Principle

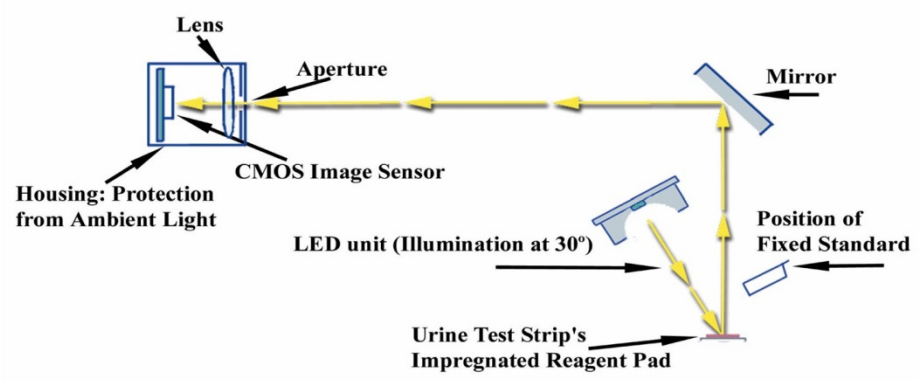
Intended Use

The iChem™100 Urine Chemistry Analyzer (iChem100) is a semi-automated benchtop urine chemistry analyzer intended for the in vitro measurement of the following analytes: glucose, protein, bilirubin, urobilinogen, pH, specific gravity, blood, ketones, nitrite, leukocyte esterase, ascorbic acid, and color. Specific Gravity will not be reported from the iChem Strips. The iChem100 is intended for use only with iChem™ 10 SG Urine Chemistry Strips provided by Iris Diagnostics. The instructions for use in this procedure have been edited from the *iCHEM100 Operators Manual*. For complete details of installation, setup and operation of this analyzer, refer to the *iCHEM100 Operators Manual*.

Theory of Operation

The iChem100 is a semi-automated urine chemistry analyzer performing measurements of urine chemical constituents utilizing test strips. The iChem100 is a reflectance densitometer.

Optics



LED Unit

For the illumination of the measurement, a LED Unit with three different wavelengths LEDs (450nm, 530nm and 625nm) is used. To increase homogeneity, the LED's are not placed regularly over the measurement window but are placed mainly towards the outer area of the LED Unit. In order to achieve a very high light intensity, one reflector and one anti-reflector are placed beside the LED line. With this optical design, the entire urine test strip is illuminated.

CMOS Image Sensor

Unlike most of the reflectometers in the market for urine test strip analysis, the iChem100 does not use a photodiode detector to measure the reflected light, but instead utilizes a CMOS (Complementary Metal Oxide Semiconductor) image sensor that captures a color image of each of the test pads. The CMOS image sensor is able to photograph almost the whole length (100mm) of the urine test strip and all of its width. As seen in the figure above, the CMOS image sensor has been placed perpendicular to the measurement level, and since the height of the instrument limits the optical length, a mirror has been used for changing the direction of the beam.

Optics Calibration

Prior to each measurement, the optics assembly is calibrated using a "fixed standard" and it permits a one-point calibration. The iChem100 is also capable of performing an internal, automated two-point calibration if the one-point calibration done before each specimen determination falls outside of the acceptable limits. A secondary "movable standard" is automatically moved into place and readings from it in conjunction with the

"fixed standard" are used to perform a two-point calibration. No external calibration strips or procedures are required.

Measurement

Once calibrated, the urine test strip is sequentially illuminated by the LEDs (Red, Blue, Green) that are located at a 30º angle to the impregnated reagent pads, and the reflected signals are sent via the mirror through the lens and captured by the CMOS camera. The captured signal is evaluated and a completed result is provided for each of the chemistries.

The iChem100 uses a compensation pad to determine the color of the urine as well as correct for color interference on the impregnated reagent pads. Since the iChem100 is capturing a pixelated image of the blood pad, a special algorithm has been developed using more than a reflectance to differentiate between intact and hemolyzed red blood cells.

iChem 10 SG Test Strips

See the *IRIS iChem 10 SG Urine Chemistry Strips* procedure for information for each of the individual tests.

The test strips have reagent-impregnated specialty paper pads to perform chemical analysis of:

bilirubin
urobilinogen
ketones
ascorbic acid – not reported at UCDHS
glucose
protein
blood
pH
nitrite
leukocytes
specific gravity – reported by refractometer

iChem100 Principle

The process requires that an operator dip the urine test strip with its reagent-impregnated pads into and out of a urine sample. This action brings the reagent impregnated pads into contact with the urine containing the analytes to be tested. Once the test strip has been dipped into the urine, color develops on each of the reagent-impregnated pads in direct proportion to the amount of analyte present in the sample. The test strips have a compensation pad to determine the color of the urine as well as correct for color interference on the impregnated reagent pads.

After the test strips are placed on the Test Strip Tray with correct orientation, they are automatically transported to the measurement window and the remainder of the operation is performed automatically by the iChem100.

Reagents, Controls and Supplies

1. IChem100 10 SG Strips (Part No. 800-7004) – 100 per vial - are ready to use strips containing pads that have been impregnated with chemicals used to perform the chemical analysis portion of the urinalysis. They have a shelf life of 2 years and are stored at room temperature. Once opened, the strips are stable until the expiration date on the vial.

2. MAS Liquid UA Controls, Levels 1 and 3 (Part Nos. 024225 and 024227), for the AX-4280 and iChem are ready to use bottles of simulated human urine comprised of appropriate chemicals, biological matter, buffer

salts, and preservatives. They are stored at 2°- 8°C, and aliquots are brought to room temperature before use. Return the bottles to the refrigerator immediately after pouring off the aliquots.

