# Principle of the Test

The Clinitek Advantus Analyzer is a semi-automated, bench top instrument designed to read Siemens Medical Solutions Diagnostics Reagent Strips for Urinalysis. The analyzer is a reflectance spectrophotometer that analyzes the color and intensity of the light reflected from the reagent area and reports the results in clinically meaningful units. No calculations are required by the operator. If desired, the operator can also enter the clarity of each specimen. Interaction with the analyzer is through the use of an integrated touch screen. Calibration is performed automatically each time a reagent strip is analyzed.

Chemical Principles of the Reagent Strips

|  |  |
| --- | --- |
| Test Name | Chemical Principle |
| Protein | At a constant pH, the development of any green color is due to the presence of protein (Protein error-of-indicators principle). Colors range from yellow for “Negative” through yellow-green and green to green-blue for “positive” reactions. |
| Blood | Hemoglobin catalyzes the reaction of diisopropylbenzene dihy­droperoxide and 3,3',5,5'-tetramethylbenzidine. Colors range from orange through green; very high levels of blood may cause the color development to continue to blue. |
| Leukocytes | Esterases in granulocytic leukocytes catalyze the hydrolysis of the derivatized pyrrole amino acid ester to liberate 3-hydroxy-5-phenyl pyrrole. This pyrrole then reacts with a diazonium salt to produce a purple product. |
| Nitrite | Nitrate (derived from the diet) is converted to nitrite by the action of Gram negative bacteria in the urine. At the acid pH of the reagent area, nitrite in the urine reacts with ρ-arsanilic acid to form a diazonium compound. This diazonium compound couples with 1,2,3,4-tetrahydroben­zo(h)quinolin-3-ol to produce a pink color. |
| Glucose | Glucose oxidase catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. Peroxidase catalyzes the reaction of hydrogen peroxide with a potassium iodide chromogen to oxidize the chromogen to colors ranging from green to brown. |
| Ketone | Acetoacetic acid reacts with nitroprusside. Colors range from buff-pink, for a negative reading, to maroon. |
| pH | The double indicator principle gives a broad range of colors covering the entire urinary pH range. Colors range from orange through yellow and green to blue. |
| Specific Gravity | pKa changes occur for certain pretreated polyelectrolytes in relation to ionic concentration. In the presence of an indicator, colors range from deep blue-green in urine of low ionic concentration through green and yellow-green in urines of increasing ionic concentration. |
| Bilirubin | Bilirubin couples with diazotized dichloroaniline in a strongly acid medium. The color ranges through various shades of tan. |
| Urobiliogen | ρ-diethylaminobenzaldehyde in conjunction with a color enhancer reacts with urobilinogen in a strongly acid medium to produce a pink-red color (the Ehrlich reaction). |

# Clinical Application and Usefulness

Siemens Diagnostics Reagent Strips for Urinalysis are for *in vitro* diagnostics use. Siemens DiagnosticsReagent Strips include test pads for protein, blood, leukocytes, nitrite, glucose, ketone (acetoacetic acid), pH, specific gravity, bilirubin, and urobilinogen.

Siemens Diagnostics Reagent Strips are intended for use in at-risk patient groups to assist diagnosis in the following areas:

* kidney function
* urinary tract infections
* carbohydrate metabolism (e.g., diabetes mellitus)
* liver function

The strips also measure physical characteristics, including acid-base balance and urine concentration. Test results can be used along with other diagnostic information to rule out certain disease states and to determine if microscopic analysis is needed.

**NOTE:** As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single result or method.

# Sample Collection and Handling

Sample Collection and Patient Preparation

|  |  |  |
| --- | --- | --- |
| med_biohazard alert 1 |  | BIOHAZARD  All products or objects that come in contact with human or animal body fluids should be handled, before and after cleaning, as if capable of transmitting infectious diseases. Wear appropriate personal protective equipments. |

* Collect freshly voided urine. A first-morning sample is preferred but random collections are acceptable.
* Collect the urine in a clean, dry, container that allows for complete dipping of all reagent strip areas.

Labeling, sample handling and storage

* Test the urine within two hours of collection.
* If unable to test within the recommended time, refrigerate the sample immediately and let it return to room temperature before testing.

