within two hours after exposures, but may be initiated up to 72 hours after exposure.
  - With appropriate drug therapy.
  - Until the source-patient blood has been obtained and analyzed. If the source-patient HIV status is determined to be negative, prophylaxis will be discontinued.
  - HBV-Prophylaxis for HBV prevention will be evaluated on an individual basis.
  - HCV-Employees/students testing positive for Hepatitis C Qualitative RNA (PCR) at 6 weeks, 3 months or 6 months, will be referred immediately to a hepatologist for early treatment to prevent chronic hepatitis C infection.

# EMPLOYEE/STUDENT CHECKLIST

❒ Wash exposed area immediately.

❒ Notify Supervisor immediately (supervisor to assist with obtaining source consent & lab work).

❒ Have supervisor document in source's medical record "source of occupational exposure" and that labs were drawn for HIV, HCV, and HBsAg (Hepatitis B surface antigen) with source's consent.

❒ Seek post-exposure care:

| *for employees on campus report to* | *for students on campus report to* |
|---|---|
| Week Days<br>Employee Health (7:30 AM-4:30 PM)<br>(409) 747-9172 | Week Days<br>Student Health (8AM-5PM)<br>(409) 747-9508 |

❒ Report to Emergency Department, after hours, weekends, or holidays (**Follow-up in Employee Health/Student Health the next business day).**

**Employee/student should report to Employee Health/Student Health or Emergency Department as soon as possible, but at least within 2 hours of exposure.**

❒ Off-site Exposures - Follow clinic specific policy.
Obtain packet from supervisor or visit website (see below) ‡ for required forms, procedures, and information.

❒ Complete "Blood Borne Pathogen (BBP) Exposure Notification Form" [In packet & available at Employee Health].

- Off-site – Complete form and fax to Employee Health/Student Health.
- On-campus – Report to Employee Health/Student Health (form will be completed there).
- If seen in the Emergency Department, form should be completed there and faxed
- to Employee Health/Student Health.

| Employee Health | Student Health |
|---|---|
| Fax (409) 747-9182 | Fax (409) 747-9330 |

*****You must report the exposure and have HIV lab testing done within ten (10) days to receive maximum benefits if a Worker's Comp claim were to be filed in the future.**

❒ Follow up with Employee Health/Student Health.

❒ ‡***For questions, visit:*** ***www.utmb.edu/policy/hcepidem/search/01-02.pdf***

# SUPERVISOR/FACULTY CHECKLIST

❒ Refer employee/student for post exposure care immediately.

| *for employees on campus report to* | *for students on campus report to* |
|---|---|
| **Employee Health**<br>**(409) 747-9172** | **Student Health**<br>**(409) 747-9508** |

Employee/student should report to Emergency Department, after hours, weekends, or holidays (**Follow-up in Employee Health/Student Health the next business day).**

**Employee/student should report to Employee Health/Student Health or Emergency Department as soon as possible, but at least within 2 hours of exposure.**

❒ Assist employee/student with obtaining source consent and source lab work.

❒ Document in source's medical record "source of occupational exposure" and that labs were drawn for HIV, HCV, and HBsAg with source's consent.

❒ Remind employee/student to report exposure by completing "BBP Exposure Notification Form".

- Off-site – Complete form and fax to Employee Health/Student Health.

| Employee Health | Student Health |
|---|---|
| Fax (409) 747-9182 | Fax (409) 747-9330 |

- On-campus – Report to Employee Health/Student Health (form will be completed there).
- If seen in the Emergency Department, form should be completed there and faxed to

Employee Health/Student Health.

| Employee Health | Student Health |
|---|---|
| Fax (409) 747-9182 | Fax (409) 747-9330 |

❒ For questions call Employee Health Center at (409)747-9172 or Student Health at (409)747-9508; after hours call the Access Center at 1-800-917-8906.

***For questions, visit www.utmb.edu/policy/hcepidem/search/01-02.pdf***

# PROVIDER CHECKLIST

❒ Provide necessary medical care to treat the injury/exposure.

❒ Refer to the BBP Flow Chart and Procedures [Enclosed] as a guide for post-exposure. care

❒ Use Laboratory testing forms [enclosed] as a reference.

❒ Use UTMB Occupational Exposure prescription to prescribe only enough medication until follow-up appointment or source results available.

❒ Complete the BBP Exposure Notification Form [enclosed] and fax to Employee Health/Student Health.

- Employee Health – FAX # (409) 747-9182
- Student Health – FAX # (409) 747-9330

❒ Provide patient education information [enclosed].

❒ Complete Informed Consent for Prophylaxis form [enclosed].

❒ Billing may be submitted to:

UTMB, Employee Health
c/o Director of Employee Health
301 University Boulevard, Route 0159
Galveston, TX 77555-0159

❒ Billing instructions for Students' Off Campus Exposures

- Student's Insurance should be billed
- The balance after insurance is billed, should be brought to Student Health by the student or the student should contact Student Health at 409-747-9508.

***Reimbursement will be for reasonable & customary charges for authorized or medically necessary tests as noted in enclosed information. Any additional charges will not be reimbursed.***

# *POST-EXPOSURE PROCEDURE*

I. MANAGE THE EXPOSURE

A. Wash the area immediately with soap and water.

B. For exposure to eyes, mouth, and/or nose flush area with water.

II. NOTIFY SUPERVISOR/FACULTY IMMEDIATELY

A. Supervisors will assist in obtaining source consent and lab work.

**B. Supervisors & faculty shall release the employee or student from their duties immediately to seek post-exposure care.**

III. PROCEDURE FOR SOURCE TESTING

A. Obtain source consent & lab specimen.

B. Use Physician Order Entry (POE) for HIV consent for alert and oriented patients.

C. General consent for comatose/general anesthesia patients will suffice but needs to be documented on Lab Requisition (form MM 68693).