3. Thermal Paper (Part No. 800-7511) - 3 rolls/pack

Calibration

The iChem100 automatically self-calibrates prior to each measurement.

Quality Control

Quality control is performed daily as part of the daily maintenance for the iChem100. Controls will be run once per day.

Controls will also need to be tested on the iChem100 when a new shipment or a new lot number of iChem100 10 SG test strips is received. Parallel testing between the old shipment or lot number and the new shipment or lot number will be done to assure that it is working properly.

Values obtained should fall within the ranges provided by IRIS. Refer to the ***IRIS iChem100 10 SG Chemistry strip Quality Control*** procedure for corrective action(s) if the values fall outside of the published limits.

Software

Data Entry Fields

Data entry fields are areas in a screen where information is entered. One screen can have several data entry fields, but only one field can be selected and active for entering data at a time. Pressing an alpha or a numeric key will input that character into the data entry field. If you exceed the number of allowable characters in a field, you cannot enter more characters until some characters have been deleted.

To select a data entry field, use the keyboard up or down arrow keys to move the cursor up or down in the screen. To move back and forth between left and right columns, use the [**Tab**] key. The contents of the field will be reverse highlighted to show that they are selected or active.

To delete contents from a data field, select the field using the keyboard's up or down arrow or [Tab] keys, then press the [**Delete**] key.

To erase contents from data field one character at a time, select the field using the keyboard's up or down arrow or [**Tab**] keys, then press the [**Backspace**] key. The last character in the field will be deleted.

Toggle Fields

Toggle fields are fields setup in a circular fashion allowing you to choose one field out of a series of pre-setup fields (e.g., blank, trace, few, moderate, many, etc.). A toggle field will be indicated by a doubleheaded arrow. Only one toggle field can be active at a given time.

To select a toggle field, use the keyboard up or down arrow keys to move the cursor into the desired field.

To view the choices in a toggle field, use the keyboard right or left arrow keys to advance through the selections. To switch back and forth from a left toggle field to a right toggle field, press the [**Tab**] key.

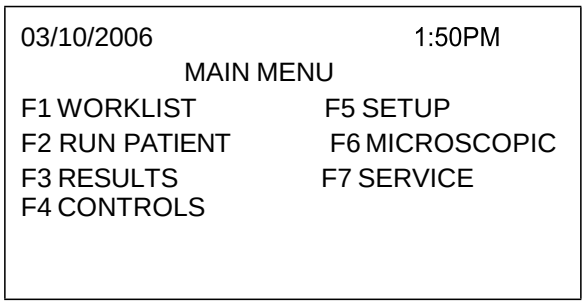
To confirm or lock in a selection, you may press the [**Enter**] key or use the up or down arrow keys. Either one will lock in the selection and advance you to the next field.

Function Keys

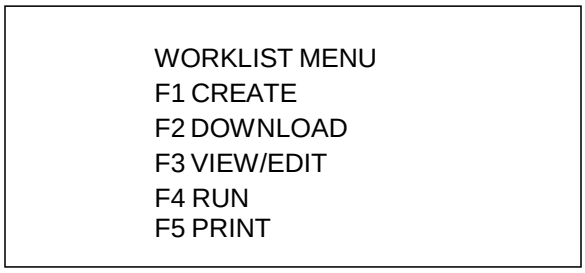
Pressing a function key, [**F1**] through [**F10**], will allow you to access the described function associated with it. For example, to choose to run a patient sample, press [**F2**] while the Main Menu screen is displayed. The function keys will only perform the function that is associated with it in the currently displayed screen.

Menu Diagram

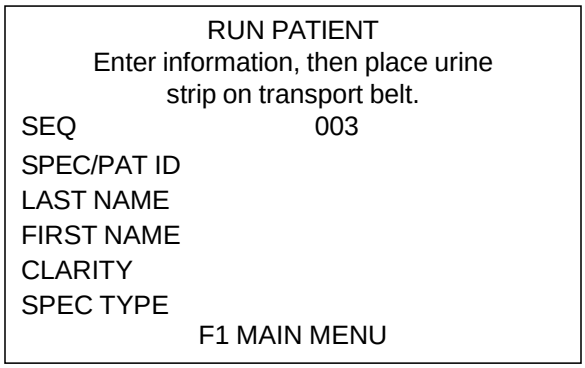
Main Menu



Worklist Menu



Run Patient Menu



Results Menu:

```
                RESULTS
                        mm/dd/yyy  hh:mm
START DATE / TIME       /  /       :     am
  END DATE / TIME
     SPEC / PAT ID
  PAT LAST NAME
   OPER NUMBER
F1 VIEW  F2 PRINT       F3 TRANSMIT
F4 DELETE               F5 MAIN MENU
```

Controls Menu

```
                CONTROLS MENU
              LOT#          EXP
FILE 1        1212UC2006    03/20/2006
FILE 2        1213UC2006    03/20/2006
FILE 3
FREQ          1             Hours

F1 SETP   F2 VIEW     F3 RUN
F4 PRINT  F5 DELETE   F6 MAIN MENU
```

Setup Menu

```
                SETUP MENU

                F1 UNITS
                F2  FLAGGING
                F3  TEST  SEQ
                F4  LOG  ON  ID
                F5 MAIN MENU
```

