

WCHO		<i>Policy and Procedure</i>	
		<i>Waived Testing</i>	
Department: Integrated Initiatives Author: Virginia Koster		Local Policy Number (if used)	
Revision Date 1/31/07	Approval Date 5/2/07	Implementation Date 6/2/07	
Archive Information			
Date:	Policy last reviewed 6/20/04		
Reason:	Regular review		

I. PURPOSE

The goal of the waived testing function is to provide a framework for waived tests by establishing minimum requirements for quality control, identifying responsibility for testing, and reporting results according to all requirements for performing waived tests including Clinical Laboratory Improvement Amendments of 1998 (CLIA88), Department of Community Health requirements, and JCAHO standards.

II. POLICY

It is the policy of the WCHO to ensure that all care and service providers will establish and implement the procedures described in this policy relative to waive testing.

III. APPLICATION

All accredited and non-accredited Washtenaw Community Health Organization (WCHO) Network Providers

IV. DEFINITIONS

Waived Tests - A wide variety of tests that are classified as waived tests (see Exhibit A), including long standing popular tests such as occult blood, urinalysis, glucose, drug screens and pregnancy testing. Waived tests are by definition those that:

- Meet the Clinical Laboratory Improvement Amendments of 1998 (CLIA88) requirements to be classified as waived tests
- Are cleared by the Food and Drug Administration (FDA) for home use
- Use methodologies that are so simple and accurate as to make the likelihood of erroneous results negligible or
- Pose no risk of harm to the member if the test is performed incorrectly.

V. STANDARDS

Applicable JCAHO standards, Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waived Tests requirements and Michigan Department of Community Health In implementing these Standards, providers shall have:

- A. Written definition of how tests will be used in diagnosis, care, and screening, and whether the results of waived testing will be considered definitive for purposes of care and diagnosis or regarded as a screening tool, in which case they may be followed by confirmation testing.
- B. Written determination of the personnel responsible for performing and supervising waived testing.
- C. Personnel performing tests have adequate, specific training and orientation to perform the tests and demonstrate satisfactory levels of competence.
- D. Specific testing-related processes are current and readily available. Written procedures will address specimen collection; specimen preservation; instrument calibration; quality control and remedial action; equipment-performance evaluation; and test performance. Referring to a manufacturer's manual is acceptable, if appropriate modifications have been made to tailor the manuals content to the organization. The policies and procedures are available and accessible to the person performing the test.
- E. Quality-control checks, as defined by the provider, is conducted on each procedure, but at minimum, the manufacturer's instructions are followed. The plan will specify how the procedures control for quality, timetables for checks and the rationale for choosing procedures and timetables including how the test is used; reagent stability; manufacturers' recommendations; the providers experience with the test; and currently accepted guidelines.
- F. Record of quality control and test records are maintained on-site. Documentation of test results may be located in the clinical record. Quality control records, instrument problems and results are correlated. A log or other record is maintained to determine annual volume of tests performed.
- G. Submit CLIA Application for Certification the Hospital, Laboratory & Medical Facilities Section of the Michigan Department of Community Health. Phone: 517 241-2648 or Fax: 517 241-2635.

VI. EXHIBITS

- A. CLIA Waived Test List – updated as of October 10, 1996
- B. Clinical Laboratory Improvement Amendments of 1988 (CLIA)
- C. Sample Glucose Testing by Finger Stick Procedure
- D. Sample Ketone Testing By Urine Dip Procedure
- E. ALCOSCREEN saliva alcohol test
- F. FASTECT II drug screen dipstick test

VII. REFERENCES

Reference:	Check if applies:	Standard Numbers:
JCAHO- Behavioral Health Standards	X	PC 16.10-16.60
CSTS Clinical Screening for Alcohol/Drugs.	X	10.080

