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1.0 Enzyme Immunoassay Screening for Drugs of Abuse

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APPROVED BY: Corinna C Ousley
Quality Manager

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Section 1.0
Blood and Urine Toxicology

1.0 Enzyme Immunoassay Screening for Drugs of Abuse

1.1 BACKGROUND

ELISA is an acronym for enzyme-linked immunosorbent assay. An ELISA is an enzyme immunoassay (EIA) in which one reactant is immobilized on a solid phase and the signal generator is an enzyme. The enzyme delivers a signal to indicate to what extent a particular antigen-antibody reaction has occurred. This reaction takes place inside of a polystyrene microtiter plate well. Horseradish peroxidase is an enzyme commonly employed as a signal generator. The small size of HRP, the ease with which small conjugates can be produced through oxidation of its carbohydrate moieties to reactive aldehyde, its rapid kinetics, and reasonable price, make it popular in ELISA.

For the qualitative determination of a specific drug, or class of drugs in blood and urine this method utilized competitive micro-plate immunoassay. Each of the serum and oral fluid assays requires a predilution step for samples, controls and calibrators. This brings the analytes into an acceptable range for optimum performance of the bound microplate antibodies. Dilutions are either performed manually with an air displacement pipette or a dilutor. Samples, calibrators or controls are added to individual wells of the microplate along with the conjugate, which is the drug or hapten labeled with the enzyme horseradish peroxidase (HRP). There is a competition between the free drug in the matrix sample (blood or urine) and drug bound to enzyme (conjugate) for antibody (sheep or rabbit) fixed on the well. The wells are washed with DI water, the substrate (3,3′,5,5′-tetramethylbenzidine (TMB) with peroxide (H_2O_2) is added, and a color is produced. HRP catalyzes H_2O_2 oxidation of the substrate by transferring one electron from the TMB to the peroxide to yield a blue colored product. The reaction is stopped when 2.0N sulfuric acid is added to the well. This acidic environment provides the necessary conditions for the loss of an additional electron to produce the final yellow color. The acidic environment also serves to inactivate the enzymatic activity of the HRP. The resulting absorbance at 450nm is inversely proportional to the amount of drug present in the sample or standard. Consequently, a more intense yellow color results in a greater absorbance and indicates a lower concentration of drug in the sample. The Micro-Plate EIA utilizes two matrix matched calibrators, one containing no drug (negative calibrator) and one at the concentration corresponding to the accepted cut-off for the drug (cut-off calibrator). In addition, negative and positive controls are used to assess the performance of the kit. An automated microplate analyzer is used for processing on the 96-well microplates. The analyzer automatically dispenses samples and all reagents required for ELISA testing. In addition, the analyzer allows for the programming of incubation times and wash steps.

A **PROTOCOL** is a set of instructions that direct the PersonalLAB™ analyzer how to run a particular assay. Protocols exist for each of the assays utilized. Protocols define the volume required of standards, controls, and reagents, each assay's steps, instrument wash and incubation parameters, sample tip specifications and the validation criteria and reading parameters. The **PROFILE** is information the software uses to actually process the samples and generate results. A **PROFILE** is a set of instructions, which direct the PersonalLAB,™ how to run a particular group of assays. The **PROFILE** includes the order of performance, the plate location(s), the standard/reagent location and the processing mode (parallel or serial dispensing).

1.2 SCOPE

This Micro-plate assay is applied for the qualitative screening for drugs-of-abuse in blood or urine specimen. The kits are either serum (S) or oral fluid (OF) based with appropriate dilutions made for application to the screening of blood and urine. The outcome of the assay is intended as only a preliminary analytical test result. The presence of a particular drug compound must be verified through analysis with a confirmatory instrument such as a gas chromatograph equipped with a mass selective detector.

As indicated in the table below, each assay in use has an established administrative threshold or cut-off. For this reason, a negative result does not indicate that no drug is present, only that the concentration is less than the administrative cut-off. For this reason there may be situations where confirmation of an analyte may be pursued even if a negative result is indicated for the compound or a class of compounds in question. The exceptions are discussed in section 1.8.2.