Service Menu

```
                SERVICE MENU
F1 DATE/TIME            F4 DIAGNOSTICS
F2 PRINTER              F5 TRANSMIT
F3 LANGUAGE             F6 TEST STRIP
                F7 MAIN MENU
```

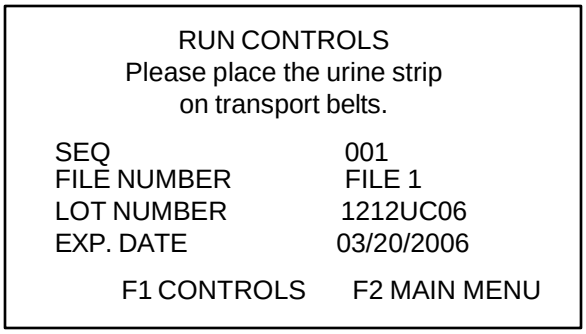
Set Up

See *iCHEM100 Operators Manual* for set up procedures.

Specimen Processing

Running Controls

1. From the ***Main Menu*** screen, press the [**F4**] key to display the ***Controls Menu*** screen.
2. Using the Up or Down arrow keys, select the control file corresponding to the control material you want to run.
3. From the ***Control Menu*** screen, press the [**F3**] key to display the ***Run Controls*** screen. The green LED light on the instrument will be illuminated, indicating the instrument is activated and waiting for a urine test strip to be placed on the transport mechanism.



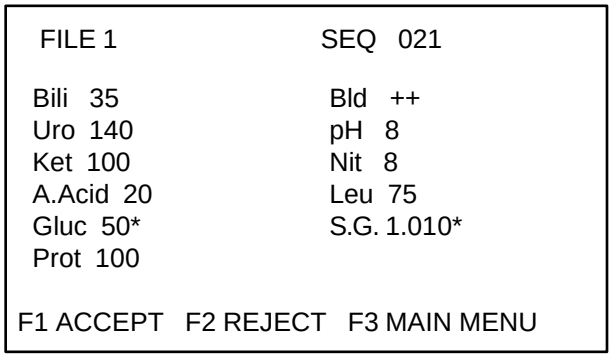
This screen allows you to run a specified quality control material and have its results stored in the selected file. The sequence number of the control is displayed at the top of the screen and reflects the number of controls that have been run for this specific control file. The instrument has the capability to store up to 100 runs in each file.

> **NOTE**: You cannot run a control material that has not been previously set up in a control file. Refer to ***Setting a Control File*** *in* ***iChem100 Operators Manual***

4. Dip a urine test strip into the control material corresponding to the control identified on the screen. Place the test strip onto the transport belt with the test pads facing up. Slide the strip forward until the strip touches the end stop.

> **NOTE**: If you move the strip away from the sensor prior to being transported, a message screen will appear requesting that you remove the urine strip from the transport belt and press the [**F1**] key to continue.

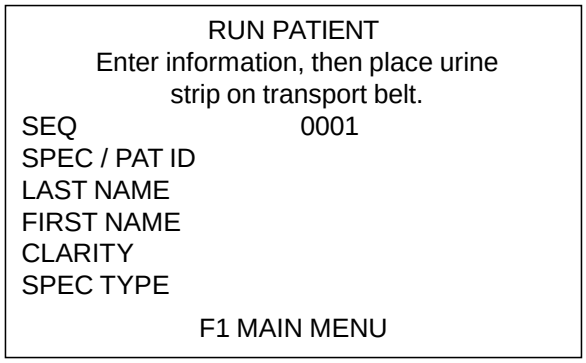
5. At the end of the analysis, the results will be displayed on the screen for review and acceptance, printed and transmitted to the LIS.



Running Single Specimen Analysis

Entering Patient Information

1. From the ***Main Menu*** screen, press the [**F2**] key to display the ***Run Patient*** screen (below) and to activate the rine strip sensor. The illuminated green LED on the instrument indicates that the sensor is active.



NOTE: If the waste container is nearly full (> 125 strips), you must empty it prior to beginning “Run Patient” analysis.

The ***Run Patient*** screen allows you to identify and run a patient specimen. You can identify the sample using a sequence number, a specimen/patient ID, a name, or all three options. Data for only one patient at a time can be entered in this screen.

Sequence Number

The sequence number field is only active for the first specimen run after entering ***Run Patient***. Thereafter, the sequence number is automatically assigned by the software each time a new patient specimen is analyzed.

Specimen/Patient ID

2. If desired, enter specimen or patient ID (up to 15 alphanumeric characters) by using the keyboard or the barcode reader. Press the [**Enter**] key or use the Up or Down arrow keys to move to the next field.

Last Name

3. If desired, enter the patient last name (up to 15 characters) using the keyboard or the barcode reader. Press the [**Enter**] key or use the Up or Down arrow keys to move to the next field.

First Name

4. If desired, enter the patient first name (up to 10 characters) using the keyboard or the barcode reader. Press the [**Enter**] key or use the Up or Down arrow keys to move to the next field.

Clarity

5. You can enter clarity by either toggling through the list of clarity options found in the software or by using the barcode reader. Barcodes are located at the top left of the instrument.

<table>
<tr><th colspan="2">Using keyboard entry</th><th colspan="2">Using barcode entry</th></tr>
<tr><td>Options</td><td>Blank Field
Clear
Hazy
Slt Cloudy
Cloudy
Turbid
Bloody
Other</td><td>Options</td><td>CLEAR
SLT CLOUDY
CLOUDY
BLOODY
OTHER</td></tr>
<tr><td colspan="2">Press the left or right arrow keys until the desired clarity result appears. Press the [Enter] key or use the up or down arrow keys to accept and move to the next field.</td><td colspan="2">To select clarity using the barcode reader, determine the clarity result and click the barcode reader over its respective barcode.</td></tr>
</table>

Specimen Type

6. You can enter the specimen type by either toggling through the list in the software or by using the barcode reader. Barcodes are located at the top left of the instrument.

