todylaboratories®

Urine Strips Reader-50S

CE IVD REF C20US1005

Urine Chemistry Analyzer Urine Strips Reader-50S User Manual



⚠	**WARNING** Please read the User's Manual before you operate this instrument. 1) Never use *the bent strip* and make sure *to remove excess urine* in the strip by using a clean absorbent soft tissue paper. 2) Clean instrument daily to prevent malfunction. *To Clean the instrument, Refer to 7. How to Clean the Strip Loading Plate after Use.* 3) If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.
☣	**BIOHAZARD** Wear personal protective equipment. Use universal precautions. Refer to Appendix A for recommended precautions when working with biohazardous materials.

1. INTRODUCTION

Urine test strips simplify diagnosis of disease through ease of use, high sensitivity and specificity. These benefits allow you to identify pathological changes in the urine quick and reliably. The addition of the Urine Analyzer to the urinalysis process allows for standardization and efficiency of urine test by eliminating potential sources of error associate with the visual reading of test strips, such as improper lighting at the workplace, or different color discrimination by the user or different timing when the values are read. The urine test strips that shall be used with the instrument are multi parameter strips for the determination of specific gravity, pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, blood, microalbumin , creatinine and so on in urine.

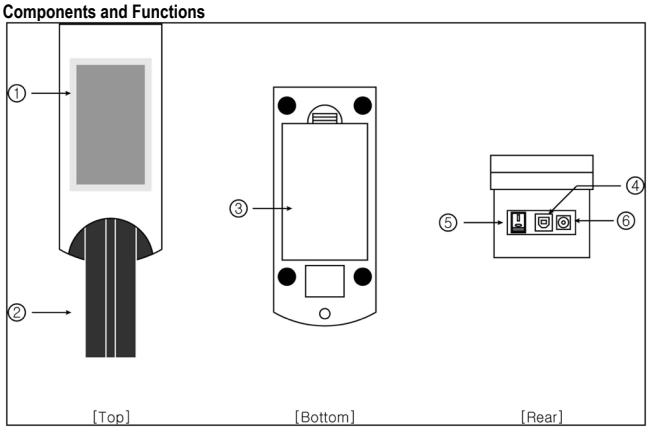
2. SYSTEM DESCRIPTION

2.1 Principles of Measurement

The R-50S is a urine strip analyzing device. The reader is semiautomatic but the forwarding, reading and evaluating are automated. The only thing that the operator need to do is to dip the strip into the urine sample and place it on the Strip Loading Plate.

The R-50S is a reflectance photometer. The strip is illuminated by white light and the reflected light from the strip is detected by the Sensor. The RGB signals are digitized and this digitized image is interpreted by the processor. The intelligent image analyzer SW locates the strip and the pads, and based on these color data the parameter values are determined. The results including the date and time of the measurement, sequence number and ID are stored.

2.2 Components and Functions



View from above View of rear

Component	Function
①Full-color 'touch-screen' TFT LCD	Displays the result and the process of test
②Strip Loading Plate	Moves the test strip to the measuring position
③Battery cover	
④USB Port	Serial interface port for connection to a PC or central laboratory (host) computer or to the optional thermal printer
⑤Power Button	Turns on/off the system
⑥Power Connector	Socket used to connect the analyzer to the external power supply

2.3 Technical Information

Measurement Method	Reflectance Photometer
Wave Length	470, 530, 626 nm
Dimensions	Width(188mm), Depth(74mm), Height(77mm)
Weight	460g
Power Supply	Input: 100-240V / Output: DC 12V, 3.33A
Battery	AAA 1.5V * 8ea
Throughput	40-50 / Hour (120 tests/hour under 'Quick' mode)
Memory	Up to 2000 samples
Operating Conditions	Temperature(2□-30□) / Humidity(10%-70%)
Serial Communication	USB Port
Options	External Printer

2.4 Interfacing System

Users can interface R-50S to Host computer through the USB port.
Baud Rate: 38400, Data bit : 8, Parity: none