Assay	*Serum or Oral Fluid Based*	*Calibrator*	*Urine Cut-off*	*Blood Cut-off*
Amphetamine Specific	Serum	d-Amphetamine	1000ng/mL	50ng/mL
Barbiturate	Serum	Secobarbital	200ng/mL	100ng/mL
Benzodiazepine	Oral Fluid	Oxazepam	300ng/mL	100ng/mL
Cannabinoid	Oral Fluid	11-Nor-9-Carboxy-THC	50ng/mL	15ng/mL
Cocaine Metabolite	Oral Fluid	Benzoylecgonine	300ng/mL	50ng/mL
Methadone	Oral Fluid	Methadone	300ng/mL	50ng/mL
Methamphetamine	Serum	Methamphetamine	1000ng/mL	50ng/mL
Opiate	Serum	Morphine	300ng/mL	50ng/mL

1.3 EQUIPMENT

1.3.1 Sample Dispensing Options

- 1.3.1.1 Air-displacement pipettes and appropriate tips.
- 1.3.1.2 Repeater Pipette and appropriate tips.
- 1.3.1.3 Automatic Dilutor equipped with appropriate syringes.

1.3.2 Plasticware

- 1.3.2.1 5mL disposable plastic sample tubes
- 1.3.2.2 75mL plastic reservoirs
- 1.3.2.3 35mL plastic reservoirs
- 1.3.2.4 5mL plastic sample cups
- 1.3.2.5 Caps for cups
- 1.3.2.6 Disposable plastic pipette tips (Use only designated tips)

1.3.3 Automated microplate analyzer

1.3.4 Tube Rocker

1.3.5 Vortex Mixer

1.4 REAGENTS

1.4.1 Assay Kits

Micro-plates coated with anti-drug antibodies.
Enzyme conjugate for specific drug/drug class.
TMB substrate reagent (universal).
2N H_2SO_4 Stopping reagent (universal).
Laboratory Specification Sheet
Package Insert

1.4.2 Processing of New Assay Supplies

1.4.2.1 When a new kit is opened note the expiration date of all components listed on each assay's specification sheet.

1.4.2.1.1 The manufacturer's kit expiration date may be based on a component not used for the analysis of blood or urine. Only the expiration of the conjugate and plate involve the use of the assay kit since the expiration date of the substrate and stop always far exceeds the expiration date of the conjugate and the plates.

1.4.2.1.2 If a lot number has changed, update lot number information on coversheet for original data printout.

1.4.2.1.3 Date and initial kit specification sheet and indicate whether it is a five or a two-plate kit.

1.4.2.1.4 Check the revision date for the package insert. Place a new revision with EIA QA data.

1.4.2.2 When new urine calibrators and controls arrive note expiration date and if necessary, update lot number information on coversheet for original data printout.

1.4.2.3 **Cocaine Assay Conjugate Preparation**

1.4.2.3.1 Using a calibrated pipette, to the vial containing *Benzoylecgonine Lypophilized Stock Enzyme Conjugate*, add 2mL *Conjugate Diluent.*

1.4.2.3.2 Place vial on tube rocker for a minimum of 10 minutes.

1.4.2.3.3 Using a calibrated pipette add the volume of reconstituted *Stock Enzyme Conjugate* listed on the kit package insert to 10mL of *Conjugate Diluent.* The volume of *Stock Enzyme Conjugate* is lot specific. *Prepare only necessary volume of conjugate.*

1.4.2.3.4 Gently mix Conjugate Diluent bottle on tube rocker for a minimum of 1 minute.

1.4.2.3.5 Prior to use, allow bottle to equilibrate for a minimum of 30 minutes at room temperature or overnight under refrigeration.

1.5 REFERENCE MATERIAL

For both urine and blood the following calibrators and controls must be included in each analysis run.

1.5.1 Urine

1.5.1.1 **Calibrators**

- Manufacturer Provided Negative Urine Calibrator
- Manufacturer Provided Cut-off Urine Calibrator

1.5.1.2 **Platform Controls**

- Manufacturer Provided Negative Urine Control (All assays except for Benzoylecgonine)

- Benzoylecgonine Negative Control

  Dilute 500µL Cut-off Urine Calibrator with 500µL Negative Urine Calibrator. Mix well.