Using keyboard entry		**Using barcode entry**	
Options	Blank field Random Cl Catch Cath Peds First AM 24 hours Fasting Gluc tol S pubital Other	Options	RANDOM CL CATCH CATH PEDS OTHER
Press the left or right arrow keys until the desired clarity result appears. Press the [Enter] key or use the up or down arrow keys to accept and move to the next field.		To select specimen type using the barcode reader, determine the specimen type and click the barcode reader over its respective barcode.	

Analyzing the Urine

Once all the patient identification information has been entered, proceed to analyzing the urine.

NOTE: The urine specimen should be fresh, well-mixed and uncentrifuged.

If refrigerated, allow the specimen to return to room temperature.

1. Dip the urine test strip into the urine, making sure all the test pads are wet.
2. Immediately remove the urine test strip from the urine, dragging the edge of the strip against the side of the container as you remove the strip.
3. Blot the urine test strip by touching the edge of the strip to a paper towel. Do not drag the strip across the paper towel; touch the edge only.
4. Place the urine test strip on the transport belt of the instrument with the test pads facing up. Slide the strip forward until the strip touches the end stop. A sensor will detect the presence of the strip and the red LED light will be turned on along with the green LED light.

> **NOTE**: If you move the strip away from the sensor prior to being transported, you will be prompted to remove the urine strip from the transport belt and press the [F1] key to continue.

5. Approximately two minutes after the urine strip is transported for analysis the printer will print the results; unless printing has been set to "**Print Function Only**" (see ***Setting up the printer*** *in* ***iChem100 Operators Manual***.)

Results will also be transmitted to the LIS.

To run another specimen, repeat from ***Entering Patient Information***, then ***Analyzing the Urine***. If no test strip is placed on the transport belt within ten (10) minutes, the screen will return to the ***Main Menu*** screen.

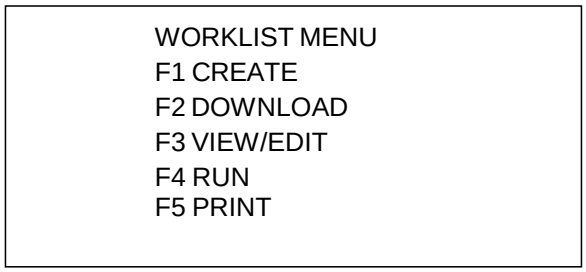
You may return to the ***Main Menu*** screen at any time by pressing the [**F1**] key. However, if the analysis of the strip is not complete, a message will appear requesting that you wait for analysis to finish.

Running Batch Specimen Analysis

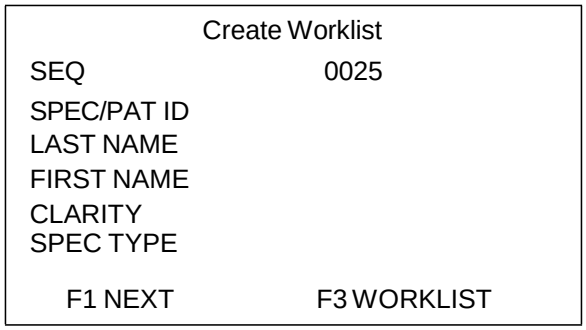
Creating a Worklist

The ***Create Worklist*** screen allows you to generate a list of specimen samples that will run in a batch mode. To create a worklist, you must enter information in at least one of the identifier fields. An error message will direct you to enter missing information before advancing to the next specimen. The sequence number field is only active for the first specimen in the ***Create Worklist*** option. After the first specimen, the instrument will automatically advance one sequence number each time a new patient specimen is entered.

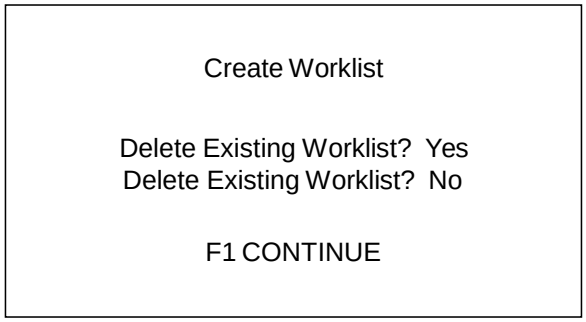
1. From the ***Main Menu*** screen, press the [**F1**] key to display the ***Worklist Menu*** screen.



2. From the ***Worklist Menu*** screen, press the [**F1**] key to display the ***Create Worklist*** screen.



3. The following screen will appear only if a worklist exists. Use the Up or Down arrow keys to select **YES** or **NO**.



a. If you select **YES** and press the [F1] key, the instrument will delete the existing worklist and advance you to the Create Worklist screen.
b. If you select **NO** and press the [F1] key, the instrument will return you to the ***Worklist Menu*** screen (above).

Sequence number

4. To reset the sequence number, change it while the initial specimen screen is active or you will need to return to the initial specimen screen in the worklist where the sequence number field will again be active.

Specimen/Patient ID

5. If desired, enter specimen or patient ID (up to 15 alphanumeric characters) by using the keyboard or the barcode reader. Press the [**Enter**] key or use the Up or Down arrow keys to move to the next field.