VIII. PROCEDURES

None

Table 1. List of Waived Tests*

- Dipstick or tablet reagent urinalysis (nonautomated) for

bilirubin	leukocytes	protein
glucose	nitrite	specific gravity
hemoglobin	pH	urobilinogen
ketone		
- Fecal occult blood
- Ovulation test - visual color comparison
- Urine pregnancy (HCG) tests - visual color comparison tests
- Erythrocyte sedimentation rate - nonautomated
- Hemoglobin - copper sulfate, nonautomated
- Hemoglobin - single analyte instrument (self contained) such as HemoCue Hemoglobin System
- Spun microhematocrit
- Glucose-monitoring devices - FDA cleared/home use, Hemocue glucose test
- Cholesterol - the ChemTrak AccuMeter/Johnson & Johnson Advance Care for total cholesterol
- Boehringer Mannheim Chemstrip - albumin in urine
- Nitrazine (pH) Paper for Body Fluid pH
- SmithKline Gastrocult Test
- Quidel QuickVue In-Line One-Step Strep A Test - Streptococcus Group A
- Cholestech L*D*X - total cholesterol, HDL cholesterol, triglycerides, glucose
- Serim Pyloritek Test Kit - Helicobacter pylori
- Boehringer Mannheim Accu-Chek InstantPlus Cholesterol test system
- Quidel QuickVue One-Step H. Pylori Test for Whole Blood

* As of October 10, 1996

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Fax: 517-241-2635

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P.02 *CLIA App*

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0930-0581

**CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA)
APPLICATION FOR CERTIFICATION**

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0930-0581. The time required to complete this information collection is estimated to average 30 minutes to 2 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: HCFA, 7500 Security Boulevard, N2-14-28, Baltimore, Maryland 21244-3550 and to the Office of the Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

I. GENERAL INFORMATION

<input type="checkbox"/> Initial Application <input checked="" type="checkbox"/> Change in Certification Type	CLIA IDENTIFICATION NUMBER
	_____ <i>(If an initial application leave blank, a number will be assigned)</i>
Facility Name	Federal Tax Identification Number
	Telephone No. (include area code) Fax No. (include area code)
	() ()
Facility Address—Physical Location of Laboratory (Building, Floor, Suite if applicable.)	Mailing/Billing address (if different from street address, include attention line and/or Building, Floor, Suite)
Number, Street (No. P.O. Boxes)	Number, Street
City State Zip Code	City State Zip Code
Name of Director <i>last first middle initial</i>	

II. TYPE OF CERTIFICATE REQUESTED (Check One)

- Certificate of Waiver (Complete Sections I - VI and VIII - X)
- Certificate for Provider Performed Microscopy Procedures (PFMP) (Complete Sections I - X)
- Certificate of Compliance (Complete Sections I - X)
- Certificate of Accreditation (Complete Sections I through X) and indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes
 - JCAHO AOA AABB
 - CAP COLA ASHI

III. TYPE OF LABORATORY (check the one most descriptive of facility type)

- 01 Ambulatory Surgery Center
- 02 Community Clinic
- 03 Comp. Outpatient Rehab. Facility
- 04 Ancillary Testing Site in Health Care Facility
- 05 End Stage Renal Disease Dialysis Facility
- 06 Health Fair
- 07 Health Maint. Organization
- 08 Home Health Agency
- 09 Hospice
- 10 Hospital
- 11 Independent
- 12 Industrial
- 13 Insurance
- 14 Intermediate Care Fac. for Mentally Retarded
- 15 Mobile Laboratory
- 16 Pharmacy
- 17 School/Student Health Service
- 18 Skilled Nursing Facility/Nursing Facility
- 19 Physician Office
- 20 Other Practitioner (specify) _____
- 21 Tissue Bank/Repositories
- 22 Blood Banks
- 23 Rural Health Clinic/Federally Qualified Health Center
- 24 Ambulance
- 25 Other (specify) _____

Is this a Medicare/Medicaid certified facility? Yes No

If yes, indicate Medicare provider number _____ Medicaid number _____

IV. HOURS OF LABORATORY TESTING (list times during which laboratory testing is performed)

	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
FROM: AM							
PM							
TO: AM							
PM							

(For multiple sites attach the additional information using the same format)

V. MULTIPLE SITES (Must meet one of the regulatory exceptions to apply for this provision)

Are you applying for the multiple site exception?

No If no, go to section VI. Yes If yes, provide total number of sites under this certificate _____ and complete remainder of this section.

Indicate which of the following regulatory exceptions applies to your facility's operation.

Is this a not-for-profit or Federal, State or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites? Yes No
If yes, list name, address and tests performed for each site below.

Is this a hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations? Yes No
If yes, list name or department, location within hospital and specialty/subspecialty areas performed at each site below.

If additional space is needed, check here _____ and attach the additional information using the same format.