3. INSTRUMENT INSTALLATION

3.1 The instrument and parts

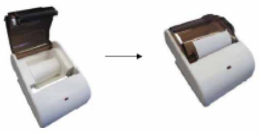
R-50S: 1EA • Strip Loading Plate: 1EA • AC adapter 100-240V / 12V DC 3.33A : 1EA • Power Cable: 1EA • Operating Manual • USB cable

3.2 Optional accessories

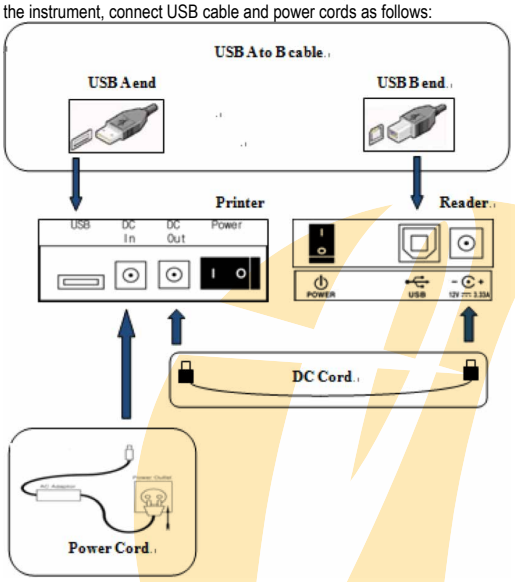
External Printer for exclusive use with The R-50S analyzer
Supplied with printer are:

- 2 paper print rolls.
- DC cord for power supply between printer and reader

To install the paper roll, open the cover of the printer and insert the roll so that 1cm comes over the edge of the cutting teeth. Make sure to insert the paper in the right direction. The printer can only print on one side of the paper.



The correct driver software for operation with reader has already been installed on the printer. To start operation with the instrument, connect USB cable and power cords as follows:



3.3 Environmental & Storage Requirements

3.3.1 Environmental Requirements

As with all sensitive electronic instruments, prolonged exposure to excessive humidity and temperature should be avoided. Place the instrument where it will not be subjected to extreme temperature variations. Avoid proximity to open windows, direct sunlight, ovens, hot plates, open burners, radiators, and dry ice baths.

3.3.2 Storage and Handling

Avoid following locations to prevent malfunctioning of the analyzer

- High humidity, high-temperature, and low-temperature storage places
- Dusty places
- Very hot places near heating appliances, etc.

Do not leave the instrument exposed to direct sunlight for long periods of time. This may deform or discolor the instrument body and cause malfunctioning. Do not touch the power-plug with a wet hand. It causes an electric shock. Use a dry towel after cleaning by a neutral detergent or water. Do not use benzene, thinner, gasoline, etc. to clean the instrument body. This may discolor the body of instrument.

3.4 Cautions & Warnings

3.4.1 AC adaptor

(AC CORD Type, Input Voltage: AC 100~240V, 50/60Hz, 1.2A Output Voltage: DC 12V/3.33A)

Handle the AC adaptor carefully. Improper handling is dangerous.

- Do not touch it with wet hands.
- Do not place heavy objects on top of it.

⚠ Be sure to connect only the AC adaptor provided with the instrument.
⚠ Disconnect the AC adaptor from the power outlet if the instrument is not going to be used for a long time.

3.4.2 Instrument

⃠ No altering or remodeling. This can cause malfunction.
⃠ No dropping or strong impacts. This can damage the instrument.
⚠ Do not forcibly pull/push the Strip Loading Plate. It may cause malfunction.
⚠ Be sure to read carefully user's manual before operating the instrument.

3.4.3 Batteries

The instrument also runs on batteries: 8pieces, type AAA 1.5V
Insert them in the correct way in the empty space below the bottom panel of the instrument.



In order to print results through the external printer, the instrument and the print should be connected through the power cord. Printing on the external printer is not possible when using batteries.

4. HOW TO OPERATE INSTRUMENT

Turn ON the power button in the rear of instrument. Automatically the reader executes System Initialize [Fig 1.1] and then the 'Standby' mode shall be shown as [Fig.1.2].