D. Refusals should be documented on Lab Requisition (form MM 68693). Notify UTMB Legal 24 hours/day. The Legal Department will make the decision on how source blood will be obtained. (Contact Legal by calling the hospital operator).

E. Complete Lab Requisition (form MM 68693).

- Employees who are off campus can contact employee health and they will fax a completed lab slip to put in the bag with the specimens.

F. Assure consent status is documented on form.

G. Obtain one (1) serum separator tube.

H. Label tube

I. Document exposure in source's medical record & that labs were drawn for "source of occupational exposure".

J. Send blood to Laboratory Medicine, Sample Management, Rm. 5.136, McCullough Building.

K. Laboratory results for personnel/students will be sent to Employee Health/Student Health for follow-up. Source laboratory results will be placed in the source's medical record when consent is granted, or when general consent is invoked. If source refuses testing, results will be sent to Employee Health/Student Health.

IV. EMPLOYEE/STUDENT POST EXPOSURE CARE

A. Monday through Friday 7:30 AM to 4:30 PM go immediately to the Employee Health Center. Students are seen in Student Health 8AM to 5PM.

B. Holidays, weekends, or after hours – Go to the Emergency Department immediately.

1. Triage to ensure initiation of prophylaxis within 2 hours of exposure (percutaneous injury or contamination of mucous membranes or nonintact skin with blood, body fluids visibly contaminated with blood, unfixed tissue, semen, vaginal secretions, and cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids).
2. Obtain consent for HIV test through Physician Order Entry (POE).
3. Submit Employee/Student specimens using form MM 68693 – two serum separator tubes labeled appropriately.
   a. Order labs for exposed individual (HIV-1/HIV-2 antibody, HCV antibody and total anti-HBc). In addition, HBV surface antibody should be ordered for employees/students who have a history of HBV immunization prior to coming to UTMB.
   b. Additional laboratory tests required if Employee/Student is starting prophylaxis for HIV exposure/possible exposure – CBC (use additional lavender top tube for CBC), ALT, AST, total bilirubin, GGT, creatinine, BUN, blood glucose and CPK. Females must have a urine or serum pregnancy test.
   c. Assure consent for testing is documented.
   d. Send specimens to Sample Management, Room 5.136 McCullough.
4. Post-exposure Prophylaxis for Tetanus/Diptheria, Hepatitis B and Hepatitis C
   a. Offer tetanus/diphtheria booster following percutaneous injury if none within last 10 years. Offer Tdap vaccine for the booster.
   b. For vaccinated HCW (who have written documentation of a complete, ≥ 3-dose of Hepatitis B vaccine series) with subsequent ≥ 10 mIU/mL, testing the source patient for HBsAg is unnecessary.

      **Exposed HCW/Student has never received Hepatitis B vaccine**

   c. Offer HBV vaccine if source is known to be positive for hepatitis B or is high risk for hepatitis B or source is unknown, (e.g., needle puncture through a trash bag) and employee/student has not been vaccinated against hepatitis B.
   d. Offer Hepatitis B Immune Globulin 0.06 ml/kg IM if source is known to be positive for hepatitis B, or is high risk for hepatitis B or source is unknown, (e.g. needle puncture through a trash bag) and employee/student has not been vaccinated against hepatitis B.

**Exposed HCW/Student has received 3 doses of Hepatitis B vaccine twice and anti-HBs < 10 mIU/mL**

e. For vaccinated HCW/Student (who have written documentation of Hepatitis B vaccination) with anti-HBs < 10 mIU/mL after two complete ≥ 3-dose Hepatitis B vaccine series, the source patient should be tested for HBsAg as soon as possible after the exposure. If the source patient is HBsAg-positive or has unknown HbsAg status, HCW/Student should receive 2 doses of HBIG. The first dose should be administered as soon as possible after exposure and the second dose should be administered 1 month later. If the source patient is HBsAg-negative neither HBIG nor Hepatitis B vaccine is necessary.

**Exposed HCW/Student has received 3 doses of Hepatitis B vaccine but has not been tested for anti-HBs**

f. For vaccinated HCW/Student (who have written documentation of a complete, ≥ 3-dose Hepatitis B vaccine series) without previous anti-HBs testing, the HCW/Student should be tested for anti-HBs and the source patient (if known) should be tested for HBsAg as soon as possible after the exposure. Testing the source patient and the HCW/Student should occur simultaneously; testing the source patient should not be delayed while waiting for the HCW/Student anti-HBs test results, and likewise, testing the HCW/Student should not be delayed while waiting for the source patient HBsAg results.

**Exposed HCW/Student has < 10 mIU/mL anti-HBs and source patient positive or has unknown HBsAg status**

g. If the HCW/Student has anti-HBs < 10 mIU/mL and the source patient is HBsAg- positive or has unknown HBsAg status, the HCW/Student should receive 1 dose of HBIG and be revaccinated as soon as possible after the exposure. The HCW/Student should then receive the second 2 doses to complete the second Hepatitis B vaccine series (6 doses total when accounting for the original 3-dose series) according to the vaccination schedule. To document the HCW's/Student's vaccine response status for future exposures, anti-HBs testing should be performed 1-2 months after the last dose of vaccine.

**Exposed HCW/Student has anti-HBs < 10 mIU/mL and the source patient is HBsAg negative**

h. If the HCW/Student has anti-HBs < 10 mIU/mL and the source patient is HBsAg-negative, the HCW/Student should receive an additional Hepatitis

B vaccine dose, followed by repeat anti-HBs testing 1-2 months later. HCWs/Students whose anti-HBs remains < 10 mIU/mL should undergo revaccination with 2 more doses (6 doses total when accounting for the original 3-dose series). To document the HCW's/Student's vaccine response status for future exposures, anti-HBs testing should be performed 1-2 months after the last dose of vaccine.

