Hackensack Meridian
HEALTH

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SUBJECT: Urines	TITLE: Routine Urinalysis using the iRICELL Automated Urinalysis System
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INTENDED USE: The iRICELL is an in-vitro diagnostic system. The Iris System consists of two analyzers, the iChem VELOCITY and the IQ 200, the iChem VELOCITY is an automated urine chemistry system performing measurements of urine physical and chemical constituents utilizing test strips read by Wavelength Reflectance, and specific gravity using the Refractive Index. Since the iChem VELOCITY also determines color and clarity, a complete urinalysis is determined automatically. The IQ200 system is an in-vitro diagnostic device used to automate microscopic sediment analysis. It produces quantitative or qualitative counts of all formed sediment elements present in urine, including cells, casts, crystals, and organisms. Rules are set up for review by a trained operator.

THEORY OF OPERATION: The iChem VELOCITY performs the chemistry panel, determines the specific gravity, color, and clarity of a urine specimen. The chemistry panel is performed using a test strip, which detects the presence of 9 elements- glucose, protein, bilirubin, urobilinogen, pH, blood, ketones, nitrite, and leukocytes by wavelength reflectance. Specific gravity is determined by measuring the refractive index. Color is measured by transmitted light and clarity is measured by scattered light.

The IQ 200 performs the microscopic portion of the urinalysis and provides a count of formed elements such as casts, cells, crystals, and bacteria. The IQ 200 photographs particles as they are passed through a digital camera. The images are classified, counted, and stored for verification by the operator.

The workcell consists of a computer that is interfaced with the iChem VELOCITY and IQ200. At the workcell, results of the chemistry profile and the microscopic analysis are collated, compared to defined criteria and stored for release or verification.

PRINICIPLE: The iChem VELOCITY is a urine chemistry analyzer that measures the chemical constituents of the urine using the iChem VEOLCITY strips, which are read by a dual wavelength reflectance system. The iChem VELOCITY strips consist of a plastic strip containing 9 pads impregnated with chemicals specific for the determination of a particular constituent. The 9 analytes measured are: glucose, protein, bilirubin, urobilinogen, pH, blood, ketones, nitrite, leukocytes esterase, ascorbic acid, and a color compensation pad. A color compensation pad is included on the strip to compensate for the natural color of urine and its effect on the color of the reaction pads. Test strips are placed onto a strip conveyor system by a mechanical extractor. The sample probe mixes the sample, aspirates and aliquot of urine and dispenses it onto each reagent pad. At defined wavelengths, the iChem VELOCITY analyzes the color changes and the intensity of reflected light from the reaction pads. These measurements are used to calculate clinically meaningful results.

The microscopic portion of a routine urinalysis is performed on the IQ200 analyzer. The IQ200 auto-identifies and processes specimens by mixing (The pipettor mixes the sample by delivering an air bolus), sampling and analyzing the data obtained from the sample. Approximately 1ml of the mixed specimen is aspirated and is sandwiched between enveloping layers of a suspending fluid called lamina. The IQ lamina is used to position the formed elements in the best orientation that presents the particles with their largest profile facing the direction of view. The camera captures 500 pictures per sample. The flash of a strobe lamp illuminates each field. The pictures are digitized and sent to the instrument processor. Individual particle images are classified into one of 12 categories using size, shape, contrast, and texture. The auto-classified categories are RBCs, WBCs, WBC clumps (WBCC), hyaline casts, unclassified casts (UNCC), squamous epithelial cells, non-squamous epithelial cells (NSE), bacteria, budding yeast, unclassified crystals (UNCX), **sperm (DO NOT REPORT),** and mucus. Any image that doesn't classify into one of these categories are placed in the unclassified category (UNCL). The particle concentration is calculated using the number of images, normalization factor and volume scanned. The tech must classify all pictures in the unclassified casts UNCC and unclassified crystals UNCX categories. The tech must also classify the cells in the NSE category as either artifact, renal or transitional epithelial cells. The tech is also responsible for estimating a bacteria count if any. Once the verification has been completed, the ACCEPT button is pressed and results cross to the LIS.

CARRYOVER:

Carryover is checked by doing a carryover study upon initial installation/evaluation of the instrument. This is performed by the field service engineer; the report is within the validation binder. A carryover study is also done by the field service engineer when there is a major repair/replacement of a pipetting assembly. After installation checks the carryover study is completed by comparing the positive QC results to the negative QC results. For the IQ controls the negative must be run after the positive control and must read 0-20 ul. The velocity QC should be run as directed in the QC rack. Velocity QC has a mix of positive and negative analytes in CA and CB. This means that carryover is not only checked by the FSE but also on a daily basis when running QC.

MATERIALS: Please see the table below for consumable information.