Mix the urine sample well before testing. Do not centrifuge.

Criteria for sample rejection

There is no substitute for the fresh urine in routine urinalysis. Do not accept the following:

* samples that have remained at room temperature for longer than 2 hours
* refrigerated urine sample over 24 hrs old
* samples with urine preservatives
* samples arrive in homemade containers (glass jars, pill bottles, etc.)

If an unacceptable sample is received, note the reason for rejection on the test requisition and request a new, acceptable sample from the patient. Provide collection container and collection instructions to the patient.

**IMPORTANT:** Some urine samples may have been collected during a critical procedure or by means of an invasive procedure; therefore, it is important to never dispose of an unacceptable sample until the caregiver has been notified.

# Equipment, Reagents, and Materials

|  |  |
| --- | --- |
| **Equipment** | Clinitek Advantus Analyzer  Clinitek AdvantusHandheld Barcode Reader |
| **Reagents** | Siemens Multistix 10 SG reagent strip  MAS UA controls Level I and II ( Normal and abnormal urinalysis control) |
| **Materials** | Clinitek Advantus Waste Bin Liners  Kova conical tubes or equivalent  Kova tubes cap or equivalent  DI water  Printer paper  Lubriplate Lubricant |

Storage and Stability, and Equipment Maintenance

Equipment

**Clinitek Advantus Analyzer**

* Ambient Operating Conditions: 18° to 30°C (64° to 86°F) with 20% to 80% relative humidity
* Optimum Operating Conditions: 22° to 26°C (72° to 79°F) with 35% to 55% relative humidity
* Clean the Clinitek Advantus analyzer once a day when in use, if it has not been used during the week, perform cleaning on Fridays:

Clean the push bar, fixed platform, moving table, and reagent strip hold down plate. Refer to *Section 5* in your *Clinitek Advantus Analyzer Operator’s Guide* for details. Record maintenance performed in Maintenance log.

Reagents

**Siemens Diagnostics Reagent Strips**

* **IMPORTANT NOTE:** Protect reagent strips against exposure to light, heat, and ambient moisture to guard against altered reagent reactivity.
* Store the unused strips in the original bottle. Transferring unused reagent strips to other containers may cause the strips to deteriorate and become un-reactive.
* Store the reagent strips at room temperature, 15° – 30°C (59° – 86°F).
* Do not store the bottle in direct sunlight.
* Do not remove the desiccant from the bottle.
* Do not use reagent strips beyond the expiration date.
* Initial and date the reagent bottle when you first open it.
* Do not remove the strip from the bottle until immediately before it is to be used for testing. Replace the cap immediately and tightly after removing the reagent strip.
* Do not touch the test pads of the reagent strip.
* Discoloration or darkening of the reagent pads may indicate deterioration. If this is evident, or if test results are questionable or inconsistent with expected findings, take the following steps: (1) confirm the product is within the expiration date shown on the label; (2) check performance against known negative and positive control materials; (3) retest with new vial of reagent strip. If proper results are not obtained, consult your local product representative, or contact the Customer Service Department for advice on testing technique and results.

**MAS UA Controls**

* The manufacturer’s expiration date printed on the control bottle’s label is for unopened bottles. Do not open and use controls beyond this date.
* Liquid stable control material prepared from human urine, containing preservative and stabilizers.
* Initial and date the control bottles when you first open them.
* Once the bottle is **opened**, bottle of control is stable for **6 weeks** when stored tightly capped at room temperature (18-25C)
* Bacterial contamination produces an increase in turbidity and/or a characteristic odor. Discard vial if evidence of microbial contamination is observed.
* Store the unopened MAS UA control solutions in the refrigerator, once the vial is open, store the vial at room temp.
* Do not use control materials after either the open or unopened bottle expiration dates.