[Fig.1.1] System Initialize



[Fig.1.2] Standby mode

4.1 Strip type Selection

Touch the strip type in order to change the strip to be tested. Use the up (▲) and down (▼) symbol to scroll through the list until the strip type you want to use is searched.
Touch the strip type to confirm and the selected strip type color change from black to blue. Touch **Test** and return to the Standby mode screen.
⚠ Do not use any reagent strip product other than what is shown on the display. Using the wrong reagent strip will give you incorrect results.

4.2 Seq (Sequence)

The test sequence numbers run from 1 to 2000 and can be reset.
Use the move left key (◄) or **C** (clear) to erase the existing sequence number.
Touch **Test** to confirm the reset or to leave the screen if you have not selected the option to reset the number. You will return to the Standby mode screen.



[Fig. 1.2.1] Strip Selection



[Fig. 1.2.2] Set Seq

4.3 ID No

Input patient/sample's ID number (Max. 16 numbers) by touching number keypad of display.
Use the move left key (◄) or **C** (clear) to erase the existing ID number.
Touch **Test** when you finish inputting the ID to return to the Standby mode screen.



[Fig. 1.2.3] Set ID No

4.4 Color

The urine sample must be visually observed and then the appropriate color must be selected.
Touch the color name to confirm, then the selected color name area change from black to blue color.
Touch **Test** to return to the Standby mode screen.
This field is for information purposes only and will not influence diagnosis of the patient sample. It will only contribute to a more complete patient test report.



[Fig. 1.2.4] Color Selection

4.5 Turbidity

The urine sample must be visually observed and then the appropriate Turbidity must be selected.
Touch Turbidity name to confirm, then the selected turbidity name color change from black to blue.
Touch **Test** to return to the Standby mode screen.
This field is for information purposes only and will not influence diagnosis of the patient sample. It will only contribute to a more complete patient test report.



[Fig. 1.2.5] Turbidity Selection

4.6 Menu



[Fig. 1.3] Menu

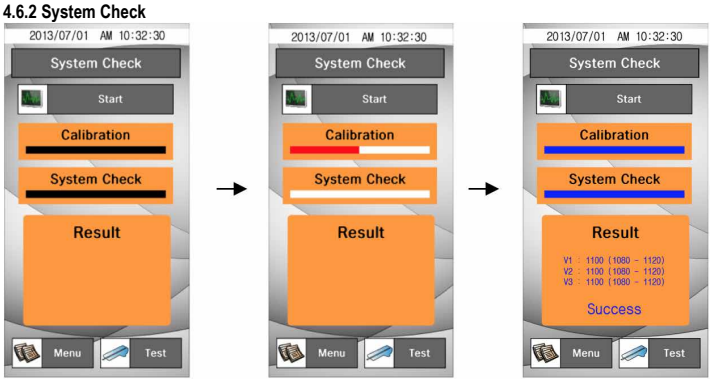
4.6.1 Date/Time

The date and time are displayed on the Select screen and are recorded with test results. If the date and time values are incorrect, change it by touching number key on the display.
Date: YY/MM/DD
Time: 24hour setting
Touch **Test** to return to the Standby mode screen.
Touch **Menu** to return to the **Menu** screen.



[Fig. 1.3.1] Date/Time

4.6.2 System Check



Touch Test | Calibration progress | Calibration Result

[Fig. 1.3.2] System Check

System Check is used for checking aging processes of the optical system and variation of other internal conditions of instrument.
At installation, after moving the instrument or in case of error, the system check and calibration have to be performed before starting measurement.
If the values are within the normal range values on the result, "**Success**" message will be displayed.
Touch **Test** to return to the Standby mode screen.
Touch **Menu** to return to the **Menu** screen.
If the values are not within the normal range values on the result, "**Fail**" message is displayed.
⚠ If **Fail** message is displayed. **Please retry for System Check!**