CONSUMABLES	STORAGE	PACKAGING AND USE
iChem VELOCITY strips (800-7212)	*Room Temp *Stable unopened until exp. On bottle. *5 days in the strip provider Module	Bottle of 100 strips
iChem Wash Solution and wash filter (800-7704)	*Room Temp *Stable unopened until exp. on bottle. *Open bottle stability= 90 days *change white filter every bottle	2 bottles per case
CA/CB/CC QC (800-7702)	*Refrigerate 2-8 C *Stable unopened until exp. on bottle *Open bottle stability= 15 days *Bring poured aliquot to room temp before use in dark space.	3 bottles of each QC in box
iChem VELOCITY CalChek Kit (800-7703)	*Room Temp *Stable unopened until exp. on bottle. *Open stability= 8 hrs; re-use within 8hrs	2 sets of 5 strips per kit Single use Done Quarterly
IQ Lamina (800-3102)	*Room Temp *Unopened/opened stability=date on bottle *change green filter every 2nd bottle	2 bottles per case
Iris System Cleanser (800-3203)	*Room temp *Unopened/opened stability= date on bottle	4 bottles per case
Iris Diluent (800-3202)	*Room temp *Unopened/opened stability= date on bottle	4 bottles per case
IQ Calibrator (800-3103)	*Refrigerate 2-8 C *Unopened stability=date on bottle *Open bottle= 24 hours	4 bottles per box use monthly
IQ Control/Focus Set (800-3104)	*Refrigerate 2-8 C *Unopened stability= date on bottle *Open bottle stability= 30 days	1 bottle each of pos and neg 2 bottles of focus Lot specific barcodes
Urine conical tubes (globe)	N/A	1000 per case

SPECIMEN TYPE:

A freshly voided urine sample (<2hours at room temperature). The first morning sample yields the most meaningful results. Samples are collected in the BD urine collection system or a sterile collection cup and are sent to the lab for analysis. Urines should be sent to the lab as soon as possible after collection and should be examined within 1-2 hours of collection. If samples are not able to be analyzed within 1-2 hours of collection, please store the sample in the refrigerator at 2-8 C. Samples must be brought to room temp prior to analysis. Urine samples containing preservative are not acceptable and must be re-collected.

Specimen volume placed on the iRICELL must be at least 4mL. If iChem VELOCITY testing alone the minimum volume is 2mL.

QUALITY CONTROL:

Quality Control must be run every 24 hours of patient testing for both chemistry and microscopy modules. Use IRISPEC CA/CB/CC iCHEM URINE CONTROL TRIPLET SET as your QC material for the iCHEM VELOCITY.

Intended use:

This is assayed QC material and is designed for the monitoring of urine chemistry analytes on the iCHEM VELOCITY.

Storage:

Store at 2° - 8°C. Protect from light. Refrigerate immediately upon receipt.
Unopened stability: Stable until expiration date printed on bottles.
Open stability: 15 days at 2° - 8°C.

Limitations:

Minimize oxygen exposure of product. DO NOT SHAKE/MIX BOTTLES. Improper storage and handling may reduce analyte concentration (specifically bilirubin) and may prematurely result in a negative reading.

Additional QC is run:

When a new lot number or shipment of iChem VELOCITY Strips is opened. IriSpec CA/CB/CC controls should be run. Document on QC printout the new lot#, this is to ensure that the system is operating within acceptable criteria.
After major maintenance or service.
When you have questionable results.

Acceptability:

Each new lot number of IRISPEC CA/CB/CC is supplied with a package insert with assay values and acceptable result ranges. Those result ranges as well as lot number and expiration date are entered in the instrument screen on the computer. Beckman will in close a card in the QC box notifying the user of a change in parameters.

- Select Consumables
- Select Chemistry QC

- Enter Chemistry control CA lot and expiration date listed on the reagent box
- Select next
- Enter Chemistry control CB lot and expiration date listed on the reagent box
- Select next
- Enter Chemistry control CA lot and expiration date listed on the reagent box
- Select OK.

When a new lot of IRISPEC CA/CB/CC arrives it will need to be run 10 times along with the current lot to verify the manufacturers recommended values. These printouts will be saved in the QC binder under lot/lot. Make a note on paper work as to what it is.

Running QC:

Running QC on the iChem VELOCITY

1. Obtain the iChem QC rack.
2. Remove the CA/CB/CC QC from the refrigerator and pour a 3 mL aliquot of each level into conical bottom urine tube and place into the appropriate color position on rack. Let stand at room temp for 15 minutes in the dark.
3. Place the rack on the iChem VELOCITY.
4. The system compares the expiration date of the QC material and chemistry strip to the current instrument date/time, to verify that the material or chemistry strip is valid for use.
5. If an expired material was used, the system will display a red alarm for the iCHEM VELOCITY only, and sample processing cannot be performed.
6. QC results will print after analysis. Please review each level for PASS and initial and file papers in QC binder
7. Record on Corrective Action Log if QC fails what you did to correct the problem in order to run patients

Possible reasons for QC failure

- Aliquots placed in wrong position on rack. Re-pour and re-run.
- Check the open date of the QC bottle. Good for 15 days.
- Check strips for discoloration- if found, replace strips and re-run.
- Pour new bottle of QC.
- Repeat the run using a new lot number.
- If results are still not acceptable, contact supervisor and/or call hotline.
- Patient samples will not be processed by the analyzer until the QC issue is resolved.