- Manufacturer Provided Positive Urine Control

1.5.1.3 **Sample Rack Urine Controls**

- Commercially or in-house obtained Negative Control urine
- Commercially obtained drugs-of-abuse Positive Control urine

1.5.2 Blood

1.5.2.1 **Stock Reference Material Solutions**

Obtain Amphetamine, Methamphetamine, Benzoylecgonine, Methadone, Morphine, 11-nor-9-Carboxy-Δ9-THC, Oxazepam and Secobarbital* drug reference material from Cerilliant, Alltech, Sigma or other appropriate vendor. Different vendors should be used to make up the Calibrator and Control Working Solutions. Certificates of analysis must be stored centrally.

1.5.2.2 **Working Standard Solution**

Add ≅9mL methanol to 10mL volumetric flask. Add 50µL each of stock amphetamine, methamphetamine, benzoylecgonine, methadone and morphine. Add 100µL oxazepam and secobarbital*. Add 150µL c-THC. QS to 10mL with methanol. Record lot numbers of stock reference material on reagent log.

*Include secobarbital when barbiturate screen is used.

Solution is stable for 12 months when stored at 4°C.

1.5.2.3 **Blood Calibrators**

1.5.2.3.1 Negative Blood Calibrator

Negative Whole Blood

1.5.2.3.2 Cut-off Calibrator

1.5.2.3.2.1 **Direct Spiking Preparation**

Add 10µL working standard solution to 1mL negative blood.

1.5.2.3.2.2 **Serial Dilution Preparation**

Prepare 300% of cut-off solution as described below in 1.5.2.4.1. To 1mL of negative

blood, add 500µL 300% blood stock.

1.5.2.4 **Platform Blood Controls**

1.5.2.4.1 Direct Spiking Preparation

To 1mL of negative blood, add working standard solution as indicated below.

Control Type	% of cutoff	Working Standard Solution
Negative	50%	5µL
Positive	300%	30µL

1.5.2.4.2 Serial Dilution Preparation

Prepare 300% of cut-off solution as described in 1.5.2.4.1. Refer to table below for additional dilutions.

Control Type	% of cutoff	Whole Blood Stock	Whole Blood Dilution
Negative	50	500µL of 100%	500µL
Positive	100	500µL of 300%	1000µL

1.5.2.5 **Sample Rack Blood Controls**

1.5.2.5.1 Negative Blood Control

Negative Whole Blood

1.5.2.5.2 Positive Whole Blood Controls

25% Above Cut-off Positive Control

Each run must include a control at 25% above the cut-off control concentrator. To prepare, add 25µL quality control working standard solution to 2mL of negative blood.

Drugs-of-Abuse Positive Control

Each run must include a commercially obtained drugs-of-abuse blood control. The concentration of analytes may be varied.

1.6 PROCEDURE

1.6.1 General Rules of Operation for analyzer

1.6.1.1 Care should be taken to not impede the arm action.

1.6.1.2 Run instrument with the top down. Having the top down is safer for the operator and better for the substrate.

1.6.2 Initial Processing of Samples

1.6.2.1 If necessary, (depending on the version of the Toxicology Submittal Form), note the condition of the inner container seal.

1.6.2.2 On toxicology analysis worksheet, record the following information:

- Description/type of sample collection kit
- Condition of inner seal
- Type and number of specimen container(s)
- Condition of specimen container seals.
- Kit lot number and expiration date.

1.6.2.3 Place laboratory number on each sample container.

1.6.2.4 When two samples are present, the samples should be labeled "A" and "B" or equivalent.

1.6.2.5 If particulates or clots are visible in a blood sample, it may be homogenized with tissue grinder or clarified by centrifuging.