4.6.3 Memory

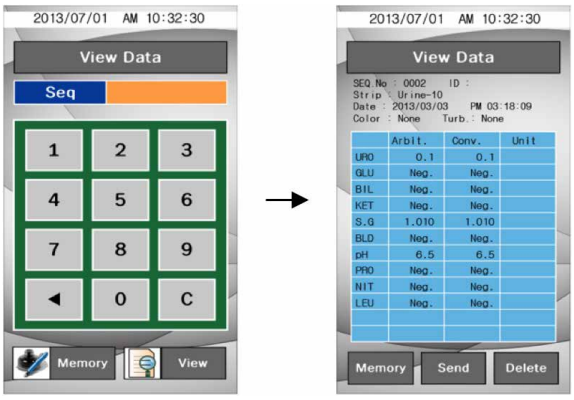
This allows managing the result data saved in the memory, touch Memory on the MENU.
Touch Test to return to the Standby mode screen.
Touch Menu to return to the Menu screen.



[Fig. 1.3.3] Memory

4.6.3.1 View Data

This allows seeing the saved result selectively



Input SEQ No | Result Data

[Fig. 1.3.4] View Data

After selecting the Seq. number, touch <**View**> to see the saved result. The data of the selected SEQ number shows on the screen.
If you press <Send>, the result will either be transferred to:
External printer / PC software

4.6.3.2 Send Data

This allows sending the saved data to PC.
After selecting the **Start**-number and **End**-number of the result data's Seq., touch the **Send** icon, then the selected data is sent to PC.
⚠ Confirm the condition of connecting communication with PC before performing the command.



[Fig. 1.3.5] Send Data

4.6.3.3 Delete Data

This allows deleting the saved data selectively.
After selecting the **Start**-number and **End**-number of the result data's Seq., touch the **Delete** icon, then part of saved data is deleted.



[Fig. 1.3.6] Delete Data

4.6.4 Instrument Setting

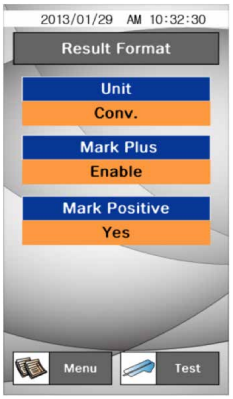
It has a series of screen to control & change the Result format, System Setting and %R value.
Touch **Test** to return to the Standby mode screen.
Touch **Menu** to return to the **Menu** screen.



[Fig. 1.3.7] Instrument Setting

4.6.4.1 Result Format

This allows selection and change of the result display format.
Unit: Select the result format (**Conv. / SI**)
Mark Plus: inclusion of arbitrary results
Select <**Enable**> if you wish to make plus symbol (+) instead of clinical units such as mg/dl or mmol/L shown in the results.
Select <**Disable**> if you wish to express the result only in Conventional or SI units, as selected in the <Unit> area (see above).
Mark Positive: Allows you to choose whether the positive results are highlighted in red color. (**Yes/No**)
Select <Yes> to make a distinction between positive(red) and normal(blue) results.
Select <No> if you wish to express all results in the same color.



[Fig. 1.3.8] Result Format



[Fig. 1.3.11] System Info.

4.6.4.2 System Setting

This allows selecting the measurement Speed, Sound and Baud rate.
Speed: To select the measurement speed. Default speed is <**General**>.
The <**General**> mode includes an incubation time inside the instrument. So after handling, you can place the strip on the loader and the strip will be read at the correct time.
<**General**>mode = 60seconds of operation by the instrument
By using the <**Quick**> mode, the analyzer immediately reads the strip without the incubation time. This implies that the soaked strip should be incubated at room temperature for 30 seconds prior to launching analysis(=outside of the reader).
<**Quick**> mode = 30seconds of operation by the instrument
Sound: To select the audible tones while operating reader.
(Enable/Disable)
Baud rate: To select the speed rate of transferring data with each other between the reader and PC. **(9600/38400/19200)**
Make sure that the baud rate of the instrument and the used PC are always the same. Baud rate of the instrument can easily be changed in this menu. Baud rate of the PC is usually fixed at **38400**.