**Exposed HCW/Student has anti-HBs ≥ 10 mIU/mL at time of exposure**

i. If the HCW/Student has anti-HBs ≥ 10 mIU/mL at the time of exposure, no postexposure HBV management is necessary, regardless of the source patient's HBsAg status.

**Exposed HCW/Student unvaccinated or incompletely vaccinated (including those who refused vaccination)**

j. For unvaccinated or incompletely vaccinated HCW/Student (including those who refused vaccination), the source patient should be tested for HBsAg as soon as possible after the exposure. Testing unvaccinated or incompletely vaccinated HCW/Student for anti-HBs is not necessary and is potentially misleading, because anti-HBs ≥ 10 mIU/mL as a correlate of vaccine-induced protection has only been determined for persons who have completed an approved vaccination series.
k. If the source patient is HBsAg-positive or has unknown HBsAg status, the HCW/Student should receive one dose of HBIG and one dose of Hepatitis B vaccine administered as soon as possible after the exposure. The HCW/Student should complete the Hepatitis B vaccine series according to the vaccination schedule. To document the HCW's/Student's vaccine response status for future exposures, anti-HBs testing should be performed approximately 1-2 months after the last dose of vaccine. Because anti-HBs testing of HCW/Student who received HBIG should be performed after anti-HBs from HBIG is no longer detectable (6 months after administration), it will likely be necessary to defer anti-HBs testing for a period longer than 1-2 months after the last vaccine dose.
l. Employees/Students testing positive for Hepatitis C Qualitative RNA (PCR) at 6 weeks, 3 months or 6 months, will be referred immediately to a hepatologist for treatment.
m. Recommend HIV prophylaxis following percutaneous injury or contamination of mucous membranes or nonintact skin with blood, body fluids visibly contaminated with blood, unfixed tissue, semen, vaginal secretions, and cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids (**goal is to begin prophylaxis within 2 hours of exposure**).
**n.** Prophylaxis medications – write "***UTMB Occupational Exposure***" on prescription

1) Dolutegravir 50 mg tablet (Tivicay) One tablet by mouth with or without food once daily for 4 weeks.
2) Emtricitabine/tenofovir 200mg/300mg tablet (Truvada),One tablet by mouth with or without food once daily for 4 weeks.
3) If the employee/student is on sucralfate, buffered medications (e.g., buffered aspirin), calcium, magnesium, or iron supplements, dolutegravir should be taken 2 hours before or 6 hours after any of these agents. Close monitoring is recommended when starting or stopping dolutegravir and metformin together. A dose adjustment of metformin may be necessary. If the employee/student is on dofetilide, **do not give** dolutegravir. If dolutegravir cannot be given, prescribe the regimen in o. below. This regimen will also be effective prophylaxis for persons who are not pregnant.
4) Provide with 72-96 hour supply of medication.
5) Assure Consent for Post-Exposure Prophylaxis is completed.

o. Employee/Student is Pregnant – For pregnant women, prophylaxis should be reserved for those with HIGH RISK exposures, and tenofovir (Viread) should not be used. In this case, an alternate regimen should be used:
1) Lopinavir/ritonavir 200/50mg tablet (Kaletra) Two tablets by mouth with or without food every 12 hours for 4 weeks.*
2) Zidovudine/lamivudine 300mg/150mg tablet (Combivir) One tablet by mouth with or without food every 12 hours for 4 weeks.
3) Provide with 72 – 96 hour supply of medication.
4) Assure Consent for Post-Exposure Prophylaxis is completed.
5) Pregnant employees/students will be followed up by Employee Health/Student Health and will be referred to the Maternal/Child Clinic (409)772-2798.

*See Appendix A for prescription and over-the-counter drugs that should not be administered with protease inhibitors.

V. OFF-CAMPUS EXPOSURE OF UTMB EMPLOYEES/STUDENTS

A. Maternal-Child Health Clinics – refer to clinic specific policies for initial management.

B. Primary Care Outpatient Clinic – refer to clinic specific policies for initial management.

C. TDCJ – refer to TDCJ specific policies for initial management. Procedure Questions

| Employee Health (7:30 AM-4:30 PM) | Student Health (8AM-5PM) |
|---|---|
| (409) 747-9172 | (409) 747-9508 |

D. Students who are off campus and 2 hours or LESS away from UTMB

1. Notify your faculty immediately
2. Between 8am-5pm, come directly to campus and UTMB Student Health or call Student Health at 409-747-9058 for guidance. Seek treatment within 2 hours.
3. After hours, weekends, or holidays call the UTMB Access Center at 409-772-2222 or go directly to the UTMB Emergency Room for initial evaluation and then follow up with Student Health the next day. Seek treatment within 2 hours of the exposure. Follow up with Student Health the next business day. Student baseline laboratory tests to be drawn are HIV, HCV, total anti-HBc and anti-HBs.
4. Have the clinical facility order the source laboratory tests for HIV, HCV, and HBsAg. Follow the clinical facility's protocol for source laboratory tests and find out the contact person at the facility for the source laboratory test results. Have your faculty assist in this process.
5. School of Medicine student's in the Houston and Austin based programs, should follow the prearranged protocol with specific facilities.