NAME AND ADDRESS / LOCATION	TESTS PERFORMED / SPECIALTY / SUBSPECIALTY
Name of laboratory or hospital department	
Address/location (number, street, location if applicable)	
City, State, ZIP	Telephone No. ()
Name of laboratory or hospital department	
Address/location (number, street, location if applicable)	
City, State, ZIP	Telephone No. ()
Name of laboratory or hospital department	
Address/location (number, street, location if applicable)	
City, State, ZIP	Telephone No. ()

VI. WAIVED TESTING

Indicate the estimated **TOTAL ANNUAL TEST** volume for all waived tests performed. _____

VII. NONWAIVED TESTING (including PPMP testing)

If you perform testing other than or in addition to waived tests, complete the information below. If applying for one certificate for multiple sites, the total volume should include testing for **ALL** sites.

Place a check (✓) in the box preceding each specialty/subspecialty in which the laboratory performs testing. Enter the estimated annual test volume for each specialty. Do not include testing not subject to CLIA, waived tests, or tests run for quality control, calculations, quality assurance or proficiency testing when calculating test volume. (For additional guidance on counting test volume, see the information included with the application package.)

If applying for certificate of accreditation, indicate the name of the accreditation organization beside the applicable specialty/subspecialty for which you are accredited for CLIA compliance. (JCAHO, AOA, AABB, CAP, COLA or ASHD)

SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME	SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME
<input type="checkbox"/> Histocompatibility			<input type="checkbox"/> Hematology		
<input type="checkbox"/> Transplant			<input type="checkbox"/> Immunohematology		
<input type="checkbox"/> Nontransplant			<input type="checkbox"/> ABO Group & Rh Group		
<input type="checkbox"/> Microbiology			<input type="checkbox"/> Antibody Detection (transfusion)		
<input type="checkbox"/> Bacteriology			<input type="checkbox"/> Antibody Detection (nontransfusion)		
<input type="checkbox"/> Mycobacteriology			<input type="checkbox"/> Antibody Identification		
<input type="checkbox"/> Mycology			<input type="checkbox"/> Compatibility Testing		
<input type="checkbox"/> Parasitology			<input type="checkbox"/> Pathology		
<input type="checkbox"/> Virology			<input type="checkbox"/> Histopathology		
<input type="checkbox"/> Diagnostic Immunology			<input type="checkbox"/> Oral Pathology		
<input type="checkbox"/> Syphilis Serology			<input type="checkbox"/> Cytology		
<input type="checkbox"/> General Immunology			<input type="checkbox"/> Radioassay		
<input type="checkbox"/> Chemistry			<input type="checkbox"/> Clinical Cytogenetics		
<input type="checkbox"/> Routine					
<input type="checkbox"/> Urinalysis					
<input type="checkbox"/> Endocrinology					
<input type="checkbox"/> Toxicology					

TOTAL ESTIMATED ANNUAL TEST VOLUME _____

VHL TYPE OF CONTROL

Enter the appropriate two digit code from the list below _____ (enter only one code)

Voluntary Nonprofit	For Profit	Government	
01 Religious Affiliation	04 Proprietary	05 City	08 Federal
02 Private		06 County	09 Other Government _____
03 Other _____ (Specify)		07 State	(Specify)

IX. DIRECTOR AFFILIATION WITH OTHER LABORATORIES

If the director of this laboratory serves as director for additional laboratories that are separately certified, please complete the following:

NAME OF LABORATORY	ADDRESS	CLIA IDENTIFICATION NUMBER

X. INDIVIDUALS INVOLVED IN LABORATORY TESTING

Indicate the total number of individuals involved in laboratory testing (directing, supervising, consulting or testing). Do not include individuals who only collect specimens or perform clerical duties. For nonwaived testing, only count an individual one time, at the highest laboratory position in which they function. (Example Pathologist serves as director, technical supervisor and general supervisor. This individual would only be counted once (under director)).