[Fig. 1.3.9] System Setting

4.6.4.3 Change %R



Password Input **Item Selection** **Grade Selection** **Change Value**

[Fig. 1.3.10] Change %R

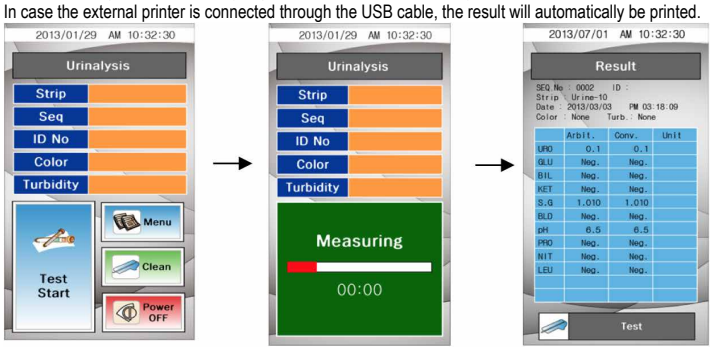
This allows changing the %R value of each parameter's concentration value limit. Select the parameter and the value change by using Direction key. (◀▶)
This menu is password-protected and only accessible for the manufacturer.

4.6.5 System Info.

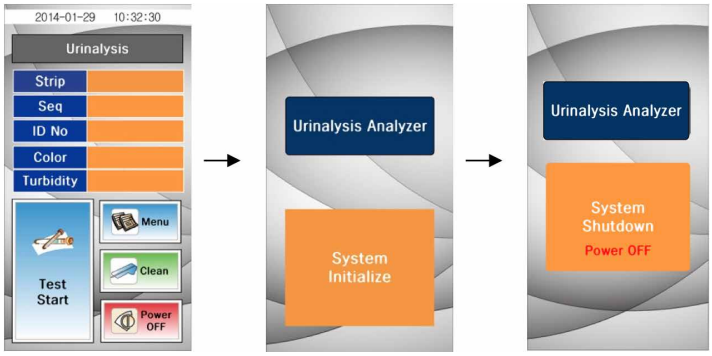
This screen has information about the analyzer.
It shows the current System information. The information can be changed if you change the setting at Result format and System Setting menu.

5. HOW TO USE

Step1.
Power-'on' and let the initial screen for starting tests displayed through the process of the calibration.
Step2.
Dip a strip into fresh urine sample and take it out immediately. Remove excessive urine by touching the edge of strip on a soft absorbent tissue. Place the strip on the plate loader. Touch the Test Start.
Step 3.
After completing the test and analyzing the result, the result is displayed.
In case the external printer is connected through the USB cable, the result will automatically be printed.



To return to the test menu, press<Test> in the bottom of the screen. You can now start measurement of the next sample.
These results are automatically stored and can be looked up and viewed afterwards. Additionally, the data can also be transmitted to a computer.
Step 4.
Touch the **Power OFF** to finish the test. To completely finish the test, press the main power button in the back of instrument.



6. TABLE OF RESULTS

Item	Abbreviation	Unit		Result of Reading						
				Neg.	±	+1	+2	+3	+4	
Uribilinogen	URO	Con.	mg/dl	Norm	1	2	4	8		
		SI	μmol/l	Norm	16	33	66	131		
		Arb	E.U./dL	norm	norm	+1	+2	+3		
Glucose	GLU	Con.	mg/dl	Neg	100	250	500	1000		
		SI	mmol/l	neg	5.5	14	28	55		
		Arb		neg	±	+1	+2	+3		
Bilirubin	BIL	Con.		neg		Small	Moderate	Large		
		SI								
		Arb		neg		+1	+2	+3		
Ketones	KET	Con.	mg/dl	neg	5	15	40	100		
		SI	mmol/l	neg	0.5	1.5	4	10		
		Arb		neg	±	+1	+2	+3		
Specific Gravity	SG	Con.		1.000	1.005	1.010	1.015	1.020	1.025	1.030
		SI								
		Arb								