1.6.2.6 Urine samples with an unusually high turbidity may be centrifuged prior to analysis.

1.6.2.7 Urine samples preferably should not contain the preservative sodium azide.

1.6.3 Sample Dilution

1.6.3.1 **Dilution Dispensing Options**

1.6.3.1.1 Option one:
Calibrated air-displacement pipettes and appropriate tips.

1.6.3.1.2 Option two:
Calibrated Repeater Pipette and appropriate tips.

1.6.3.1.3 Option three:

Automatic dilutor equipped with appropriate calibrated sample and reagent/diluent syringes.

1.6.3.2 **Dilution Volumes**

1.6.3.2.1 1 in 5 parts dilution

Sample	Forensic Diluent
160µL	640µL
200µL	800µL
250µL	1000µL

1.6.3.2.2 1 in 60 part dilution

Sample	Forensic Diluent
91µL / 1:5 dilution	1000µL
15µL	885µL

1.6.3.3 **Appropriate Dilution for Each Assay**

1.6.3.3.1 Urine

Dilution	Assays *Grouped for PROFILE*
1 in 60	Benzodiazepines (OF), Cocaine Metabolite, and Methadone
1 in 60	Amphetamine, Methamphetamine, Cannabinoids and Opiates
1 in 5	Barbiturates

1.6.3.3.2 Blood

Dilution	Assays *Grouped for PROFILE*
1 in 5	Barbiturates
1 in 5	Amphetamine, Benzodiazepines, Methadone, and Methamphetamine
1 in 5	Cocaine, Opiates, and Cannabinoids

1.6.4 Preliminary Tasks

1.6.4.1 Fill wash bottles with distilled water.

1.6.4.2 Check pipette tip tray supply. If necessary, fill with appropriate disposable tips. If tips are replaced, reset tip counter (1.6.7.11).

1.6.4.3 Check printer paper supply. Refill if necessary.

1.6.4.4 Remove samples and reagents from refrigerator for a minimum of one hour prior to starting analysis.

1.6.4.5 Prepare samples for analysis. Dilute as indicated under section 1.6.3.3.

1.6.5 Session Preparation

1.6.5.1 Turn on computer.

1.6.5.2 Double click on *PersonalLAB 2.2a-SP3* icon.

1.6.5.3 Click on Folder icon. Prompt for User Name and Password will come up. Password is case sensitive.

1.6.5.4 Open screen comes up. Select ⊙ *Session* and Click **OK**

1.6.5.5 From Open Session Screen, select appropriate template from list.

1.6.5.6 Template will show up in lower "file list" box. Note file name for run for further reference. **Double click** in box on selection or click **OK**

1.6.5.7 *Session* screen will now come up. Click on test tube icon (third from right) to bring up *Session - Sample Programming* Screen.

1.6.5.8 To clear previous programming for first analysis run of the day, click on Clear Sample Rack.

1.6.5.9 On *Session - Sample Programming* screen input in the "ID range" box the laboratory number of specimen or the source of information for positive and negative controls. The "ID range" box is located on the left portion of the screen. Information entered will appear on the right portion of the screen after Enter or ADD ID is pressed. Use only numbers, letters, or dashes with no spaces.

1.6.5.10 To select all assay PROTOCOLS in the PROFILE, double click left on rack icon. Screen will turn blue. By clicking on

the rack icon, "X"s are placed on all assays indicating that the sample will be analyzed by all indicated PROFILES.

1.6.5.11 To choose selected assay PROTOCOL(S), highlight desired sample boxes under assay and double click right mouse button while cursor is in highlighted area.

1.6.5.12 If running an additional batch of assays or if rerunning samples DO NOT PRESS CLEAR SAMPLE RACK or laboratory numbers and control information will have to be reentered. For **second** run, click twice on rack symbol which is located to the left of the assays included in the PROFILE. This will remove the {} around the programmed information (laboratory numbers, control information).

1.6.5.13 Click DONE

1.6.5.14 *Session – Protocol Position"* screen should now be displayed. This view of the plate racks illustrates the number and position of the individual strips, which are necessary for each individual assay.

1.6.5.15 **Load plate racks with appropriate strips**.
Press down on the strips to insure they are seated firmly into the tray. Improper strip positioning can result in the strip popping up and the instrument jamming during the washing or incubation step.