Last Name

6. If desired, enter the patient last name (up to 15 characters) using the keyboard or the barcode reader. Press the [**Enter**] key or use the Up or Down arrow keys to move to the next field.

First Name

7. If desired, enter the patient first name (up to 10 characters) using the keyboard or the barcode reader. Press the [**Enter**] key or use the Up or Down arrow keys to move to the next field.

Clarity

8. You can enter clarity by either toggling through the list of clarity options found in the software or by using the barcode reader. Barcodes are located at the top left of the instrument.

Using keyboard entry		**Using barcode entry**	
Options	Blank Field Clear Hazy Slt Cloudy Cloudy Turbid Bloody Other	Options	CLEAR SLT CLOUDY CLOUDY BLOODY OTHER
Press the left or right arrow keys until the desired clarity result appears. Press the **[Enter]** key or use the up or down arrow keys to accept and move to the next field.		To select clarity using the barcode reader, determine the clarity result and click the barcode reader over its respective barcode.	

Specimen Type

9. You can enter the specimen type by either toggling through the list in the software or by using the barcode reader. Barcodes are located at the top left of the instrument.

Using keyboard entry		**Using barcode entry**	
Options	Blank field Random Cl Catch Cath Peds First AM 24 hours Fasting Gluc tol S pubital Other	Options	RANDOM CL CATCH CATH PEDS OTHER
Press the left or right arrow keys until the desired clarity result appears. Press the [Enter] key or use the up or down arrow keys to accept and move to the next field.		To select specimen type using the barcode reader, determine the specimen type and click the barcode reader over its respective barcode.	

10. Once the desired patient identification information has been entered for the current specimen, proceed to the next sample by pressing the [**F1**] key. A blank ***Create Worklist*** screen will be displayed ready for the next sample. The sequence number will automatically advance by one number. Repeat this process until information has been entered for all specimens.

11. You can return to the previous specimen information by pressing the [**F2**] key.

12. When all specimens have been entered, press the [**F3**] key to return to the ***Worklist Menu*** screen.

Downloading a Worklist

See *iCHEM100 Operators Manual* for this procedure.

Viewing and Editing a Worklist

See *iCHEM100 Operators Manual* for this procedure.

Running a Worklist

1. From the ***Main Menu*** screen, press the [**F1**] key to display the ***Worklist Menu*** screen.

2. From the ***Worklist Menu*** screen, press the [**F4**] key to display the ***Run Worklist*** screen. The first specimen's information from the stored worklist will be displayed, thus identifying the specimen to be run by the operator.

The green LED light on the instrument will be illuminated, indicating that the instrument is activated and waiting for a urine test strip to be placed on the transport mechanism.

NOTE: If the waste container is nearly full (> 125 strips), you must empty it before beginning "Run Patient" analysis.

NOTE: The urine specimen should be fresh, well-mixed and uncentrifuged. If refrigerated, allow the specimen to return to room temperature.

3. Dip the urine test strip into the urine, making sure all the test pads are wet.
4. Immediately remove the urine test strip from the urine, dragging the edge of the strip against the side of the container as you remove the strip.
5. Blot the urine test strip by touching the edge of the strip to a paper towel. Do not drag the strip across the paper towel; touch the edge only.
6. Place the urine test strip on the transport belt of the instrument with the test pads facing up. Slide the strip forward until the strip touches the end stop. A sensor will detect the presence of the strip and the red LED light will be turned on along with the green LED light.

NOTE: If you move the strip away from the sensor prior to being transported, you will be prompted to remove the urine strip from the transport belt and press the [**F1**] key to continue.

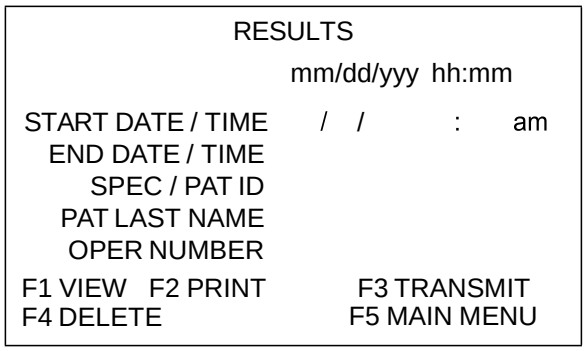
7. Approximately two minutes after the urine strip is transported for analysis, the printer will print the results; unless printing has been set to "Print Function Only" Results will also be transmitted to the LIS.
8. Once the strip is transferred to the incubation belt, the transport belt will stop, the green LED light will again come on and the screen will be updated to identify the next specimen to be run. Place the next specimen on the transport belt and the system will repeat the process. Continue until all samples have been tested.
9. After the last specimen has been analyzed from the worklist, the printer will print the results for all of the specimens processed from the worklist, unless printing has been set to "Print Function Only". Refer to Setting up the printer in the *iCHEM100 Operators Manual*. All results will be transmitted to the LIS

Printing a Worklist

1. From the ***Worklist Menu*** screen, press the [**F5**] key to print a copy of the worklist.
2. The screen notifies you that the worklist is being transmitted to and printed by the printer (internal or external).
3. To stop the printing process, press the [**F1**] key. This will return you to the ***Worklist Menu*** screen.
4. All printouts begin with a customized header (refer to Setting up the printer or the instrument name in the *iCHEM100 Operators Manual*.) Following the header information is the sequence number and specimen information for each of the specimens on the worklist. If the information for a line is not present, the line is skipped.