Reagent Ingredients

Reagent ingredients for the Siemens Diagnostics Reagent Strips are as follows:

|  |  |
| --- | --- |
| Test | Ingredients |
| Protein | 0.3% w/w tetrabromphenol blue; 97.3% w/w buffer; 2.4% w/w nonreactive ingredients |
| Blood | 6.8% w/w diisopropylbenzene dihydroperoxide; 4.0% w/w 3,3',5,5'-tetramethylbenzidine; 48.0% w/w buffer; 41.2% w/w non­reactive ingredients |
| Leukocytes | 0.4% w/w derivatized pyrrole amino acid ester; 0.2% w/w diazonium salt; 40.9% w/w buffer; 58.5% w/w nonreactive ingredients |
| Nitrite | 1.4% w/w ρ-arsanilic acid; 1.3% w/w 1,2,3,4-tetrahydro­benzo(h)-quinolin-3-ol; 10.8% w/w buffer; 86.5% w/w nonreactive ingredients |
| Glucose | 2.2% w/w glucose oxidase (microbial, 1.3 IU); 1.0% w/w peroxidase (horseradish, 3300 IU); 8.1% w/w potassium iodide; 69.8% w/w buffer; 18.9% w/w nonreactive ingredients |
| Ketone | 7.1 % w/w sodium nitroprusside; 92.9% w/w buffer |
| pH | 0.2% w/w methyl red; 2.8% w/w bromthymol blue; 97.0% w/w nonreactive ingredients |
| Specific Gravity | 2.8% w/w bromthymol blue; 68.8% w/w poly (methyl vinyl ether/maleic anhydride); 28.4% w/w sodium hydroxide |
| Bilirubin | 0.4% w/w 2,4-dichloroaniline diazonium salt; 37.3% w/w buffer; 62.3% w/w nonreactive ingredients |
| Urobilinogen | 0.2% w/w ρ-diethylaminobenzaldehyde; 99.8% w/w nonreactive ingredients |

The strips have been determined to be nonhazardous under the guidelines issued by OSHA in 29 CFR 1910.1200(d).

# Calibration

Calibrator Preparation

No calibrator preparation is required.

Calibration Procedure

Calibration is performed at each readhead immediately before each reagent strip is read. The fixed platform contains two white calibration bars, positioned directly under each readhead. As a strip comes into position under a readhead, the analyzer reads the calibration bar and calibrates for that scanning cycle. The analyzer then scans the reagent strip and stores the data in memory.

Calibration Confirmation

Use the following procedure to print a report of the most recent successful calibration:

1. At the Ready/Run screen, select **Menu**.
2. Select **Print**.
3. Select **Calibration confirmation**.

The date and time of the latest successful calibration prints. Print the calibration confirmation daily. Check the calibration confirmation box on the maintenance log.

# Quality Control (QC)

When the analyzer is in use, negative and positive controls will be run once a day after the maintenance to check the Reagent Strip performance and analyzer operation. If the analyzer has not been used during the week, perform maintenance and run negative and positive controls on Fridays to ensure analyzer functionality and user competency. Quality control testing provides confidence that the reagent strips are reacting and being read correctly. It can also detect errors resulting from user techniques.

QC Materials

MAS UA Control Level I and Level II will be used to perform quality control. QC includes chemical portion of urinalysis with Multistix 10 SG on MAS controls.

QC frequency: Run controls under the following conditions:

* at the start of the day’s run after maintenance has been completed
* when using a new bottle of reagent strips (perform lot to lot on new bottles, shipments, and lots)
* whenever test results are in doubt

***Parallel Testing***

* Parallel testing (Lot to Lot) will be performed on all new bottles, lot numbers, and shipments of urinalysis reagent strips.
* Parallel testing can be performed using a patient or control sample. Only one specimen is needed for testing.
* Complete the Parallel (lot to lot) Form in the Urinalysis QC Binder.

Preparing for a Run

* Leave the Clinitek Advantus analyzer on at all times, except during maintenance and cleaning procedures.
* When the analyzer is not in use, the screen saver or the **Ready/Run** screen displays.
* If the screen saver displays, touch the screen to access the **Ready/Run** screen.

**CAUTION:** Do not use anything hard or pointed on the touch screen. It may damage the screen.

* Check that the primary Siemens Diagnostics Reagent Strip for Urinalysis displayed corresponds to the strip type you are using, i.e. Siemens Multistix 10 SG.
* If the strip types do not agree, change the selected strip type before beginning testing. Refer to your *Clinitek Advantus Operator’s Guide, Section 8, Setup Menu 2* for instructions on changing the strip type used on your analyzer.