Viewing/Reviewing QC Results:

- Results obtained by the instrument for each control and control level are automatically compared by the software to the acceptable result ranges. These ranges had previously been entered for this lot# and are stored in the instrument software.
- When control testing is complete, the results will automatically print.
- From the instrument screen, locate the Last QC field. If all of the results are within acceptable range, the date and time will display. If any QC material failed, the Last QC field will display (--)
- To see the individual QC runs from the Instrument screen, select the **Quality Review** button. The Quality Review is displayed.
- To see the QC report for a specific material, highlight the desired ID and click the **Re-report** button. You can also double click on the desired ID to open the Re-Report destination screen.
- Ensure the **Current Row** is selected, and **Screen** is selected as the destination.
- Select **OK**

Control Material iQ200: **-**IQ Control/Focus Set is used to focus and control the instrument.
-IQ Positive control is used as an abnormal, and IQ Negative control is used as a normal control to verify accurate counting by the instrument.
-IQ Focus is used to check light level and focus the instrument.
-IQ Positive Control and IQ Focus are suspensions of fixed human red blood cells in a buffered isotonically balanced solution.

Storage: Store IQ Control/Focus Set at 2° - 8°C.
Unopened stability: Stable until expiration date printed on bottles.
Open stability: 30 days at 2° - 8°C .

Acceptability: Barcode labels that contain Lot number, Expiration date and Expected Ranges are provided for each product and lot#. A highly accurate concentration count of these cells is certified and the expected counting reference value is printed on each label.

Additional QC is run: After calibration.
After major maintenance or service.
When you have questionable results.

Running QC on the IQ200.

1. Obtain the IQ200 QC rack.
2. Place appropriate barcode labels on urine tubes for Focus, Positive and Negative QC.

3. The Focus and Positive QC must be mixed by 5 vigorous shakes followed by 5 gentle inversions. Pour these last.
4. Pour the following into the urine tubes in the IQ QC rack.
5. ****QC must be run immediately after pouring****
    a. Position 1: 3ml of Iris Cleanser
    b. Position 2: 3ml of Iris Diluent
    c. Position 3: 3ml of Iris Diluent
    d. Position 4: LEAVE EMPTY
    e. Position 5: 6ml of Focus reagent
    f. Position 6: 3ml of Positive QC
    g. Position 7: 3ml of Negative QC
6. Place rack on the IQ analyzer and press run.
7. Results for NEG and POS QC will print out. Please review for PASS and file in QC binder. Ideally the Negative count should be <5. If this trends upward it is an indicator of possible carryover. Any value over 20 for negative control will fail.
8. Record on Corrective Action Log if QC fails what you did to correct the problem in order to run patients.
9. When running Lot/Lot for new lot# of IQ QC place the Positive control in position 8 and the Negative control in position 9. Use the barcode labels from the box containing the new lot on those tubes. These values will be recorded under Secondary QC. **NOTE: The labels are lot specific. DO NOT mix barcode labels with different lots**.
10. Any new lot of control needs to be run 10 times to verify the manufacturer's ranges.
11. Secondary control positions, 8 and 9 are optional and intended to allow the lab to run controls for parallel lot/lot studies. The new lot of QC will be recorded under Secondary QC in the Iris. Place the printouts in lot/lot section of the QC binder.
12. Any control rack containing a tube in position 8 and 9 must contain tubes in position 6 and 7.
13. **Do not place tube in position 10 of IQ QC rack, it will shut down the system.**

Possible reasons for QC failure

- Look at message code to see why QC failed. If failed due to ID error or QC out of order, re-pour and re-run.
- If results are still not acceptable, call hotline.
- Do not process patient samples until QC failure has been resolved!

Viewing/Reviewing IQ QC Results:

- Results obtained by the instrument for each control are automatically compared by the software to the acceptable result ranges. These ranges are in the Bar-code label and are stored in the instrument software.
- When control testing is complete, the results will automatically print.

- Look to see that the QC passed. The negative control should ideally be less than or equal to 5 (this is a check for carryover) if this value continues to trend high there could possibly be an issue- call hotline.
- From the instrument screen, locate the Last Micro QC field. If all of the results are within acceptable range, the date and time will display. If any QC material failed, the Last Micro QC field will display (--)
- To see the individual QC runs from the Instrument screen, select the **Quality Review** button. The Quality Review is displayed.
- To see the QC report for a specific material, highlight the desired ID and click the **Re-report** button. You can also double click on the desired ID to open the Re-Report destination screen.
- Ensure the **Current Row** is selected, and **Screen** is selected as the destination.
- Select **OK**

CALIBRATION: **IQ 200**

Calibration is performed monthly on the IQ.