1.6.5.16 Click DONE

1.6.5.17 Save *Session* by clicking on save or on (save session). ***This step is crucial to prevent software glitch. Do not attempt to proceed to next step without first saving session.***

1.6.5.18 Turn on instrument.

1.6.5.19 Load sample rack.

1.6.5.20 From *Session* Screen, click on *Start Session* icon (far right/red arrow).

1.6.5.21 *Profile –Vial Locations* view appears. Load cups and reagent reservoirs onto platform.

1.6.5.21.1 Using the screen template, place the 35mL conjugate containers, and the 75mL substrate

and stop reservoirs according to their designated location on the platform.

1.6.5.21.2 Place appropriately diluted amount of controls (negative and positive) and calibrators (negative and cutoff) into the 5mL cups. Refer to section 1.6.3.3 for appropriate dilutions. Place the cup at its designated numbered location.

1.6.5.22 Note dead volume for each container listed below.

Plasticware	Dead Volume
5mL disposable plastic culture tubes	200µL
75mL plastic reservoirs	1.5mL
35mL plastic reservoirs	1.0mL
5mL plastic cups	200µL

1.6.5.23 After loading is complete, hit Continue.

1.6.5.24 Start-up screen comes up. Screen will indicate *Waiting for Instrument Initialization.*

1.6.5.25 If the lid is open, the screen will indicate *"Warning! Interlock disabled. Continue?* Respond YES for the instrument to continue operation.

1.6.6 Pre-run Maintenance

1.6.6.1 From *Session Status Box* screen, on Session Browser tab, click on OPERATION MONITOR tab.

1.6.6.2 Access *Maintenance* on OPERATION MONITOR from START UP pull down or click on station maintenance icon (second from left).

1.6.6.3 From MAINTENANCE screen, click on SELF TEST tab. To start self test click on START

1.6.6.4 When the *Self Test* is complete, the program will inquire *Print Self-Test Report?* Click Yes

1.6.6.4.1 *Self-Test Report* should be placed in P-LAB maintenance binder or stored with original data.

1.6.6.4.2 A copy of the *Self-Test Report* may be placed in the casefile.

1.6.6.5 If *Self Test* indicates that the instrument has passed all evaluations, proceed with daily maintenance. Click on tab for DAILY MAINTENANCE.

1.6.6.6 Click on Fill Syringe after priming, screen will inquire *Continue?* Indicate Yes if bubbles are observed. Press No when bubbles are no longer present.

1.6.6.7 Click on Fill Lung Screen will instruct operator to open front cover to view lung filling. Click **OK**. After an initial fill, screen will inquire re: *250 µl more.* If lung is not between = lines on lung, press Yes. Screen will continue to inquire until operator observes that lung is sufficiently full and selects No. Screen will now instruct operator to *close cover to continue operation.* Click OK .

1.6.6.8 Click on Buffer (TANK) 1 Prime.
Watch tubing lines for bubbles. Continue priming until no bubbles are present.

1.6.6.9 Click on Buffer (TANK) 2 Prime.
Watch tubing lines for bubbles. Continue priming until no bubbles are present.

Note: Buffer Ext Prime is not used.

1.6.6.10 A ✔ mark will appear when each task is complete.

1.6.6.11 To reset tip counter, access *Reset tips* from START UP pull down or click on Reset Tips icon (3rd from left).

1.6.7 Run Execution

1.6.7.1 From *Operation Monitor* folder tab, click on EXE ▶ icon (4th from left).

1.6.7.2 Instrument will remind you about rack placement. Operator can *retry* if sample rack is not in place.

1.6.7.3 Screen will indicate *Waiting for Lamp Warm-up.* Instrument will check strip/racks in carriages.

1.6.7.4 To monitor run, click on profile tab.

1.6.7.5 When run is complete *Processor Screen* will indicate *Session Terminated. Print the Operation Monitor log to troubleshoot any problem; it will not be possible to print it after you have closed the Processor.* If End (of) Work is not to be pursued at this point, click on **OK** followed by ☒. Screen will inquire *Exit from WB Processor?* Click on Yes.

1.6.7.6 To perform an additional run after results are printed, select ⊙ *Session* (1.6.6.4) from *Open Screen* and proceed as before.