**CAUTION:** Do not use a reagent strip other than the selected primary reagent strip, i.e. Siemens Multistix 10 SG. Only use Siemens Diagnostics brand reagent strips. Use of other strips may cause erroneous results.

* The analyzer automatically enters the Run mode when you place a strip on the fixed platform. If the push bar is positioned at the left side of the loading station, the analyzer is ready to accept placement of a strip. If the bar is positioned to the right, the analyzer is not ready and ignores any strip placed on the platform.
* Ensure that the strip loading station and push bar are clean and in the correct position. If contaminants are present, remove and clean the push bar, the platform, and the moving table.
* The startingsequence number increments with each strip placed onto the analyzer. If necessary, change the starting number following the procedure in *Section 2* of your *Clinitek Advantus Operator’s Guide*.
* Currently, we are not entering any tech ID when testing. But **Tech ID** (technician identification) may be also changed as follows:

1. Select **Menu**.
2. Select **Tech ID**. A numeric keyboard displays.
3. Enter an identification number of up to 13 digits.
4. Select A-Z to enter alphabetic characters.
5. Select Enter to return to the numeric keypad.
6. Select **Enter** to save the Tech ID.

* Perform printing jobs as required:

1. Select **Menu**.
2. Select **Print** to print:

* the ID list if a loadlist exists in memory
* confirmation of the last calibration
* a report of the setup parameters

1. Select **Enter**.

Testing QC Samples

1. Use Siemens Multistix 10 SG reagent strip.

**CAUTION:** Do not use a reagent strip other than the selected primary or alternative reagent strip. Only use Siemens Diagnostics brand reagent strips. Use of other strips may cause erroneous results.

1. Label two tubes as MAS I and MAS II respectively. Pour adequate amount of MAS UA Controls into the respective tubes for testing.
2. At the Ready/Run screen, select **Menu**.
3. Select **QC**.
4. The display changes to a numeric keypad.
5. Scan the pre-printed lot barcode on the machine for the MAS I control, e.g.
6. When you are ready to test the control, select **Enter**.
7. Remove a Siemens Multistix 10 SG reagent strip from its container. Completely immerse all of the reagent pads on the reagent strip, except the white ID band, into the MAS UA control sample.
8. Immediately remove the reagent strip.
9. While removing the strip, run the edge against the side of the container to removes excess liquid.

**CAUTION:** **Do not** **blot** the edge of the strip. This could affect results.

1. Place the reagent strip onto the supports of the strip loading station, with reagent pads facing up.

Place the strip to the right and parallel to the push bar, line up with the triangle mark on the top of the loading station. Ensure that the end of the strip is against the back wall of the platform and that it is not touching the bottom of the strip loading station.

**CAUTION:** Improper placement may cause the analyzer to jam or the strip to incorrectly align under the readheads.

1. Repeat steps 5 through 10 for MAS II control.

The strip automatically advances along the strip loading station, under the readheads, and into the waste bin.

The printer is set on On, the results are printed and stored in memory. The computer port is set to computer port, the control results are also transmitted to the host computer.

1. After all controls are run, select **Return to Ready/Run** to exit the quality control screen.

**IMPORTANT:** Compare the control results to the established control ranges. If any results are not within the expected range, do not test patient specimens. Troubleshoot and rerun the controls. You should only test and report patient results when control results are acceptable.

Troubleshooting Out-of-Range QC Values

If the control results fall outside of the values stated in the product’s package insert, the following sources of error may have occurred:

|  |  |
| --- | --- |
| Cause | Corrective Action |
| Improper technique or analyzer setup. | Verify that the reagent strip used corresponds to the reagent strip name given on the top of the Ready/Run screen.  Carefully repeat the control procedure described above. |
| Deterioration of the reagent strip test areas due to exposure to light, ambient moisture, or heat. | Use a fresh bottle of Siemens Diagnostics Reagent Strips to repeat the quality control procedure.  If fresh reagent strips fail to give results within the expected values, proceed to the next possible cause. |
| Deterioration of the control solution. | Use a fresh control solution to repeat the quality control procedure.  If fresh solution fails to give results within the expected values, proceed to the next possible cause. |
| Deterioration of the quality control product. | Prepare control solution using a fresh bottle of control product.  Repeat the quality control procedure.  If control solution from a fresh bottle fails to give results within the expected values, proceed to the next possible cause. |
| Clinitek Advantus analyzer malfunction. | Perform the procedure in *Performing the Initial Analyzer Check* in *Section 8* of your *Clinitek Advantus Operator’s Guide*.  If you cannot successfully complete the initial analyzer check or the quality control procedure, an analyzer malfunction or reagent strip problem may exist. Refer to *Troubleshooting* in *Section 6*, of your *Clinitek Advantus Operator’s Guide* for more information, or contact your local technical support provider for assistance. |