1. Obtain the IQ Calibration Pack from the fridge
2. Take 10 urine tubes and place in the IQ CAL Rack
3. Place a barcode label from the box on ONLY tube #1
4. Shake the Calibrator vigorously 5 times followed by 5 gentle inversions and pour 4mls into each of the 10 tubes.
5. Load CAL rack on IQ 200 press start.
6. You will know if it passed when the current date and time update on the instrument page under IQ Calibration and new REF value. You will get a pop up box if it fails.
7. If calibration fails, you must repeat the calibration with new Calibrator material. Follow above mixing procedure.
8. RUN QC and indicate on the papers POST CALIBRATION and file in the QC binder.
9. QC must be acceptable before patient samples can be run.

Reasons for Failure

1. Barcode label ONLY goes on tube 1
2. You didn't mix the bottle well- use a new bottle and MIX well.
3. If the repeat Cal still fails Call hotline.

ICHEM VELOCITY REFLECTANCE CALCHEK AND CGM CALCHEK

Calibration Check is Performed Quarterly

- **Performing iChem Velocity Reflectance Check:**

NOTE: Since the test strips remaining inside the test strip chamber must be discarded, it is recommended to perform a reflectance CalChek when the chamber is empty.

1. Click on the **Instrument** button on the top right side of the main screen.
2. Click on the **Maintenance** button located at the bottom of the **Instrument** screen
3. Click on the **Reflectance Check** button. The system will display a series of six screens. Follow the instructions on the screens.
4. If needed, access the test strip provider. Remove and discard all chemistry test strips present inside the chamber
5. Pull the Strip Loader out of the system. Before loading CalChek strips wipe each strip with a Kim wipe to remove any static charge. Load the CalChek strips inside the Strip Loader, and then push the Strip Loader back inside the system. Rotate the Strip Loader 180 degrees counter clockwise to transfer the strips to the Strip Provider Module.
6. Verify that the Lot ID number and the expiration date from the CalChek strip container match the data from the screen. Modify if necessary.
7. Follow the directions on the screens.
8. When Completed, Reload iChem Velocity Test Strips.
9. Press Finish to return to the Chemistry strip lot information screen. Check the information related to the loaded test strips, modify if necessary.
10. The reflectance CalChek results can be reviewed in the Quality Review screen. The date and time will be updated on the Instrument screen under-Last Reflectance Check. If calibration check fails- call hotline for direction.

- **Performing iChem Velocity CGM CalChek (Specific Gravity, Color, and Clarity CalChek):**

1) Obtain 10 CalChek solution tubes from Calchek kit, stored at room temperature.
2) Gently invert the tubes to mix the solution.
3) Number caps with corresponding tube number before removing the cap from each tube, remove each cap, and then place the tubes into corresponding number and color on the Calibration iChem navy blue rack (in position 1(pink), 4(blue) and 8(green)). Make sure that the barcode labels are placed at the correct positions and visible to the barcode reader.
4) Load the Calibration rack onto the right side of the iChem Velocity sampler.

5) The rack will be processed and all calculations performed automatically. The CalChek liquid reagents can be re-used within eight (8) hours.
6) When the CalChek is successful, the date/time of the new SG/CC CalChek will be displayed on the summary screen. The SG/CC CalChek status (Pass/Fail) can be reviewed in the QC Review screen. The measured values are compared to acceptance ranges stored in the system. If all the values fall within the appropriate ranges, the CalChek is verified and found acceptable.

CalChek Failure

1) Repeat the run using the same lot number.
2) Repeat the run using a new lot number.
3) If the repeat CalChek still fails Call hotline.

MAINTENANCE

Maintenance is performed at timed intervals on both the iChem VELOCITY and the IQ 200.

Daily Maintenance

iChem VELOCITY

1. Empty and clean the strip waste container with a damp cloth followed by an alcohol prep.
2. Clean the STM (Strip Provider Module) by placing a 1:10 solution of Iris Cleanser on a paper towel or gauze pad, followed by distilled water and dry.
3. Clean the instrument surface the same as above.
4. Check wash solution (**change the white filter each time wash is changed**).
5. Run QC - CA/CB/CC.
6. Initial the maintenance log.