1.6.8 Obtaining Results - Post-Run

1.6.8.1 From *WorkBench* screen, click on Open Results icon (third from right) or Open icon and select ⊙ *Results.*

1.6.8.2 Highlight session name of choice under *File List.*

1.6.8.3 Click OK

1.6.8.4 Select Report icon (far right). "*FETCHING*" (data processing) will commence.

1.6.8.5 When processing of data is complete, the Report Browser screen will appear. To print results click on Assay/Profile tab for each assay or select assay from profile list on Report Index tab. The box to the right of the Print icon should have *Light Reporting* selected.

1.6.8.6 After data has printed, click ☒, click ☒ to close out screens.

1.6.9 Obtaining Archived Results

1.6.9.1 Click on Open Folder icon and select ⊙ Results.

1.6.9.2 On Database Results tab, Highlight Session ID, Name or Entry Date.

1.6.9.3 Click OK. *Results* page comes up.

1.6.9.4 Click on report icon. After data processing is complete *Report Browser* will appear. To print results click on Assay/Profile TAB for each assay or select assay from profile list on Report Index tab. The box to the right of the Print icon should have *Light Reporting* selected.

1.6.9.5 After data has printed, click ☒, click ☒ to close out screens.

1.6.10 Post-run Tasks

1.6.10.1 **General Clean-up**

1.6.10.1.1 Return conjugates, stop and diluent reservoirs to refrigerator.

1.6.10.1.2 Dispose of used calibrator, controls, micro-plates, used tips in drawer and samples into appropriate biohazard container.

1.6.10.2 **Instrument Shut-down**

1.6.10.2.1 For *End-of-Work* routine, access *Maintenance* on OPERATION MONITOR from START UP pull down or click on station maintenance icon (second from left).

1.6.10.2.2 Click on End Work.

1.6.10.2.3 Display will instruct operator *Please fill in buffer 2 with distilled water.* Click OK.

1.6.10.2.4 Screen will direct operator to *Please, empty waste tank.* Click OK after depressing button on left side of instrument. This is a gravity flow water system and the button must be held in for it to fully empty.

1.6.10.2.5 Screen will direct operator to *Please, empty used tips drawer.* Click OK.

1.6.10.2.6 Screen will advise operator *Do not forget to turn the instrument off after you have closed the Processor.*

1.6.10.2.7 When End Work is complete click OK.

1.6.10.2.8 Click on ☒ to close *WorkBench* window. Screen will inquire *Exit from WB Processor?* Select Yes.

1.6.10.2.9 Exit from program and use software to shut down computer.

1.6.10.2.10 Turn off instrument.

1.7 RUN ACCEPTANCE CRITERIA

1.7.1 P-LAB Calibrators and Controls

1.7.1.1 The individual replicates for the absorbance of the *negative calibrator* must be less than 1.2 times the mean *negative calibrator* and greater than 0.8 times the mean *negative calibrator*.

1.7.1.2 The individual replicates of the *cut-off calibrator* must be less than 1.2 times the mean *cut-off calibrator* and greater than 0.8 times the mean *cut-off calibrator*.

1.7.1.3 The mean absorbance for the *negative calibrator* is greater than the absorbance for the *negative control*.

1.7.1.4 The absorbance for the *negative control* is greater than the mean absorbance for the *cut-off calibrator*.

1.7.1.5 The mean absorbance for the *cut-off calibrator* is greater than the absorbance for the *positive control*.

1.7.2 Urine and Blood Sample Controls

1.7.2.1 Matrix matched urine and blood controls, analyzed as samples, should indicate an appropriate positive or negative response.

1.7.2.2 For purposes of this criterion, a significantly depressed absorbance qualifies as a positive result.

1.8 INTERPRETATION OF RESULTS

1.8.1 Positive Result

A positive result for a sample is indicated by an absorbance less than or equal to the *Cut-off Calibrator*.