<p>A. WAIVED TESTING Total No. of Individuals _____</p>	<p>B. NONWAIVED TESTING (INCLUDING PFMP) Total No. of Individuals _____</p> <p>Director _____ Technical supervisor _____ Clinical consultant _____ General supervisor _____ Technical consultant _____ Testing personnel _____ Cytotechnologist _____</p>
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ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING APPLICATION

ANY PERSON WHO INTENTIONALLY VIOLATES ANY REQUIREMENT OF SECTION 353 OF THE PUBLIC HEALTH SERVICE ACT AS AMENDED OR ANY REGULATION PROMULGATED THEREUNDER SHALL BE IMPRISONED FOR NOT MORE THAN ONE YEAR OR FINED UNDER TITLE 18, UNITED STATES CODE OR BOTH, EXCEPT THAT IF THE CONVICTION IS FOR A SECOND OR SUBSEQUENT VIOLATION OF SUCH A REQUIREMENT SUCH PERSON SHALL BE IMPRISONED FOR NOT MORE THAN 3 YEARS OR FINED IN ACCORDANCE WITH TITLE 18, UNITED STATES CODE OR BOTH.

CONSENT: THE APPLICANT HEREBY AGREES THAT SUCH LABORATORY IDENTIFIED HEREIN WILL BE OPERATED IN ACCORDANCE WITH APPLICABLE STANDARDS FOUND NECESSARY BY THE SECRETARY OF HEALTH AND HUMAN SERVICES TO CARRY OUT THE PURPOSES OF SECTION 353 OF THE PUBLIC HEALTH SERVICE ACT AS AMENDED. THE APPLICANT FURTHER AGREES TO PERMIT THE SECRETARY, OR ANY FEDERAL OFFICER OR EMPLOYEE DULY DESIGNATED BY THE SECRETARY, TO INSPECT THE LABORATORY AND ITS OPERATIONS AND ITS PERTINENT RECORDS AT ANY REASONABLE TIME AND TO FURNISH ANY REQUESTED INFORMATION OR MATERIALS NECESSARY TO DETERMINE THE LABORATORY'S ELIGIBILITY OR CONTINUED ELIGIBILITY FOR ITS CERTIFICATE OR CONTINUED COMPLIANCE WITH CLIA REQUIREMENTS.

SIGNATURE OF OWNER/DIRECTOR OF LABORATORY (sign in ink)	DATE
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SAMPLE GLUCOSE TESTING BY FINGER STICK PROCEDURE

I. Purpose

To determine blood sugar level. Testing blood sugar is an integral part of diabetes management. Testing helps monitor diabetes and make adjustments in diet and exercise regimen as needed. The goal is to keep blood sugar level as close to normal as possible. In doing so, long term health problems caused by abnormal blood sugar levels may be delayed or prevented.

II. Specimen

One large drop of whole blood collected by finger stick at the time of testing. Glucose tests are to be performed as indicated by physician or nurse.

III. Materials

One Touch Basic Meter
Test Strips
Lancets
Penlet II
Alcohol Prep Pads
Gloves
Sharps Container

IV. Procedure

1. Wash hands and put on gloves.
2. Ask consumer to wash hands with soap and warm water and dry thoroughly to clean area for prick.
3. Press the On/ Off Button on Meter.
4. Press C Button until the code number matches the code number on the Test Strip package. The Meter will remember this code until it is changed for a new package of Test Strips.
5. Insert test strip
6. Remove Penlet II Cap and insert Lancet by pushing it into the Lancet holder. Twist off the protective disk and replace Penlet II Cap.
7. Cock the Penlet II by pulling out the dark gray sliding barrel on the end of the device.
8. Place Penlet II against the side of finger and press the dark gray Release Button on its side. Be sure to rotate which finger you use to avoid soreness or callouses.
9. Squeeze the finger gently to get a large, hanging drop of blood.
10. Apply drop of blood to test spot by only touching the drop to the test spot. Allow 45 seconds for results.
11. Use caution when removing the Lancet and Penlet II Cap. Remove cap and grasp the dark gray T-Shaped prongs. Point the Lancet down and away from

- you into the sharps container. Pull back on the dark gray sliding barrel until the Lancet drops out into the sharps container.
12. Remove Test Strip and discard after obtaining and documenting results.
 13. Remove gloves and wash hands.

V. Interpretation

1. Follow physician/ nurse orders regarding interpretation of test results. Client's home staff must communicate to habilitation staff any changes in physician/ nurse orders regarding glucose levels as changes occur. Current physician orders must be on site. Test results and any interventions must be documented and communicated to home staff when client returns home.