IQ 200

1. Check the Lamina supply- replace if necessary. **(Change green filter- every newly opened box**)
2. Clean the STM (Strip Provider Module) by placing a 1:10 solution of Iris Cleanser on a paper towel or gauze pad, followed by distilled water and dry.
3. Clean the instrument surface same as above.
4. Run QC in the IQ QC rack.
5. Record the negative control value to monitor the sample filter.
6. Initial the maintenance log

Weekly Maintenance

iChem VELOCITY

1. Clean the strip provider module with a lintless tissue or vacuum and initial the maintenance log.

2. Perform Weekly CGM clean and initial the maintenance log.
   a. You will need Iris Cleanser, diH20, 2 yellow chemistry only racks, and 20 empty urine tubes.
   b. Place 10 urine tubes in rack 23 (chemistry only rack- yellow)
   c. In tubes 1-2 add 3ml of Iris Cleanser.
   d. In tubes 3-10 add 3ml of diH20.
   e. Run the rack through the VELOCITY as you would a patient sample.

   f. Place 10 tubes in the 2nd yellow chemistry only rack.
   g. Add 3 ml of diH20 to all 10 tubes.
   h. Run the rack through the VELOCITY as you would a patient sample.
   i. Delete the specimens from the Iris monitor.

IQ200

No weekly maintenance

MONTHLY MAINTENANCE

iChem VELOCITY

1. Clean the outer area of the wash station bath using a tex wipe/Q-tip and dH20. Do not put the Q-tip into the well.
2. Clean the strip conveyor module using a small amount of detergent or soap and water. Brush off visible urine buildup using a small brush and rinse clean. Shake excess water and pat dry with paper towel. Place in front of a fan to allow to dry**. DO NOT PUT BACK WET.**
3. Initial maintenance log.

IQ 200

1. Perform Instrument calibration- see under calibration.
2. Initial maintenance log.

Backup

1) If the system is online, select Go Off line. The system must be offline to perform a backup.
2) Select Backup. The system directs you to insert a blank media.
3) Label a blank CD using a sharpie with label given on the screen.
4) Follow directions on the screen.
5) When the backup is complete, select OK to close the dialog box.
6) Place CD into a CD sleeve in the binder.
7) Initial maintenance log.

Quarterly Maintenance

iChem VELOCITY

1. Perform Reflectance and SG/CC CalChek - see under calibration.
2. Initial maintenance log.

PATIENT SAMPLES:

1. Make sure samples are at room temperature at the time of analysis.
2. Mix sample by full inversion. If received in a cup aliquot 4 ml of patient sample into a conical bottom tube. If received in a urine collection tube **remove the YELLOW CAP.** Affix patient label about a thumbs width down from the top of the tube.
3. Put the sample in a numbered sample rack if you are running both a chemistry and micro sample. Place sample in a yellow rack if you are running only the chemistry.
4. Load the rack on the right hand side of the iChem VELOCITY. Ensure that the notch of the rack base is placed onto the sampler track ridge. Press Start or pull the rack towards you to activate run sensor. The natural path of the rack will take the sample through the iChem VELOCITY and then load the rack onto the IQ 200. The type of rack used will dictate whether or not the IQ 200 will sample the specimen.
5. Only Urines with positive results for any Blood, Protein, Leukocytes and/or Nitrite will automatically perform a microscopic on the IQ 200.
6. On all urines with a POS BILI, and ICTOTEST must be performed.
7. Results that require tech intervention will populate into the worklist.
8. Double click on the CID and the sample information of both the chemistry and microscopy can be viewed. If a flag is present, it must be reviewed then the accept button must be pressed indicating your review before continuing.
9. All abnormal results chemistry results will be red in color. It is important to take note of the positive reactions as well as the ASP number. The all small particles number can be used as a tool for the tech for the presence of bacteria. There is a strong likelihood that an ASP >7,500 will have bacteria in the sample- there is still a possibility to have bacteria in the sample if the ASP is <7,500.
10. The microscopy portion will present in three colors. Red for abnormal results, green for normal results, and yellow for tech decision making.
11. When ready to begin, hit the EDIT button.

12. A series of categories with pictures will be presented to the user. If the user agrees, the next button is pressed. If the user disagrees but can identify the formed element, they can reclassify it by choosing the category on the right, then the type. If moving all the pictures, press next. If moving some of the pictures, select the category and type, then choose the pictures then return to the left category button. If the remaining pictures are artifact, the ART category should be selected followed by the NEXT button.
13. The UNCL category is a representation of all 500 pictures taken from the sample organized by size. The user must scan for clinically significant items- casts, renal epithelial, and transitional epithelial cells. If found, the user must identify the category on the right, select the type, then select the pictures, and return to the UNCL button on the left.
14. It is important to always classify or ART out NSE- non squamous epithelial (renals and transitional), UNCX unclassified crystals, and UNCC unclassified casts.
15. The tech is responsible for looking for bacteria on every sample if there is red in the - Culture Indicator Area. Bacteria can be observed in the backgrounds of the WBC'S, WBCC, SQEP and MUCS pictures and should be noted. The IQ will only place bacteria rods in the category. The tech is responsible for looking for cocci.
16. Once the micro is completed, the tech must review the micro results and correlate to the chemistry results. When complete, the Accept button is pressed, which sends the results to the LIS.
17. The results will file into the computer system without tech intervention. The chemistry results will file first. After the results for the microscopic have been accepted in the IRIS software, those results will also auto-file into the computer system.