# Instrument Operating Procedure

Testing Routine Samples

|  |  |  |
| --- | --- | --- |
| med_biohazard alert 1 |  | BIOHAZARD  All products or objects that come in contact with human or animal body fluids should be handled, before and after cleaning, as if capable of transmitting infectious diseases. Wear proper personal protective equipment. |

Testing Without a Loadlist using the Specimen ID

**NOTE**: You can use this procedure only if Enter Sample IDs is On. Refer to your *Clinitek Advantus Operator’s Guide, Section 8, Setup Menu 7* for information on this setting.

**NOTE**: Observe the color and turbidity of each specimen, and examine the urine for presence of gross bile (indicated by a dark golden color) and gross blood. Care should be exercised that the reagent strip bilirubin and ictotest should also be positive if gross bile is positive, and reagent blood also should be positive if gross blood is reported positive.

1. At the Ready/Run screen, select **ID**.
2. Enter the ID number for the specimen you are about to test.

Select **A-Z** to enter alphabetic characters. You can also scan the ID (Barcode #) from a barcoded label using the handheld barcode reader.

1. Use the cycle key to enter the color and clarity, or scan the color and clarity by scanning the barcoded symbols provided with the handheld barcode reader.
2. When this information is correctly entered, select **Enter** or scan the **Enter** code from the color or clarity card.

The display changes to allow entry of the next ID number, and the push bar moves to the left so you can place a strip on the loading station. Do not enter another urine sample ID if you just want to proceed to the analysis of the sample you have just entered. If another ID is entered without a strip being detected, the analyzer automatically creates a load list.

1. Remove a Siemens Multistix 10 SG reagent strip from its container. Completely immerse all of the reagent pads on the strip, except the white ID band, into the sample.
2. Immediately remove the reagent strip from the sample.
3. While removing the strip, run the edge against the side of the container to remove excess liquid.

**CAUTION:** **Do not** **blot** the edge of the strip. This could affect results.

1. Place the reagent strip onto the supports of the strip loading station, with reagent pads facing up.
2. Place the strip to the right and parallel to the push bar, line up with the triangle mark on the top of the loading station. Ensure that the end of the strip is against the back wall of the platform and that is not touching the bottom of the strip loading station.

**CAUTION:** Improper placement may cause the analyzer to jam or the strip to incorrectly align under the readheads.

1. The strip automatically advances along the strip loading station, under the readheads, and into the waste bin.
2. The printer is set on On, the results are printed and stored in memory. The computer port is set to computer port, the results are also transmitted to the host computer.
3. Repeat steps 2 through 9 of this procedure for additional specimen you are going to test.

Testing Using Loadlists

You can enter a loadlist of up to 200 Specimen IDs before starting the run. Enter the IDs from the analyzer display.

**NOTE**: You can use this procedure only if Enter Sample IDs is On. Refer to your *Clinitek Advantus Operator’s Guide, Section 8, Setup Menu 7* for information on this setting.

**Entering a Loadlist from the Display**

To report color and clarity, enter initial values at the same time as the ID. You can edit color and clarity while running the specimens, immediately prior to the dipping of each reagent strip.

**NOTE:** Duplicate ID numbers are allowed by the analyzer, so be careful when entering the ID numbers.

1. At the Ready/Run screen, select **ID**.
2. Enter the ID for the first specimen. Select **A-Z** to enter alphabetic characters. You can also scan the ID from a barcoded label using the handheld barcode reader.
3. Enter or scan the color and clarity before select or scan **Enter**.
4. Select **Enter** or scan the **Enter** code.
5. Repeat steps 2 through 4 for each specimen.
6. To edit the loadlist once initial entry is complete use the following procedure:
7. Use **Move Up** and **Move Down** to select the record to edit.
8. Edit the ID number.