VI. Quality Control

1. Check the One Touch II meter using Normal Glucose Control Solution-Blue Formula, which is available from drug stores or Authorized Life-Scan Distributor. To do a Control solution test, follow the same procedure you would if you were testing a blood sample. The Control Solution results will appear on the meter display. The acceptable level for the One Touch Normal Control Solution- Blue Formula is marked on the test strip vial or the foil wrapper. In addition, a Check Strip is included with the meter. Follow manufacturer's instruction for use of the Check Strip.
2. Use the Glucose Control Solution at least once a week, when using a new package of Test Strips, or whenever the meter is suspected to not be working properly. Use Check Strip at least once a week, after cleaning the meter, whenever results seem to be inaccurate or inconsistent, or whenever the meter's "NOT OK REDO" message appears on the meter.
3. Document quality control results in maintenance log.

Exhibit D

SAMPLE KETONE TESTING BY URINE DIP PROCEDURE

I. Purpose

To determine whether ketones are being spilled into urine. An individual with diabetes is likely to spill ketones into urine as a result of burning too much fat. Burning too much fat and producing too many ketones may be a sign that an individual's diabetes is out of control. When this occurs, a complication called ketoacidosis develops which may lead to serious medical complications such as coma.

II. Specimen

Fresh urine sample voided within 10 minutes. If there is a greater than 10 min delay in testing specimen, obtain a second specimen.

III. Materials

Clean and dry paper cup
Ketostix Reagent Strip
Gloves

IV. Procedure

1. Put on gloves and hand client clean and dry paper cup. Have client collect urine sample in bathroom. Have client leave specimen in bathroom.
2. Remove strip from bottle replace cap immediately and tightly. Do not touch test area of strip. Check expiration date printed on the bottle label. If date has passed, discard and retest with strips from a new bottle. If the bottle has been opened, check the date recorded from when it was first opened.
3. Dip the end of the strip into fresh urine sample and remove it immediately drawing the edge of strip against rim of the urine container to remove excess urine.
4. Begin timing and at exactly 15 seconds, match the reagent area to the ketone color chart. Ignore color changes that occur after 15 seconds.
5. Document results and discard test strip.

V. Interpretation

1. Follow physician/ nurse orders regarding interpretation of test results. Client's home staff must communicate to habilitation staff any changes in physician/ nurse orders regarding changes occur. Current physician orders must be on site. Test results and any interventions must be documented and communicated to home staff when client returns home.

VI. Quality Control

1. Always check the expiration date on the bottle. A new bottle can be used for 6 month after being opened. Always write the date you open a bottle on the label. Do not use product (opened or unopened) after expiration date.

Introduction to Drug Screens

Two kinds of waived testing are being performed at Washtenaw County Community Support & Treatment Services:

- a) AlcoScreen saliva alcohol test, and
- b) Fastech II drug screen dipstick test.

Washtenaw County Community Support and Treatment Services have a CLIA certificate (#23D0982199). Waived Testing is used definitively. Waived testing is only performed by CSTS clinical staff who are trained by a qualified medical staff. Clinicians performing waived testing demonstrate initial competency, then demonstrate ongoing competency annually. Staff training and the method of assessing current competency will be documented.

The Director or qualified designee will initiate a review/update before initial use of waived test; periodically as defined by the Director/designee but at least once every three years, or when there are changes in procedures.

ALCOSCREEN SALIVA ALCOHOL TEST

I. Purpose

To detect the presence of alcohol in saliva and to provide a semi-quantitative approximation of relative blood alcohol concentration.

II. Specimen

Saliva specimen is obtained by placing the test strip in the saliva in the mouth or sputum. The person tested must abstain from placing anything in the mouth prior to the beginning of the test procedure.

III. Materials

AlcoScreen Saliva Alcohol Test Kit
Sputum cup (optional)
Timing device
Gloves

IV. Procedure (per Manufacturer's manual)

1. Abstain from placing anything in the mouth for fifteen (15) minutes prior to beginning the test. This includes non-alcoholic drinks, tobacco products, coffee, breath mints, food, candy, etc.
2. Open the foil package and remove the test strip. Observe the reactive pad on the end of the test strip. The pad should be light cream color. A test strip with a reagent pad which is dark tan in color or otherwise discolored must be discarded.
3. Saturate the reactive pad with saliva from mouth or sputum cup. Immediately start timer.
4. At two (2) minutes observe the color change (if any) in the reactive pad. A color change of green or blue indicates the presence of alcohol and a positive result. Results obtained after more than 2 minutes and 30 seconds may be erroneous.
5. Estimate the approximate blood alcohol concentration by comparing the color of the reagent with the color chart appearing on the test package.
6. Document the results and discard the test kit.