. **The tech must return to the microscope for the following:**

1. Trichomonas (observe motility)
2. Cellular casts

Running grossly bloody, viscous, or mucoid samples:

1. The chemistry portion of the urinalysis must be run in an orange rack- indicating chemistry only. When the undiluted sample (orange rack) reaches the furthest end of the IQ 200 then you can place the diluted sample rack onto the IQ 200.
2. A dilution must be prepared for the IQ 200 analyzer. Follow the following
    a. Decide on dilution, you should be able to see print through your diluted sample. Dilute sample using chart on the IQ 200.
    b. Affix a patient label to a conical bottom tube and prepare dilution according to the chart on the IQ 200 using Iris diluent.
    c. Chemistry and diluted micro results will combine and if review is required, will display in worklist. Follow procedure above for performing microscopic.

NOTE: *If the sample is extremely turbid, a manual microscopic should be performed*

Manual microscopic:

a. Resuspend sediment in fluid remaining. Place 1 drop onto slide and cover with coverslip
b. Examine 10-15 fields under low power with reduced light. The constituents examined under low power are the following to be reported as LPF:

MUCOUS:	Trace (0-1 strand) 1+ (1-3 strands) 2+ (3-10 strands) 3+ (10-20) 4+ (TNTC) too numerous to count
CASTS:	Count per LPF. Report type and average number of type seen.

c. Examine 10-15 fields under high power with maximum light. The constituents examined under high power are the following:

EPITHELIAL CELLS:	Rare; few (0-3) Moderate (3-10) Many (greater than 10)
WBCs:	Average the number of cells, report as: (0-2), (3-5), (8-10), (15-20), (30-50), (60-80), or TNTC (Too numerous to count)
RBCs:	Same as above
CRYSTALS:	Report type of crystal few (0-2), moderate (2-10), or many (greater than 10) NOTE: amorphous crystal can be identified by the pH of the sample. Report in the same way.
BACTERIA:	Report as follows: rare, few, moderate, many
MISC:	**Yeast:** report as rare, few, moderate, many (note budding/hyphae present) **Trichomonas:** report as few, moderate, many **Sperm:** **Do not report**

*Examine the sediment microscopically in correlation to the UMAC results. EX. If ++UBLO and no RBC's are seen, check for Ascorbic Acid if present, reexamine the sample ID; possibly repeat UMAC.

REFERENCE INTERVALS

The following represents the reference intervals for all reported components in the urinalysis.

Chemistry Results

Specific Gravity	1.005-1.030
pH	4-8
Leukocyte Esterase	NEG
Nitrite	NEG
Protein	NEG
Glucose	NEG
Ketones	NEG
Urobilinogen	<2.0
Bilirubin	NEG
Blood	NEG
Color	varies
Clarity	clear

Microscopy Results

RBC	0-2 /hpf
WBC	0-2 /hpf
WBC Clumps	none seen /hpf
Bacteria	none seen /hpf
Budding Yeast	none seen /hpf
Hyphae yeast	none seen /hpf
Squamous epithelial	few /hpf
Transitional epithelial	few /hpf
Renal epithelial	few /hpf
Oval fat body	none seen /hpf
Fat body	none seen /hpf
Mucous	few /lpf
Trichomonas	none seen /hpf
Hyaline Cast	0-2 /lpf
Epithelial Cast	none seen /lpf
White blood cell cast	none seen /lpf
Red blood cell cast	none seen /lpf
Granular cast	0-2 /lpf
Cellular cast	none seen /lpf
Broad cast	none seen /lpf
Fatty cast	none seen /lpf
Waxy cast	none seen /lpf
Triple phosphate crystal	none seen /hpf
Calcium oxalate crystal	none seen /hpf
Calcium phosphate crystal	none seen /hpf
Calcium carbonate crystal	none seen /hpf
Uric acid crystal	none seen /hpf
Leucine crystal	none seen /hpf
Cystine crystal	none seen /hpf
Tyrosine crystal	none seen /hpf
Amorphous crystal	none seen /hpf

CHEMICAL REACTIONS: Please see the table below for iChem VELOCITY dipstick chemical reactions.