Re-Printing Results

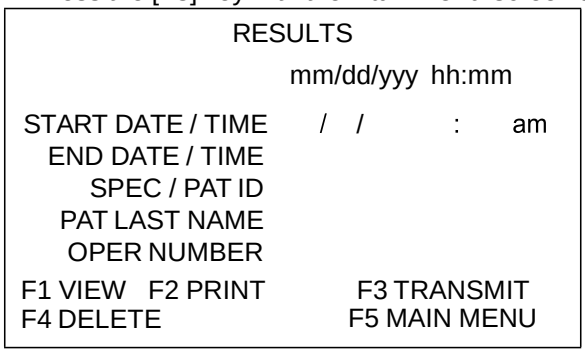
1. Press the [**F3**] key with the ***Main Menu*** screen active to bring up the ***Results*** screen.



2. Select the results you wish to re-print by specifying the date, specimen or patient ID, patient last name, or operator number in the search fields.
3. Press the [**F2**] key to print results. A screen will appear indicating that results are being printed.
4. Press the [**F1**] key to stop printing, if desired. The printing will stop after the print queue is emptied.
5. At the end of printing, the screen will revert back to the ***Results*** screen.

Re-Transmitting Results

1. Press the [**F3**] key with the ***Main Menu*** screen active to bring up the ***Results*** screen.



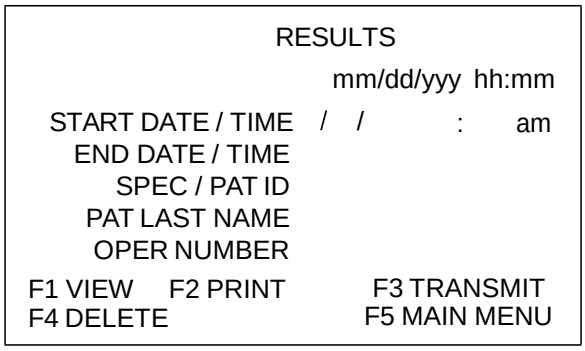
2. Select the results you wish to re-transmit by specifying the date, specimen or patient ID, patient last name, or operator number in the search fields.
3. Press the [**F3**] key to send results to the laboratory information system (LIS). A screen will appear indicating that results are being transmitted. Transmitted results will include:
   - Date and time of analysis
   - Sequence number
   - Patient first and last name, if available
   - Specimen or patient ID
   - Operator's name, if available
   - Specimen type, if available

- Color
- Clarity, if available
- Chemistry results with flagging
- Microscopic results, if available

4. Press the [F1] key to stop the transmission, if desired.
5. At the end of transmission, the screen will revert back to the Results screen.

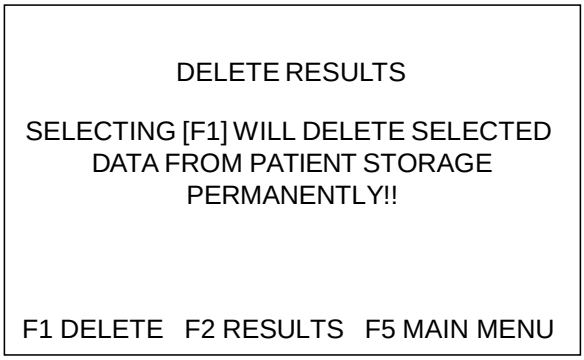
Deleting Results

1. Press the [**F3**] key with the ***Main Menu*** screen active to bring up the ***Results*** screen.



2. Select the results you wish to delete by specifying the date, specimen or patient ID, patient last name, or operator number in the search fields.
3. Press the [**F4**] key to delete results from patient storage.

WARNING: If no entry has been made into any of the search fields, the instrument will delete ALL results from patient storage. You will receive a warning message asking for confirmation to delete results.



- Press [**F1**] confirm the deletion and return to the ***Results*** screen.
- Press [**F2**] return to the ***Results*** screen without deleting results.
- Press [**F3**] return to the ***Main Menu*** screen without deleting results.

Maintenance

Recommended Maintenance & Cleaning

Instrument parts that may be cleaned or disinfected:

- Main Housing
- Transport Mechanism Enclosure
- Waste Container
- Chassis
- Strip Catch Plate
- Pulleys

DO NOT wash or rinse:

- Keyboard
- Printer
- Power supply
- LCD display screen
- Electrical or computer connection

Daily Maintenance

Material needed: Iris System Cleanser (**Part number 800-3203**)

1. Power OFF instrument.
2. Wipe (do not spray) surfaces that come in contact with specimens/strips with Iris System Cleanser. Rinse with water and dry with a soft cloth or paper towel. Avoid excess moisture.
3. Empty waste container of strips and clean with Iris System Cleanser. Rinse with water and dry with a soft cloth or paper towel. Refer to ***Emptying Waste Container***.
4. Examine belt assembly and pulleys for debris, damage, belts off track, twisting or spills.

Weekly Maintenance

1. Clean belt assembly. Refer to ***Cleaning the Belt Assembly***.

Emptying Waste Container

Material needed: Iris System Cleanser (**Part number 800-3203**)

1. To empty the waste container, slide the transport mechanism enclosure towards you and away from the instrument.
2. Set the container on the counter or some other flat surface. (An error message may be displayed on the screen.)