E. Students who are off campus MORE than 2 hours away from UTMB

1. Notify your faculty immediately
2. Between 8am-5pm, call Student Health at 409-747-9508 for guidance as soon as incident occurs or follow the clinical facility's protocol for initial evaluation. Seek treatment within 2 hours of the exposure. Always follow up with Student Health. Student's insurance should be billed, if necessary, for treatment.
3. If after hours, weekends, or holidays, call the UTMB Access Center at 409-772-2222 for guidance. Follow the clinical facility's protocol for initial evaluation or go to the nearest Emergency room. Seek treatment within 2 hours of the exposure. Follow up with Student Health the next business day. Student's insurance should be billed if treatment is necessary. Student baseline laboratory tests to be drawn are HIV, HCV, total anti-HBc and anti-HBs.
4. Have the clinical facility draw and run the source laboratory tests for HIV, HCV, and HBsAg. Follow the clinical facility's protocol for source laboratory tests and find out the contact person at the facility for the source laboratory test results. Have your faculty assist in this process.

5. School of Medicine students in the Houston and Austin based programs should follow the prearranged protocol with the specific facilities for evaluation.

F. If the student's insurance is billed for an occupational exposure as in scenario E2, and a bill is received for the balance after insurance coverage, the student should contact Student Health at 409-747-9508 immediately after receiving the bill.

VI. **Any employee claiming a work-related exposure to HIV infection must provide the employer with the BBP Notification Form and document that within 10 days after the date of the exposure, the employee had a test result indicating absence of HIV, HBV, or HCV infection. (Texas Vernon's Civil Statute, Health & Safety Code Section 85.116 (c) for the purpose of qualifying for workers' compensation or any other similar benefits or compensation.**

After hours, weekends, and holidays – call the Access Center (1-800-917-8906). Employees/students with off campus exposure shall notify Employee Health/Student Health as soon as possible even when treatment was initiated elsewhere.

References:

1. Kuhar DT, Henderson DK, Struble KA, Heneine W, et al. Updated US Public Health Service Guidelines for the Management of Occupational Exposures to Human Immunodeficiency Virus and Recommendations for Postexposure Prophylaxis. Infect Control Hosp Epidemiol 2013;34:875-892.
2. Centers for Disease Control and Prevention. CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management, 2013;62(No. RR-10):1-16.
3. Jaeckel E, Cornberg M, Wedemeyer H, et al. Treatment of acute hepatitis C with interferon alfa-2b. N Engl J Med 2001; 345:1452-7.
4. Tivicay package insert. Research Triangle Park, NC: GlaxoSmithKline; 2013 Aug.
5. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. Available at:**http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf. Accessed January 29, 2008.**

## NOTIFICATION FORM

Person completing form_____Signature_____Date/Time_____

Name_____ ❒ Employee ❒ Student

Dept/School _____

Supervisor/Faculty _____

Home # _____Work # _____Pager #_____

Employee# or Student SSN _____Date of Exposure ____/_____/____Time ____am_ pm _

Location where exposure occurred *(Building, Floor, Rm)* _____

Personal Protective Equipment Used: ❒Gloves ❒Goggles/Mask/Faceshield ❒Gown ❒Other
Was a safety device being used? ❒Yes ❒No If so, did it work? ❒Yes ❒No
Type & Brand of safety device _____
Body part exposed *(circle one)* hand, eye, mouth, other *(please identify)*_____
Describe how exposure occurred. _____
_____

Type of body substance exposed to: ❒blood ❒body fluid contaminated by blood ❒semen, ❒vaginal secretions and ❒cerebrospinal, ❒synovial, ❒pleural, ❒peritoneal, ❒pericardial and ❒amniotic fluids and ❒unfixed human tissue

Type of exposure: ❒needlestick…..Depth of injury _____
(check all that apply) ❒cut…….Depth of injury _____
Fluid injected ❒Yes ❒No – Estimated volume: _____
❒Mucous membranes
❒Non-intact skin (e.g., chapped, abraded, or otherwise non-intact)

Did this exposure occur during the employee's/student's normal work activities? ❒Yes ❒No
Is patient source known? ❒Yes ❒No Was source consent obtained? ❒Yes ❒No
Source lab testing done? ❒Yes ❒No Source on antiretroviral therapy? ❒Yes ❒No
List Drugs _____
Was source blood sent to lab? ❒Yes ❒No
Source name _____ UH#_____ Location_____
Exposed employee/student lab testing done? ❒Yes ❒ No
(For Females)- Pregnancy test result_____
Was prophylaxis initiated? ❒Yes ❒No Date/Time of 1st dose ____/_____/____Time ____am_ pm __
Have you had training on Standard Precautions within the last 12 months? ❒Yes ❒No

## FAX THIS FORM TO:

## (409) 747-9182-Employees (409) 747-9330-Students

**For questions call:**

**Mon-Fri 7:30am-4:30 pm Mon-Fri 8:00am-5:00pm**
**(409) 747-9172-Employees (409) 747-9508-Students**
**Access Center 1-800-917-8906**

# BLOOD BORNE PATHOGENS EXPOSURE MANAGEMENT FORM *

**University of Texas Medical Branch – Employee Health/Student Health**

Name _____
(Last) (First) (MI)

❒Employee ❒Student Employee Dept._____ Position_____

Phone: _____ _____ _____
(Home) (Pager) (Work)

Date of Exposure _____ Time of Exposure _____ am/pm

Initial Care of Injury/Exposure

Site_____

_____

Date of Evaluation (Initial) _____ Time of Evaluation (Initial) _____ am/pm

❒ Completed BBP Notification Form attached.

**SOURCE INFORMATION AT TIME OF INCIDENT** ❒Known Source ❒Unknown Source

Name _____UH#_____

Account # _____Location _____

**SOURCE LAB RESULTS**

| | Date Drawn | Results |
|---|---|---|
| HIV | | |
| HBsAg (Hep B surface antigen) | | |
| HCV | | |

## HEPATITIS AND TETANUS

Hepatitis B Vaccine [ 0 ] [ 1 ] [ 2 ] [ 3 ]
Date Last Dose: _____
Antibody Response: ❒ anti-HBs ≥10 mIU/mL ❒ anti-HBs <10 mIU/mL ❒ Unknown
Hepatitis B Vaccine Given: ❒ Yes ❒ No Date Given: _____
Immunoprophylaxis: HBIG ❒ Yes ❒ No Date Given: _____
Tetanus/Diptheria Booster (Tdap†): Date of Last Dose: _____
Booster Given: ❒ Yes ❒ No Date Given: _____

* See Appendix B for flow diagram on exposure management.
† If patient refuses Tdap, offer Td.