1.8.2 Depressed absorbances

At the discretion of an analyst, confirmatory techniques may be applied to samples that exhibit depressed absorbances. For purposes of this exception, depressed absorbances are those which fall between the value observed for the cut-off calibrator and the negative control. If data for confirmatory techniques supports the presence of an analyte, the analyte may be reported as present. This is especially applicable if the cross-reactivity for the analyte of interest is known to be low. Examples of cases where this exception could apply include infant testing and samples collected as the result of a drug recognition examination (DRE).

1.8.3 Negative Result

A negative result for a sample is indicated by an absorbance that is greater than the Cut-off Calibrator. Special considerations may apply as outlined in above (1.8.2).

1.9 DISTRIBUTION OF ASSAY INFORMATION

1.9.1 Assay results are to be recorded on the case file toxicology analysis form.

1.9.2 A cover sheet containing the date of the run and the lot number for each assay should be included with original data. This original data will be stored centrally in the laboratory where the analysis was performed in the location designated for the storage of the assay printouts until archiving.

1.9.3 A copy of assay results need not be included in individual case files. When necessary, a copy of the control and standard printouts may be prepared from the centrally stored document.

1.10 P-LAB MAINTENANCE

1.10.1 When-in-use Daily End-of-day Maintenance/Tasks

1.10.1 Inspect for fluid in the vacuum pump condensation trap.

1.10.2 Wipe down instrument with 70% isopropanol.

1.10.2 Periodic Maintenance

The extent of P-LAB use should be used as the indicator of when periodic maintenance is warranted. The following is intended as suggested maintenance frequency. The schedule should be adjusted according to individual laboratory needs.

1.10.2.1 **Monthly Maintenance**

1.10.2.1.1 Wash, air dry and replace the Wash Tanks water.

1.10.2.1.2 Wipe the outside off the removable sample needle with 70% isopropanol.

1.10.2.1.3 Disinfect the discard tip tray by rinsing with 70% isopropanol.

1.10.2.2 **Quarterly to Semi-Annual Maintenance**

Depending upon the use of the analyzer, the following maintenance should be performed.

1.10.2.2.1 Wash Needle Station Disinfecting

Add 70% isopropanol to needle wash station.
Brush with small brush. Remove isopropanol.
Rinse well with DI water.

1.10.2.2.2 Wash Tank (black and red top)/Line Disinfecting
Place 10-15% isopropanol in wash tanks
Circulate alcohol 3-5 times.
Wipe off floats.
Replace isopropanol with fresh DI water.
Circulate water 5-7 primes to rinse system.

1.10.2.2.3 Needle cleaning tank (white top)
Place 14% isopropanol/MeOH in tank.
Allow to soak for 10-15 minutes.
DO NOT PRIME.

1.10.2.2.4 Wash Head Stylet Cleaning
Turn off instrument.
Run stylets through wash head tips.
Clean wash head tips with 70% isopropanol.
Move arm back to home (far left).

1.10.2.2.5 Removable/sample needle cleaning
Soak needle in 10-15% isopropanol.

1.10.3 **Preventative Observations**

1.10.3.1 Watch wash head process plates to verify that head is functioning properly.

1.11 REFERENCES

1.11.1 Butler, J.E. **Enzyme-Linked Immunosorbent Assay**. pp. 759-803 *In*: "Immunochemistry". Van Oss, C.J.; van Regenmortel, M.H.V., eds., Marcel Dekker, inc., New York, NY: 1994.

1.11.2 PersonalLAB™ User's Manual, 080040-001 REV.01, 1998.

1.11.3 OraSure Technologies PersonalLAB™ Training Guide.

1.11.4 OraSure Technologies Package Inserts for Serum Microplate EIA.

Section One
Screening of Blood and Urine for Drugs of Abuse

Procedure: Background and Standard Operating Procedure for Screening of Whole Blood and Urine by Enzyme Immunoassay

Revision #	Issue Date	History
0	04-24-00	Original Issue
1	04-24-02	Updated and made STC name change corrections
2	09-13-02	Clarification of distribution of assay information (1.7.1)
3	01-03-03	Further clarification of distribution of assay information (1.7.1)
4	08-13-04	Reformat, software/computer upgrade and assay configuration changes
5	05-07-2007	Revamp, updated.