Blood	BLD	Con.	RBC/µl	neg	trace	10	50	250		
		SI								
		Arb		neg	±	+1	+2	+3		
pH	pH	Con.								
		SI		5	6	6.5	7	8	9	
		Arb								
Protein	PRO	Con.	mg/dl	neg	trace	30	100	300	1000	
		SI	g/l	neg	trace	0.3	1	3	10	
		Arb		neg	±	+1	+2	+3	+4	
Nitrite	NIT	Con.								
		SI		neg	pos					
		Arb								
Leukocytes	LEU	Con.	WBC/µl	neg		25	75	500		
		SI								
		Arb		neg		+1	+2	+3		
Ascrobic Acid	AsA	Con.	mg/dl	neg		20	40			
		SI	mmol/l	neg		1.2	2.4			
		Arb		neg		+1	+2			
Microalbumin	ALB	Con.								
		SI	mg/l	10	30	80	150			
		Arb								
Creatinine	CRE	Con.	mg/dl	10	50	100	200	300		
		SI	mmol/l	0.9	4.4	8.8	17.7	26.5		
		Arb		10	50	100	200	300		
Albumin to Creainine ratio	A:C	Con.	mg/g	<30		30-300		>300		
		SI	mg/mmol	<3.4		3.4-33.9		>33.9		
				Nor mal		Abnormal		High Abnormal		
Protein to Creainine ratio	P:C	Con.	mg/g	<150		>=150				
		SI	mg/mmol	<17.0		>=17.0				
				Nor mal		Abnormal				

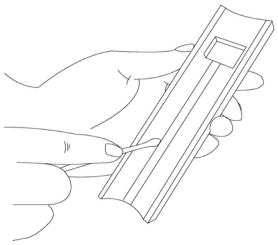
7. HOW TO CLEAN THE STRIP LOADING PLATE AFTER USE

Clean the dirty 'Strip Loading Plate' by using a neutral detergent or water-wet towel or swab. Do not use volatile matters like thinner, gasoline and benzene for cleaning the body. It is better to clean the Strip Loading Plate everyday because the rest urine from the tested strip can smear on the 'Strip Loading Plate'.

Step1. Touch the Clean icon 

and separate the Strip Loading Plate from the body of the instrument.

Step2. Completely wipe the groove of the detached Strip Loading Plate with a water-wet swab.



Step3. After the cleaning, put back the Strip Loading Plate on the reader and touch the Clean icon. Then the Strip Loading Plate is moving in its original position. If the loader is not retreated immediately, slightly push the loader.

Step4. The Strip Loading Plate slightly goes in and comes out then it is ready to start the test.

8. QUALITY CONTROL

Performance of reader result should be confirmed by testing known negative and positive specimen or controls whenever a new bottle is first opened or for calibration. **Water should NOT be used as a negative control.**

Controls should be tested after performing maintenance or service on the reader. Quality Control materials should be used in accordance with local, state, and/or federal guidelines.

1) **Quantimetrix** Dipper Urine Dipstick, Dropper Urine Dipstick, Dip&Spin Urine Dipstick (Homepage: www.4qc.com)

2) **Thermo SCIENTIFIC** MAS UA Control (Homepage: www.thermoscientific.com)

3) **Bio-Rad** qUAntify Plus Control (Homepage: www.bio-rad.com)

9. TROUBLESHOOTING & MAINTENANCE

9.1 Maintenance

No maintenance is required other than routine cleaning.

- Clean the outside of the R-50S body with a dry towel after wiping clean with a towel dampened by a neutral detergent or water.
- Do not wipe the body of the R-50S clean with benzene, thinner, gasoline, etc.
- **Do not force the Strip Loading Plate**. It works automatically. Refer to How to Clean the Strip Loading Plate after use of the user's manual.
- If you want to know detailed information for environmental factors and cautions, refer to Specifications, Cautions & Warnings under User's manual.