## HIV EXPOSURE
### INITIAL VISIT

BP_____ P_____ R_____ T_____ WT_____ HT_____
Medication(s) _____ Drug Allergy(s) _____
_____
_____

Clinical Findings:

_____

_____

_____

_____

_____

**EMPLOYEE/STUDENT BASELINE LAB**

Consent for HIV Testing ❒Yes
❒No

Date _____

## EMPLOYEE/STUDENT RESULTS

| | Date Drawn | Results |
|---|---|---|
| HIV1/HIV2 | | |
| anti-HBs* (Hep B surface antibody) | | ❒anti-HBs ≥ 10mIU/mL<br>❒anti-HBs < 10mIU/mL |
| Total anti-HBc | | |
| HCV antibody | | |

*For employees/students who have never received vaccine or who have a history of HBV immunization prior to coming to UTMB, an HBsAg (Hepatitis B surface antigen) test should be done.

| **Prophylaxis Baseline Labs:** | **RESULTS** |
|---|---|
| CBC | |
| Total bilirubin, ALT, AST, GGT | |
| Pregnancy Test (urine or serum) | |
| Creatinine, BUN | |
| Blood glucose | |
| CPK | |

Employee/Student (Circle one)
Results
Reported ___/___/___ Via _____ By_____

**CHECK FOLLOW-UP NEEDED:**

- ❒ **2 Weeks** (If on prophylaxis)
- ❒ **4 Weeks** (If on prophylaxis)
- ❒ **6 Weeks** (HIV+source. HCV+source)
- ❒ **3 Months** (HIV+source. HCV+source. Unknown source)
- ❒ **6 Months** (HIV+source. HCV+source. Unknown source).
- ❒ **12 Months** (HIV+source)

**FOLLOW-UP DIRECTIONS:**

HIV+source = HIV drawn
HCV+source = **HCV Qual-RNA (PCR)** drawn
HIV/HCV (-) = HIV drawn
Unknown source = HIV and HCV drawn

**2 WEEK FOLLOW-UP ___/___/___ RESULTS**

If placed on prophylaxis:

| | |
|---|---|
| CBC | |
| Total bilirubin, ALT, AST, GGT | |
| Pregnancy Test (urine or serum) | |
| Creatinine, BUN | |
| Blood glucose | |
| CPK | |

Results Reported __/__/__ Via ____ By _____

**4 WEEK FOLLOW-UP __/__/__ RESULTS**

If placed on prophylaxis:

| | |
|---|---|
| CBC | |
| Total bilirubin, ALT, AST, GGT | |
| Creatinine, BUN | |
| Blood glucose | |
| CPK | |

Results Reported __/__/__ Via ____ By _____

**6 WEEK FOLLOW- UP ___/___/___ RESULTS**

| | |
|---|---|
| HIV, CBC | |
| Total bilirubin, ALT, AST, GGT<br>Creatinine, BUN, blood glucose | |
| HCV Qual RNA (PCR) (only if source blood Hep C+) | |
| CPK | |

Results Reported __/__/__ Via ____ By _____

**3 MONTH FOLLOW-UP __/__/__ RESULTS**

| | |
|---|---|
| HIV | |
| HCV Qual RNA (PCR)<br>(only if source blood Hep C+) | |

Results Reported __/__/__ Via _____ By_____

**6 MONTH FOLLOW-UP __/__/__ RESULTS**

| | |
|---|---|
| HIV | |
| HCV Qual RNA (PCR)<br>(only if source blood Hep C+)<br>HBsAg<br>Total anti-HBc | |

Results Reported ___/___/___ Via _____ By _____

**12 MONTH FOLLOW UP __/___/___RESULTS**

| | |
|---|---|
| HIV | |

Results Reported ___/___/___ Via _____ By_____

**ASSESSMENT/RECOMMENDATIONS:**

Warnings discussed to avoid pregnancy and/or breast feeding during treatment (females) ❒Yes ❒No

Employee Assistance Program/Counseling ❒ Referral Made ❒ Declined

Post-Exposure Treatment: ❒ Recommended ❒ Not Recommended

Informed Consent: ❒ Obtained ❒ Refused

Post-Exposure Prophylaxis: ❒ Declined ❒ Provided

Date/Time of 1st dose ____/____/____-_____AM/PM

Printed Materials Provided: ❒ Yes ❒ No

Comments: _____

_____

_____

Nurse :_____Date:_____

Healthcare Provider: _____Date:_____

Provider Information: Name: _____

Clinic: _____

Address:_____

_____

Phone: _____

After follow-up is completed, provider is to forward to:

| *for employees* | *for students* |
|---|---|
| Employee Health | Student Health |
| Primary Care Pavilion | Rebecca Sealy Hospital |
| 400 Harborside Drive | 301 University Boulevard |
| Route 1161 | Route 0169 |
| FAX (409) 747-9182 | FAX (409) 747-9330 |

For questions call: Employees (409) 747-9172 Students (409) 747-9508
Access Center (800) 917-8906

**Situations for which Infectious Diseases Consultation for Human Immunodeficiency Virus (HIV) postexposure prophylaxis (PEP) is recommended.** ***Provision of PEP should not be delayed while awaiting expert consultation.***

- Delayed (ie, later than 72 hours) exposure report. Interval after which benefits from PEP are undefined.
- Breastfeeding in the exposed person
- If source person's virus is known or suspected to be resistant to one or more of the drugs considered for PEP, selection of drugs to which the source person's virus is unlikely to be resistant is recommended.
- Toxicity of the initial PEP regimen
  - Symptoms (eg, gastrointestinal symptoms and others) are often manageable without changing the PEP regimen by prescribing antimotility or antiemetic agents.
- Serious medical illness in the exposed person who is already taking multiple medications may increase the risk of drug toxicity and drug-drug interactions.