WARNING! Transport mechanism enclosure is ajar. Please remove all urine strips on belt After replacing enclosure, Press F1 if enclosure was not emptied, or Press F2 if enclosure was emptied. F1 NOT EMPTIED F2 EMPTIED

3. Remove the lid of the transport mechanism enclosure.
4. Remove the waste container from the enclosure and discard the urine test strips in an appropriate waste container.
5. Clean with Iris System Cleanser, rinse with water and dry with a soft cloth or paper towel.
6. The entire transport mechanism enclosure can be cleaned with Iris System Cleanser and then rinsed with water and dried, or wiped with a damp cloth at this time, if needed.
7. Replace the waste container in the transport mechanism enclosure and replace the lid.
8. Slide the transport mechanism enclosure back on the instrument until you hear a click. This assures you that it is properly positioned for running.
9. Press [**F2**] if you emptied the waste container, or press [**F1**] if you did not. The instrument will reset the counter when emptied.

Cleaning the Belt Assembly

Material needed: Iris System Cleanser (**Part number 800-3203**)

1. Press the power switch located at the back right of the instrument to power the instrument off.
2. Remove the transport mechanism enclosure by sliding it towards you and away from the instrument. The belt assembly is now visible.
3. Gently remove belts from transport and incubation pulleys. Wash with soap and water, and then dry them with a soft cloth or paper towel.

NOTE: Do not soak the belts.

4. Wipe the incubation and transport rollers with Iris System Cleanser and dry carefully.
5. Replace the belts in their original grooved positions.
6. Replace the cover and slide the transport mechanism enclosure back on the instrument until you hear a click indicating that it is properly positioned for running.
7. Press the power switch located at the back right of the instrument to power the instrument on.
8. After replacing the belts (and prior to running strips), run the Transport [**F3**] and Incubation [**F4**] drives for 1 minute to reseat belts and remove any twists. Refer to ***Load Drive Test*** and ***Inc Drive Test***.

As needed - Replacing the Paper Roll

Material needed: Thermal paper rolls (**Part number 800-7511**)

1. Tear off any excess paper from the paper feed.
2. Pull out the remaining paper and remove the empty core.
3. Feed the paper manually under the printer roller with the inside face of the paper upward and away from you.
4. Make sure the instrument is powered on.
5. Press the [**Page Up**] key until the paper comes through the opening at the top of the instrument as shown above.
6. Place the paper roll into the paper holder at the top of the instrument.

Diagnostics

This function provides you with a set of diagnostic functions to help troubleshoot an instrument performance issue. Selecting one of the functions will activate the instrument to perform the specific function.

1. From the ***Main Menu*** screen, press the [**F7**] key, then press the [**F4]** key. The ***Diagnostics*** screen will be displayed.

DIAGNOSTICS

F1 LCD TEST	F6 RGB TEST
F2 PRINTER TEST	F7 MECHANICAL TEST
F3 LOAD DRIVE TEST	F8INTERNL STD TEST
F4 INC FRIVE TEST	F9 SERVICE MENU
F5 LED TEST	F10 MAIN MENU

NOTE: The transport mechanism enclosure can be removed while performing any of the tests.

LCD Test

1. From the ***Diagnostics*** screen, press the [**F1**] key to activate the LCD display to perform a number of diagnostic procedures that tests its operational capabilities, (completely reversed screen, clear screen and a screen with alphanumeric characters). Press the [**F1**] key until the ***Diagnostics*** screen is displayed

Printer Test

1. Insure that paper is present before testing.
2. From the ***Diagnostics*** screen, press the [**F2**] key to print several lines of alphanumeric characters.

Load Drive Test

This test is performed after cleaning or replacing the transport belts to reseat belts and remove any twists.

1. From the ***Diagnostics*** screen, press the [**F3**] key to activate the transport belts on which the urine test strips are loaded. After one minute, press the [**F1**] key to stop the belts.

Inc Drive Test

This test is performed after replacing the incubation belts to reseat belts and remove any twists.

1. From the ***Diagnostics*** screen, press the [**F4**] key to activate the incubation belts on which the urine test strips are transported for analysis. After one minute, press the [**F1**] key to stop the belts.

LED Test

1. Remove the transport mechanism enclosure before performing the test.
2. From the ***Diagnostics*** screen, press the [**F5**] key to bring up the LED Test screen.

LED TEST
Please select with function keys

F1 GREEN LED ON
F2 RED LED ON
F3 LEDs ON
F4 LEDs OFF

F5 CONTINUE

3. Use the designated function keys to activate the different LED light combinations and observe the LED lights located above the transport belts on the left side of the instrument.

Press the [F] key	LED On	LED Off
[F1]	Green	Red
[F2]	Red	Green
[F3]	Red and Green	-
[F4]	-	Red and Green

4. When completed, press the [**F5**] key to return to the ***Diagnostics*** screen.

RGB Test

1. Remove the transport mechanism enclosure while performing the test.
2. From the ***Diagnostics*** screen, press the [**F6**] key to bring up the following RGB (Red, Green, and Blue LEDs) optics test screen.

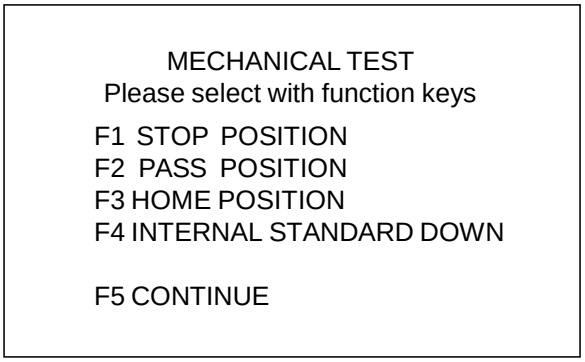
RGB TEST
Please select with function keys

F1 START RGB MEASUREMENT
F2 CONTINUE

3. Press the [F1] key to activate the RGB test. Observe under the second incubation roller (right of the instrument) to see if all three wavelengths (red, green and blue) illuminate. Repeat this step, if necessary.
4. Press the [**F2**] key to return to the ***Diagnostics*** screen.