Bilirubin	This test is based on the coupling of bilirubin and diazonium salt in an acidic medium. A pinkish tan color proportional to bilirubin concentration is generated.
Urobilinogen	This test is based on the coupling reaction of urobilinogen with a stable diazonium salt in buffer. A pink to red color proportional to the urobilinogen concentration is generated.
Ketone	This test is based on Legal's method in which the test pad contains sodium nitroprusside and glycine in and alkaline medium. A violet color proportional to the methylketone is generated.
Ascorbic Acid	This test is based on Tillman's reaction in which the presence of ascorbic acid leads to the decolorization of the pad from grey-blue to orange.
Glucose	This two step enzymatic reaction uses glucose oxidase, peroxidase and a chromogen. Glucose oxidase catalyzes the formation of gluconic acid and hydrogen peroxide via the oxidation of glucose. Peroxidase then catalyzes the reaction of hydrogen peroxide with a chromogen via the oxidation of chromogen to colors ranging between green and gray-blue.
Protein	This test is based on the "protein error of pH indicators" on the green color developed from the presence of protein. This dye-binding is particularly strong with albumin.
Blood	This pseudo-enzymatic test contains organic peroxide and a chromogen. The peroxidase effect of hemoglobin and myoglobin causes a color change to green.
pH	This test contains a mixed indicator which assures a marked change in color between pH 5 and pH9. Colors range from orange through yellow and green to cyan.
Nitrate	This test is based on modified Griess reaction in which nitrite in the urine reacts with amide to form a diazonium compound. The subsequent coupling reaction yields a pick color in the presence of nitrite. Some gram positive and non nitrite-forming bacteria are not detected in this test.
Leukocytes	This enzymatic test pad contains an indoxyl ester and a diazonium salt. Granulocyte esterases react with indoxyl ester and diazonium salt to generate a violet color.

CLINICAL SIGNIFICANCE OF URINE CHEMISTRY RESULTS

Glucose	The presence of glucose in the urine called glucosuria is caused by hyperglycemia or renal condition. Diabetes mellitus is the most common disease resulting in hyperglycermia. Renal conditions causing dysfunction of tubular reabsorption of glucose occur in many conditions including pregnancy.
Protein	The presence of protein in urine is often the first indicator of renal disease, but its appearance in the urine doesn't always signify renal disease. Although proteinuria may indicate nephritic syndrome, multiple myelomia, glomerulonephritis, and pre-eclampsia, a transient mild proteinuria can be present after exposure to cold, strenuous exercise, high fever, dehydration, or an acute phase of severe illness. The strip is primarily sensitive to albumin.
Bilirubin	The appearance of urinary bilirubin can be a sign of liver disease or extra or intra-hepatic bilary obstruction.
Urobilinogen	The normal urine has a small amount of urobilinogen(less than or equal to 2.0 mg/dL). The strip is unable to detect a decreased amount, which may appear in infants patients on antibiotic therapy, or patients with obstructive disease. Increased amounts appear in hemolytic anemias and liver dysfunction.
pH	Along with the lungs, the kidneys are the major regulator of acid-base balance. Freshly voided urine has a pH of 5.0 – 6.0. The pH of urine can be controlled by dietary regulation and medication.
Blood	A positive reaction for blood may indicate red cells, hemoglobin, or myoglobin present in the urine. Hematuria can be seen due to bleeding as a result of trauma or irritation (renal calculi, glomerulonephritis, and tumors, toxic or chemical exposure). Hemoglobinuria occurs when there is lysis of red cells in the urinary tract, intravascular hemolysis or transfusion reactions. Very dilute or extremely alkaline urine can also lyse the cells. Myoglobinuria indicates muscular destruction that may appear in hypothermia, convulsions, and extensive exertions.
Ketones	Ketonuria appears when there is an increased use of fat instead of carbohydrate as a source of metabolism. Conditions of ketonuria include diabetes mellitus, vomiting, and inadequate intake of carbohydrates due to starvation, weight reduction, or pregnancy.
Nitrite	Bacteria, specifically gram negative organisms, are detected by this nitrite reducing reaction. In order for the reaction to take place there must be adequate dietary nitrates, and the urine must be in the bladder at least four hours for the bacteria to react with nitrate for a positive reaction. Unusually colored urine due to medication or dyes can interfere with this reaction.
Leukocytes	The presence of white blood cells in the urine is an indicator of inflammation. Lysed and intact WBC's are detected because both may have produced esterase.
Specific Gravity	Specific gravity is a measure of the dissolved substances present in the urine. Specific gravity is one measure of the concentrating and diluting ability of the kidneys and hydration status of the patient. The specific gravity is obtained by measuring the refraction angles of light passing through a triangle prism. An LED emits a beam of light through a slit and a lens. The refractive index changes according to the specific gravity of the sample, the higher the specific gravity the greater is the angle of measurement. The change in the angle of the light is reported as the specific gravity. The result is automatically corrected for the elevated protein or glucose concentrations as measured on the test strip.
Color	Color variation can indicate the presence of a disease process, metabolic abnormality, or an ingested food or drug, or the variation simply due to excessive physical activity or stress. The color of the specimen is measured by transmitted light. The colors obtained are colorless, yellow, orange, brown, red, violet, blue, green, and other, including light and dark of each.
Clarity	Substances that cause urine turbidity may be pathologic or non-pathologic. The clarity or turbidity of a urine specimen is measured by passing a beam of light through the sample and measuring how the light is scattered. The amount of scattered light increases as the specimen becomes more turbid. The amount of clarity is reported as clear, turbid, hazy, or extremely turbid.