9.2 Troubleshooting

SYMPTOM	POSSIBLE CAUSE	REMEDY
The instrument will not work even though power is on.	1. The connection part for power source may be loose. 2. Defective system electronics	Turn the instrument power off. Check that the power cord is firmly plugged into the instrument and into a live AC electrical outlet then turn the power ON (AC adapter: 100-240V/ 12VDC 3.33A) If it is still unable to be operated, contact your local Customer Service Office.
Display a message "Loader error"	The calibration pad is not fit on the loader.	Replace the strip loader.
System Check values results show "Fail"	1. The calibration pad is not fit on the loader 2. There is a lot of dirty contamination on the calibration loader 3. Unusually calibration 4. The calibration loader works incorrectly during operation	Replace strip loader or Retry to calibration.
Strip Loading Plate stops unexpectedly during operation.	1.Unstable electricity. 2.Measurement motor gear or bolster error	Use a rated current. Contact your local Customer Service Office if it doesn't operate correctly
1. Can't make program update 2. Can't connect to LIS 3. When connect to PC, the items can't be shown correctly to the results	1. Check the USB Com Port Number 2. USB cable between analyzer and PC is incorrectly connected 3. Not recognize USB Driver	1. It the set up condition is different from the left conditions, make it as same like left side Check the USB COM Port Number and then change the USB COM port Number 2. Correctly connected. But if it is not working, replacement USB Cable(A-B Type). 3. Install USB Driver

APPENDIX A: SAFETY INFORMATION

Protecting Yourself from Biohazards

This information summarizes the established guidelines for handling laboratory biohazards. This summary is based on the guidelines developed by the Centers for Disease Control, the Clinical and Laboratory Standards Institute, and the Occupational Safety and Health Administration.

Use this summary for general information only. It is not intended to replace or supplement your laboratory or hospital biohazard control procedures.

By definition, a biohazardous condition is a situation involving infectious agents biological in nature, such as the hepatitis B virus, the human immunodeficiency virus, and the tuberculosis bacterium. These infectious agents may be present in human blood and blood products and in other body fluids.

The following are the major sources of contamination when handling potentially infectious agents:

- needlesticks
- hand-to-mouth contact
- hand-to-eye contact
- direct contact with superficial cuta, open wounds, and other skin conditions that may permit adsorption into subcutaneous skin layers
- splashes or aerosol contact with skin and eyes

To prevent accidental contamination in a clinical laboratory, strictly adhere to the following procedures:

- Wear gloves while servicing parts of the system that have contact with body fluids such as serum, plasma, urine, or whole blood
- Wash your hands before going from a contaminated area to a non-contaminated area, or when you remove or change gloves
- Perform procedures carefully to minimize aerosol formation
- Wear facial protection when splatter or aerosol formation are possible
- Wear personal protective equipment such as safety glasses, gloves, lab coats or aprons when working with possible biohazard contaminants
- Keep your hands away from your face
- Cover all superficial cuts and wounds before starting any work
- Dispose of contaminated materials according to your laboratory's biohazard control procedures
- Keep your work area disinfected
- Disinfect tools and other items that have been near any part of the system sample path or waste area with 10% v/v bleach
- Do not eat, drink, smoke, or apply cosmetics or contact lenses while in the laboratory
- Do not mouth pipet any liquid, including water
- Do not place tools or any other items in your mouth
- Do not use the biohazard sink for personal cleaning such as rinsing coffee cups or washing hands

Do not recap, purposely bend, cut, break, remove from disposable syringes, or otherwise manipulate needles by hand. Needlestick injuries may result.

REGISTRATION SHEET

Please complete the following Registration Sheet, and fax back within two weeks to your local distributor. These data are recorded in the Service Registration File, providing assistance for our Support Service.

Serial Number of the Instrument: _____

Date of delivery: _____

Date of Installation: _____

The Institution / Laboratory: _____

address: _____

telephone: _____

todylaboratories®

Tody Laboratories Int. SRL
22 Vadul Moldovei, s1, OP 18, Bucharest, CP 014033, ROMANIA
+4021 269 00 00 +4021 269 06 41
ISO 15189, 17043, 9001, 13485
www.todylaboratories.com