V. Interpretation

A color change of green or blue indicates the presence of alcohol and a positive result. An estimate of the approximate blood alcohol level is obtained by comparing the color of the reagent pad to the color appearing on the test package (ranging from 0.02%; 0.04%; 0.08%; 0.30%). A reading of 0.08 or greater denotes legal impairment in the State of Michigan.

VI. Quality Control (per Manufacturer's manual)

1. Always check the Use Before date on the front of the test kit. Log and discard outdated testing material.
2. Failure to wait 15 minutes after placing food, drink, etc. in the mouth before running the test can provide erroneous results.
3. If the presence of alcohol vapors is suspected in the testing area, the test should be performed in an area known to be free of these vapors.

FASTECH II DRUG SCREEN DIPSTICK TEST

I. Purpose

The Fastect II Drug Screen Dipstick Test is an in vitro screen test for the rapid detection of multiple drugs and drug metabolites in human urine at or above the determined cutoff concentrations. This test provides only a preliminary screening test result.

II. Specimen

Only freshly voided, untreated urine obtained in a clean collection cup should be used. Urine samples should be collected so that testing may be performed as soon as possible, preferably during the same day.

III. Materials

Dipstick Test Device
Clean collection cup
Disposable towel upon which test device laid
Gloves

IV. Procedure (per Manufacturer's manual)

1. Test device and donor sample (urine specimen) should be at room temperature. Do not open sealed pouch until ready to perform the assay.
2. Remove the test device from the sealed pouch.
3. Push the sleeve on the test device all the way up.
4. Dip the sample pad of the test device into the urine sample for at least 10 seconds. Dip up to, but not beyond, the tips of the arrows.
5. Slide the sleeve down to the read indicator mark and lay the device on a level surface.
6. Once the control band (C) appears (in 5 minutes or less) results are ready to interpret. (Results are stable and may be interpreted up to 1 hour after the control band forms.)
7. Record results and properly dispose of urine sample and test device.
8. Precaution: The urine sample and all materials coming in contact with the urine sample should be handled and disposed of as if potentially infectious. Established universal precautions must be followed.

V. Interpretation

For interpretations of results, manufacturer's procedures must be followed:

1. Negative Results: The presence of a colored band at the control region (C) and a colored band at a specific test region (T) regardless of the intensity indicate that the result is negative for that particular test.

2. Positive Results: The presence of a colored band at the control region (C) and the absence of a colored band at the test region (T) indicate a positive result for that particular test.
3. Invalid Results: No band appears at the control region (C). The test is inconclusive even if there is a band at the test region (T). If the test device does not produce a band at the control region, check testing procedure, sample, and/or control materials, and repeat the test using a new device.

VI. Quality Control (per Manufacturer's manual)

1. The Fastech II test device has built-in internal procedural controls (See Invalid Results above).
2. The assay is designed for use with human urine only.
3. Positive results only indicate the presence of drug/metabolites and do not indicate or measure intoxication.
4. There is a possibility that technical or procedural errors as well as other substances in certain foods and medication may interfere with test and cause false results.
5. If a drug/metabolite is found present in the urine specimen, the assay does not indicate frequency of drug use or distinguish between drugs of abuse and certain food and/or medication.
6. If it is suspected that the sample may have been tampered with, the test should be repeated, and a new specimen should be collected.

STAFF TRAINING/COMPETENCE

1. Training and documented competency will be done by a qualified medical staff member identified by the Director.
2. Clinical Staff members who perform waived testing will have documented training and competency assessed prior to administering tests. Training and competency will be conducted and documented on an annual basis.
3. Methods to assess current competency include at least two of the following:
 - Performing test on an unknown/blind specimen
 - Have qualified medical staff periodically observe testing by clinical staff member.
 - Monitoring of each user's quality control performance
 - Having written testing that is specific to the method assessed.
4. Training and competency will be documented and placed in staff personnel file.
5. The identity of staff who direct/supervise the training is documented. The identity of current staff trained to perform testing is documented and maintained.
6. Current and complete written policies and manufacturer's instructions are readily available to qualified persons performing the tests.