LIMITATIONS & INTERFERENCES [PAGE 1/2]

Analyte	Causes of False Negative Results	Causes of False Positive Results
Bilirubin	Elevated concentrations of nitrite may inhibit the reaction. Bilirubin is light sensitive and prolonged exposure of urine specimens to light may result in diminished or false negative values	Some urine specimens may contain impurities such as food dyes and therapeutic pigments to produce a yellowish or reddish discoloration of the test pad that may lead to interference. Elevated urobilinogen concentrations may slightly enhance the response to this test pad.
Urobilinogen	This test is inhibited by elevated concentrations of formaldehyde and nitrite ≥10mg/dl. Prolonged exposure to light may lead to diminished or false negative results.	Food dyes and medications that have an intrinsic red color in acidic medium such as red beets, azo dyes, phenazo pyridine and p-amino benzoic acid may produce false positive results.
Ketones	Elevated concentrations of phenyl pyruvic acid may interfere with the test pad and produce a variety of colors. Phthaleins and anthraquinonoid derivate exhibit a red color in alkaline medium and this may mask the response. Large amounts of levodopa and medications containing sulfhydryl groups may produce atypical color reactions.	N/A
Ascorbic Acid	No interferences reported.	No interference reported.
Glucose	Ascorbic acid concentrations of up to 50 mg/dl did not interfere with glucose results (no false negatives). Acetoacetic Acid concentrations of up to 200 mg/dl did not interfere with glucose assay test results (no false negatives). High specific gravity, acidic pH values, and gneissic acid may inhibit color formation.	Cleaning agents such as hypochlorite and peroxide may lead to false positive results.

LIMITATIONS & INTERFERENCES CONTINUED [PAGE 2/2]

Analyte	Causes of False Negative Results	Causes of False Positive Results
Protein	Food dyes such as red beets and therapeutic pigments such as methylene blue and pygidium may mask the coloration of the test pad. Interference may occur with high specific gravity. Interference may also occur with disinfectants, wetting agents and blood substitutes (quaternary ammonium compounds, polyvinylpyrolidone, and chlorohexidine.	
Blood	Reducing agents such as ascorbic acid, uric acid, glutathione and gneissic acid may cause false negative results. Samples with a pH of 5 may interfere with this test. High concentrations of nitrite can delay the reaction.	Preservatives (formalin) and cleaning agents such as bleach may result in false positives.
pH	No interferences reported.	No interferences reported.
Nitrite	A negative response in the presence of bacteriuria may be caused by the following: non-nitrite producing microorganisms, low nitrate diet, antibiotic therapy, strong dieresis, or insufficient urinary retention time in the bladder.	Food dyes and therapeutic pigments such as red beets and pygidium may cause false positive responses.
Leukocytes	High concentration of protein, glucose, cephalexin and gentamicin may diminish the color response. The test can be negative in the presence of visible leukocytes if they have not been lysed and/or are not granulocytes.	False positive results may occur in the presence of preservatives such as formaldehyde and formalin. Test results may be positive in the absence of observable cells if the granulocytes have been lysed.
Specific Gravity	N/A- measured by refractometer	N/A- measured by refractometer
Color	N/A- measured by scattered light	N/A- measured by scattered light

Note: Grossly bloody urines or urines from patients on medication that turn the urine red or orange pigmented urine may produce false positive results due to color interference. Certain analytes cannot be accurately evaluated. Replace any positive results of GLUC, KET, BILI and/or NITRITE with the code “COLIN” which translates to: Color interference, unable to analyze.

Units for Reporting Results:

The iCHEM VELOCITY analyzer is capable of reporting results in conventional and SI units.

Test	Units	Report
Glucose	mg/dL	Neg, 50, 150, >=500
Bilirubin		Neg, Small, Moderate, Large
Protein	mg/dL	Neg, 30, 100, >=500
pH		5.0, 6.0, 7.0, 8.0, 9.0
Blood		Neg, Small, Moderate, Large
Ketone	mg/dL	Negative, 5, 20, 80
Urobilinogen	mg/dL	<2.0, 2.0, 4.0
Nitrite		Negative, Positive
Leukocyte		Negative, Trace, Small, Moderate, Large
Specific Gravity	Refractive Index	1.000 to >=1.060
Color	Straw, Yellow, Amber, Red, Brown	
Clarity	Clear, hazy, Cloudy, turbid	

Critical values:
Newborn: **Ketones 40 mg/dl or greater** and **any positive glucose.**
All critical values must be called in accordance with our critical value policy.

Computer codes:
Device/Method: JIRIS
Worksheet: UMAC/UMIC
Order Code: UMACR
Pending Log: UA

REFERENCES:

1. Iris IQ 200/Velocity Operations Manuals.
2. Fundamentals of Urine and Body Fluid Analysis, Nancy A. Brunzel, 2nd edition.
3. Urinalysis and Body Fluids, Susan King Strasinger, 5th edition,2008

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