## Occupational Exposures to Blood Borne Pathogens
## Patient (Employee/Student) Information

Risk of HIV Infection

The average risk of HIV infection due to all types of reported percutaneous exposures to HIV-infected blood is 0.3%. A percutaneous exposure is defined as a needlestick or laceration/puncture with a sharp object.

The risk appears to be greater than 0.3% for exposure to HIV (+) patients involving deep injury, visible blood on the device causing the injury or a device previously placed in the source patient's vein or artery.

Risk of Hepatitis B or Hepatitis C Infection

The average risk of Hepatitis B virus (HBV) infection in susceptible persons after percutaneous exposure to HBV-infected blood is 6 – 30%. The risk of Hepatitis C virus (HCV) infection after percutaneous exposure to HCV-infected blood is 7.4% (95% CI 3.9%-12.5%).

Prophylaxis for Exposure to HIV (Revised September, 2013)

Prophylaxis is being offered to employees and students who have a percutaneous injury or contamination of mucous membranes or nonintact skin exposure to HIV during the performance of their duties. Prophylaxis in these circumstances is voluntary. The FDA has not approved antiretroviral therapy for post-exposure use; therefore, use of these medications post-exposure for healthcare workers/students is considered investigational. The CDC says, "Because most occupational exposures to HIV do not result in infection transmission, potential toxicity must be carefully considered when prescribing post-exposure prophylaxis (PEP)".

Medication Schedule

**Regimen 1**

**Prophylaxis will be treatment for four weeks with:**

**Dolutegravir 50 mg tablet (Tivicay) One tablet by mouth with or without food once daily for 4 weeks.**

**AND**

**Emtricitabine/Tenofovir 200mg/300mg tablet (Truvada) One tablet by mouth with or without food once daily for 4 weeks.**

Side effects associated with dolutegravir (Tivicay) include nausea, diarrhea, headache, dizziness, abnormal dreams and difficulty sleeping.

Side effects associated with emtricitabine/tenofovir (Truvada) include nausea, vomiting, diarrhea, abdominal pain, dizziness, gas, loss of appetite, headache, rash, skin discoloration, joint pain and muscle pain. Rarely, this medication may cause jaundice with dark urine and yellowing of the skin or eyes.

**Regimen 2 (see below) is to be used instead of Regimen 1 during pregnancy or if pregnancy is possible, or if there is intolerance to components of Regimen 1 or if there could be a possible drug interaction between the medications in regimen 1 and medications the employee/student is already taking.**

**Regimen 2**

**Prophylaxis will be treatment for four weeks with:**
**Lopinavir/ritonavir 200/50mg tablet (Kaletra) Two tablets by mouth with or without food every 12 hours for 4 weeks.**
**AND**
**Zidovudine/lamivudine 300mg/150mg tablet (Combivir) One tablet by mouth with or without food every 12 hours for 4 weeks.**

Side effects associated with lopinavir/ritonavir (Kaletra) include nausea, vomiting, diarrhea, weakness, hyperlipidemia, elevated serum transaminases, hyperglycemia, and fat maldistribution.

Side effects associated with zidovudine include headache, nausea, muscle aches and pains, fatigue, and trouble sleeping. These side effects are expected to stop when zidovudine is discontinued. Severe anemia (low red blood cells), neutropenia (low white blood cells), and liver cell damage are serious side effects that may develop in individuals taking zidovudine.

Side effects associated with lamivudine are uncommon and include nausea, diarrhea, abdominal pain, muscle pain, headache, dizziness, and difficulty sleeping. Any history of pre-existing renal impairment should be noted, and the dose should be reduced if renal insufficiency (creatinine clearance < 50 ml/min) is present.

The risk of long-term toxicities, for example, birth defects, reproductive capacity, development of tumors, or other long-term effects of these medications are unknown.

Pregnancy

The risks of adverse effects to a developing fetus from antiretroviral therapy taken by a pregnant woman are unknown, but the risks are likely to be greater in the first trimester. Therefore, females taking antiretroviral therapy post-exposure should be aware that there may be risks associated with antiretroviral therapy during pregnancy, and prophylaxis should be reserved for those with HIGH RISK exposures. If a female is found to be HIV ELISA positive or to have a low value on viral load test, they should be referred to the HIV Maternal Fetal Child Health Clinic (409) 772-2798.

Routine Occupational Exposure Follow-up

Follow-up is determined by the results of the initial lab work drawn on the source of the occupational exposure. It proceeds as follows:

| | | |
|---|---|---|
| Known HIV(+) source | Obtain HIV antibody @ exposure | |
| | | 6 weeks |
| | | 3 months |
| | | 6 months |
| | | 12 months |
| Known HBV (+) source | Obtain Total anti-HBc @ exposure | |
| Obtain HBsAg and Total anti-HBc | | 6 months |
| Known HCV(+) source | Obtain HCV antibody @ exposure | |
| Obtain HCV Qual RNA (PCR) | | 6 weeks |
| | | 3 months |
| | | 6 months |

| | |
|---|---|
| Unknown source | Obtain HIV & HCV antibody @ exposure<br>3 months<br>6 months<br>Obtain Total anit-HBc @ exposure and<br>HBsAg and Total anti-HBc<br>6 months |

If the source results are HIV (-) and HCV (-), you will be offered a one-time 6-month follow-up at which time only an HIV will be drawn.