Mechanical Tests

1. Remove the transport mechanism enclosure while performing the test.
2. From the ***Diagnostics*** screen, press the [**F7**] key to bring up the ***Mechanical Test*** Screen.



3. Use the designated function keys to activate the different mechanical functions. Check for correct positions under the optics.

Press the [F] Key	Action	Use for
[F1]	Position the urine test strip alignment device at its lowest position.	Stopping the urine test strips for alignment and measurement at the optics.
[F2]	Position the urine test strip alignment device at its middle position.	Allowing the urine test strips to pass the optics and to go into the waste container
[F3]	Return the urine test strip alignment device to its home position.	
[F4]	The internal standard should move to its lower position touching the incubation belts.	Test the functionality of the internal moveable standard.
[F5]	Return to the Diagnostics screen.	

Internal Standard Test

This test is designed to verify the optics system via a check of the nonmoveable “fixed” standard.

1. Make sure the transport mechanism enclosure is in place on the instrument before performing the test.
2. From the ***Diagnostics*** screen, press the [**F8**] key to initiate the test. The screen will display "*Internal Standard will be measured. Please wait*."
3. If the calibration check is acceptable, the screen will return to the ***Diagnostics*** screen. If the calibration check fails, the following screen will be displayed

4. If this test fails, repeat it at least one more time. If it fails again, contact Iris Technical Support group (see ***Before Calling for Service***).

Exit Diagnostics

1. You may exit the ***Diagnostics*** screen at anytime by pressing the [**F9**] key to return to the ***Service Menu*** screen, or pressing the [**F10**] key to return to the ***Main Menu*** screen.

Table of Results

Parameter	Conventionl Units	S.I. Units	Qualitative Units
Bilirubin	Neg 1 mg/dL 2 mg/dL 4 mg/dL	Neg 17 umol/L 35 umol/L 70 umol/L	Neg + ++ +++
Urobilinogen	Norm 2 mg/dL 4 mg/dL 8 mg/dL 12 mg/dL	Norm 35 umol/L 70 umol/L 140 umol/L 200 umol/L	Norm + ++ +++ ++++
Ketones	Neg 25 mg/dL 100 mg/dL 300 mg/dL	Neg 2.5 mmol/L 10 mmol/L 30 mmol/L	Neg + ++ +++
Ascorbic Acid*	Neg 20 mg/dL 40 mg/dL	Neg 1.14 mmol/L 2.28 mmol/L	Neg + ++
Glucose	Neg 50 mg/dL 150 mg/dL 500 mg/dL >= 1000 mg/dL	Neg 3 mmol/L 8 mmol/L 28 mmol/L >= 56mmol/L	Neg + ++ +++ ++++
Protein	Neg 30 mg/dL 100 mg/dL >= 500 mg/dL	Neg 0.3 g/L 1 g/L >= 5 g/L	Neg + ++ +++
Blood Hemoglobin	Neg 0.03 mg/dL 0.2 mg/dL 1 mg/dL	Neg 0.3 mg/L 2 mg/L 10 mg/L	Neg + ++ +++
Blood RBCs	Neg 5-10 RBCs/uL 50 RBCs/uL 300 RBCs/uL	Neg 5-10 RBCs/uL 50 RBCs/uL 300 RBCs/uL	Neg 5-10 RBCs/uL 50 RBCs/uL 300 RBCs/uL
pH	5 6 7 8 9	5 6 7 8 9	5 6 7 8 9
Nitrite	Neg Pos	Neg Pos	Neg +
Leukocytes	Norm 25 WBCs/uL 75 WBCs/uL 500 WBCs/uL	Norm 25 WBCs/uL 75 WBCs/uL 500 WBCs/uL	Norm 25 WBCs/uL 75 WBCs/uL 500 WBCs/uL

* Ascorbic Acid is not reported at UCDHS

Table of Results (continued)

Parameter	Conventional Units	S.I. Units	Qualitative Units
Bilirubin	Neg 1 mg/dL 2 mg/dL 4 mg/dL	Neg 17 umol/L 35 umol/L 70 umol/L	Neg + ++ +++

Parameter	Available Results
Color	Blank, Colorless, Straw, Yellow, Orange, Amber, Red, Red Brown, Green, Brown, Black, Other
Clarity	Via barcode reader: Clear, Slt Cloudy, Cloudy, Bloody, Other Via Keyboard: Clear, Hazy, Slt Cloudy, Cloudy, Turbid, Bloody, Other
Specimen Type	Via barcode reader: Random, Cl Catch, Cath, Peds, First am, 24 hrs, Fasting, Gluc Tol, S Pubital, Other

References

1. Iris Operators Manual for the iChem100 Urine Analyzer, 300-4410 Rev B 06/2006, Iris Diagnostics, A Division of IRIS International, INC., Chatsworth, CA 91311

Prepared By	Date Adopted	Supersedes Procedure #
Michael Inn	07/09/2008	New

Revision Date	Type of Revision	Revised by	Review/Annual Review Date	Reviewed By
			07/09/2008	G. Kost
			09/15/2009	G. Kost
			10/12/2010	G. Kost
			11/16/2011	G. Kost
			11/20/2013	G. Kost
03/20/2015	Change to MAS Urine Controls and SG Reported by Refractometer	kdagang	04/15/2015	J. Gregg