Special Precautions after an HIV(+) or High Risk Exposure

- Do not share a toothbrush. Gums can bleed easily, getting blood on the toothbrush.
- Do not share razors as blood may go undetected on the blade.
- Avoid pregnancy until HIV infection is ruled out (i.e. generally 6 months following exposure, but up to one year).
- Use safe sex practices-male/female latex condoms for barrier protection or abstain from sex during the follow-up period until HIV infection has been ruled out.
- Do not donate blood, plasma, organs, tissue or semen during the follow-up period.
- Seek medical evaluation for any acute illness that occurs during the follow-up period.

# INFORMED CONSENT FOR PROPHYLAXIS AFTER BLOOD BORNE PATHOGENS EXPOSURE

As a patient, you have the right to be informed about your risk after a blood borne pathogens (BBP) exposure and the recommended prophylaxis. This disclosure is not meant to alarm you; however, there are certain side effects which are associated with prophylaxis. I have read and understand the patient information entitled "Occupational Exposures to Blood Borne Pathogens-Patient Information," which explains risks of infection, prophylaxis, medication schedule, pregnancy precautions, follow-up and special precautions.

❒ I hereby voluntarily consent to prophylaxis for exposure to blood and body fluids infected or possibly infected with human immunodeficiency virus-1(HIV-1). The medications include:

_____

_____

_____

_____

_____

_____

_____

❒ I hereby decline prophylaxis following my exposure to blood borne pathogens. The healthcare provider has informed me of the possible risks associated with refusing this medication. The nature and purpose of the proposed prophylaxis & the risks and hazards if the treatment is withheld, have been explained to me by a healthcare provider. I have had an opportunity to discuss these matters with a healthcare provider and to ask questions about my exposure, alternatives, and the proposed treatment.

_____

EMPLOYEE Date Time

_____

HEALTHCARE PROVIDER Date Time

_____

WITNESS Date Time

***** Please forward to Employee Health/Student Health *****

## Prescription for All Employees/Students Who are not Pregnant

The University of Texas Medical Branch Hospitals
301 University Boulevard • Galveston, Texas 77555-0701
(409) 772-1011

(Pt. Name) _____

(Address) _____

AGE: _____ WT: _____

DATE: ALLERGIES:

A generically equivalent drug product will be dispensed unless the practitioner hand writes the words **"Brand Necessary"** or **"Brand Medically Necessary"** on the face of the prescription.

℞

Dispense:
6 months ☐
3 months ☐
1 month ☐

SIG:

1. *Dolutegravir 50 mg*
   a. *One tablet p.o. Q day x ___ days supply*
2. *Truvada*
   a. *One tablet p.o. Q day x ___ days supply*

Quantity # _____

(CONTROLLED SUBSTANCES REQUIRE QUANTITY NUMBER AND WRITTEN WORD.)

DO NOT REFILL ☐

REFILL ☐1 ☐2 ☐3 ☐4 ☐5

INDICATION: _____

M.D. _____ M.D.
PRINTED NAME M.D. SIGNATURE

DEA No. AG3353973- _____ or DEA No. _____ Telephone/ Pager _____

MM68706–Rev. 5/02

**<u>Emergency Department Instructions:</u>**

Sun – Thurs … prescribe 2 days of medication

Fri – Sat … prescribe 3 days of medication

(Allow for additional days if a Holiday falls in this time period)

# Prescription for Pregnant Employees/Students

The University of Texas Medical Branch Hospitals
301 University Boulevard • Galveston, Texas 77555-0701
(409) 772-1011

(Pt. Name) _____

(Address) _____

AGE: _____ WT: _____

DATE: ALLERGIES:

A generically equivalent drug product will be dispensed unless the practitioner hand writes the words **"Brand Necessary"** or **"Brand Medically Necessary"** on the face of the prescription.

℞

Dispense:
6 months ☐
3 months ☐
1 month ☐

Quantity # _____

(CONTROLLED SUBSTANCES REQUIRE QUANTITY NUMBER AND WRITTEN WORD.)

DO NOT REFILL ☐

REFILL ☐1 ☐2 ☐3 ☐4 ☐5

SIG:

1. *Kaletra (Lopinavir/Ritonavir 200/50mg)*
   a. *Two tablets p.o. Q 12 hours x ___ days supply*
2. *Combivir*
   a. *One tablet p.o. Q 12 hours x ___ days supply*

INDICATION: _____

M.D. _____ M.D.

**PRINTED NAME** **M.D. SIGNATURE**

DEA No. AG3353973- _____ or DEA No. _____ Telephone/ Pager _____

MM68706–Rev. 5/02

**<u>Emergency Department Instructions:</u>**

Sun – Thurs … prescribe 2 days of medication

Fri – Sat … prescribe 3 days of medication

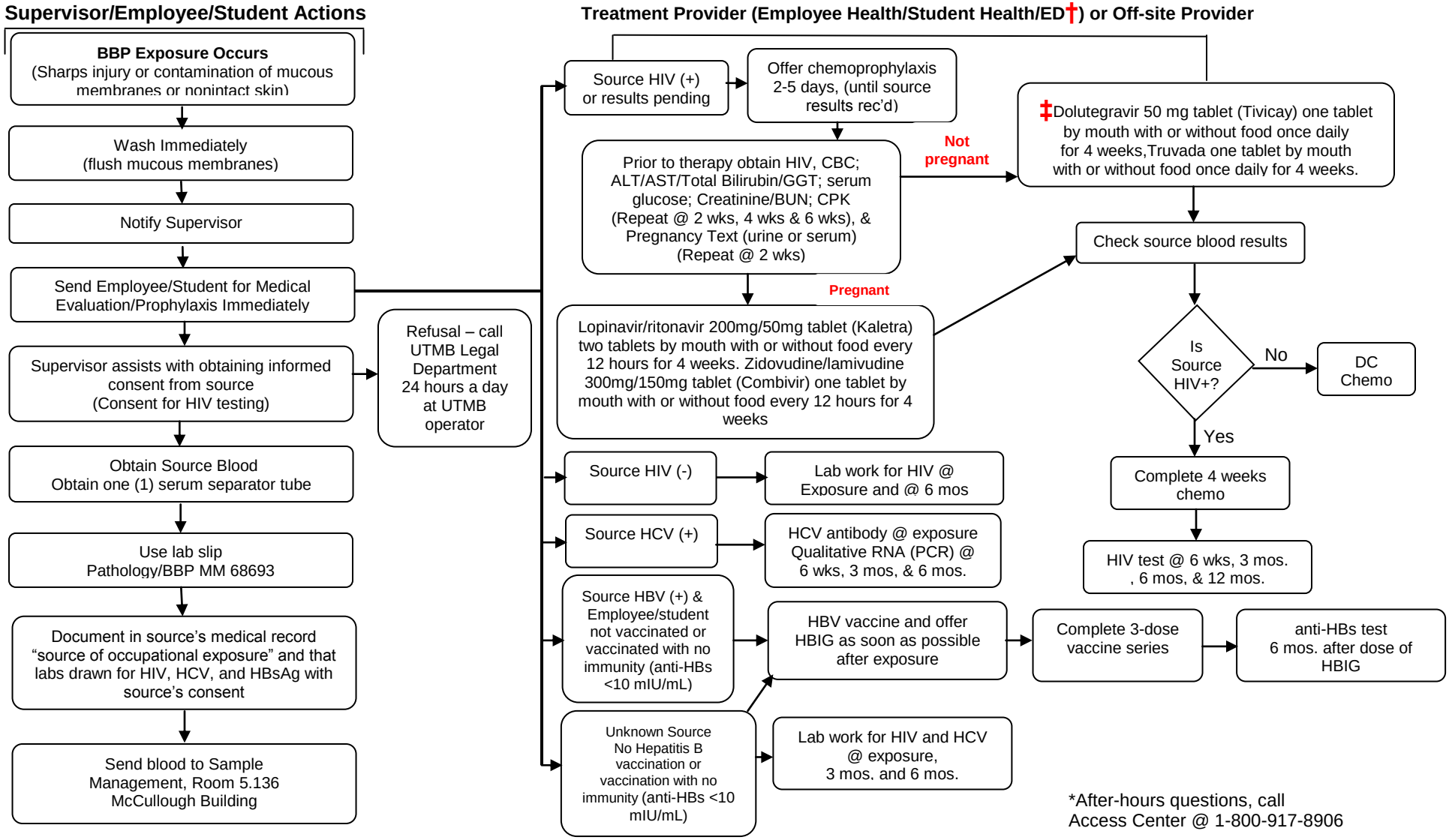
(Allow for additional days if a Holiday falls in this time period)

# Appendix A. Prescription and over-the-counter drugs that should not be administered with protease inhibitors (PIs) because of drug interactions.

| Drug | Comment |
|---|---|
| Antimycobacterials: rifampin | Decreases plasma concentrations and area under plasma concentration curve of the majority of PIs by approximately 90%, which might result in loss of therapeutic effect and development of resistance |
| Benzodiazepines: midazolam, triazolam | Contraindicated because of potential for serious or life-threatening events (e.g., prolonged or increased sedation or respiratory depression) |
| Ergot derivatives: dihydroergotamine, ergotamine, ergonovine, methylegonovine | Contraindicated because of potential for serious or life-threatening events (e.g., acute ergot toxicity characterized by peripheral vasospasm and ischemia of the extremities and other tissues) |
| Gastrointestinal motility agent: cisapride | Contraindicated because of potential for serious or life-threatening events (e.g., cardiac arrhythmias) |
| HMG-CoA reductase inhibitors (“statins”): lovastatin, simvastatin | Potential for serious reactions (e.g., myopathy, including rhabdomyolysis); atorvastatin may be used cautiously, beginning with lowest possible starting dose, and monitoring for adverse events |
| Neuroleptic: pimozide | Contraindicated because of potential for serious or life-threatening events (e.g., cardiac arrhythmias) |
| Inhaled steroids: fluticasone | Coadministration of fluticasone and ritonavir-boosted protease inhibitors are not recommended unless the potential benefit to the patient outweighs the risk for systemic corticosteroid side effect |
| Herbal products: | Coadministration might reduce plasma concentrations of protease inhibitors, which might result in loss of therapeutic effect and development of resistance |
| St. John’s wort (hypericum perforatum), | |
| garlic | Garlic might lower saquinavir level |

This table does not list all products that should not be administered with PIs (atazanavir, lopinavir/ritonavir, fosamprenavir, indinavir, nelfinavir, saquinavir).
Product labels should be consulted for additional information regarding drug interactions.
Sources: US Department of Health and Human Services. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Washington, DC: US Department of Health and Human Services; 2005. Available at http://www.aidsinfo.nih.gov/guidelines/adult/AA_040705.pdf; University of California at San Francisco Center for HIV Information. Database of antiretroviral drug interactions. Available at http://hivinsite.ucsf.edu/InSite?page=ar-00-02.

# Appendix B. OCCUPATIONAL EXPOSURES TO BLOOD BORNE PATHOGENS (BBP)*




* Off-site clinics refer to your agency specific policy
† Emergency Department
‡ See n. 3) on page 9 for drug interactions with dolutegravir