**NOTE:** You cannot change or delete the ID number during Run mode. Make any changes while the analyzer is in the Ready mode.

1. Select **Delete** to delete an item from the loadlist.

You can delete only the ID number being displayed or all IDs in memory.

1. Edit the color and clarity.
2. Select **Enter** to accept the new number, color, and clarity.
3. Select **Enter** to accept the new color and clarity.
4. Select **Return to Ready/Run** to begin testing specimens.

You can also print the ID list from the Ready/Run screen if necessary.

1. Select **Menu**.
2. Select **Print**.
3. Select **ID list**.

**NOTE:** You must make changes to the loadlist before starting testing.

1. Test each specimen.

The Ready/Run screen displays each ID number and the color/clarity descriptions in the same

order as they were entered into the loadlist.

1. Check that the ID number, color, and clarity descriptions are correct for the specimen you are about to test.
2. Edit the color and clarity, if necessary.
3. Dip and place a reagent strip following steps 5 through 9 of the *Testing Without a Loadlist using the Specimen ID* procedure in this document.

When the Strip for the last loadlisted specimen is moved to the read area, you are not allowed to place any additional strips on the table. The push bar stays at the right side and the analyzer completes the run.

**Performing a STAT Test**

Use this procedure to run a STAT test when using a loadlist. After the STAT test the analyzer will continue testing specimens from the loadlist.

1. At the Ready/Run screen, select **STAT**.
2. Enter an ID for the STAT test.
3. Edit the color and/or clarity, if necessary.
4. Use Siemens Multistix 10 SG reagent strip.

**CAUTION:** Do not use a reagent strip other than the selected reagent strip. Only use Siemens Diagnostics brand reagent strips. Use of other strips may cause erroneous results.

1. Dip and place a reagent strip following steps 5 through 9 of the *Testing Without a Loadlist using the Specimen ID* procedure in this document.

The result is printed when the STAT test is complete. The analyzer displays any confirmatory from the STAT test.

1. Run another STAT test or resume loadlist testing.

The next test is allocated the SEQ # which follows the number used for the STAT test just completed.

Cancelling a Run

Select **Stop Run** if you need to stop the run before all readings are complete.

If you cancel the entire run, all strips on the platform are moved immediately to the waste bin. No results are reported. No SEQ # is assigned for any strip that was not read at both readheads before Stop Run was selected. You must retest all the specimens for all cancelled strips.

If you cancel only the last strip, the run continues and you can test a new strip using the same SEQ #.

Managing Results

Results are transmitted to the printer and computer as soon as all reagent areas on the strip are read. If a record is flagged for a confirmatory report and Edit flagged results is On, that record is not transmitted until after the end-of-run reports complete.

Requesting End-of-Run Reports

The analyzer may display up to 3 end-of-run reports when the run, or a STAT test, is completed. These reports display if you have marked any analytes to flag for confirmatory, and if Mark positives is On.

1. Specify 1 or more tests for the Confirmatory Reports A and B.
2. In the Setup routine, select On for Edit flagged results.

The Confirmatory Report screens display the **SEQ #** and **ID** of the record, and the abbreviation for each positive analyte marked for flagging.

Up to 5 records may be displayed on 1 screen.

1. Use **Move Up** and **Move Down** to view additional records.
2. Edit these results before exiting the Confirmatory Report. *Refer to Editing Results in the Confirmatory Reports* in the next section of this document.
3. Select **Print** to print a report.
4. Select **Return to Ready/Run** to exit the report screen.

If an error is reported for 1 or more analytes, a report displays after the Confirmatory Reports. This report displays last.

1. Perform confirmatory testing will not be performed.

Editing Results in the Confirmatory Reports

1. During the end of run review, access the Confirmatory Report screens.
2. Select a record from the Confirmatory Report A screen.

The flagged positive test results display.

1. Select the cycle key next to the test name to review the displayed result and perform necessary confirmatory test.

When the cycle key is selected, the result for that test is printed and stored with an exclamation point (!) to indicate that it was edited, even if the result is reset to its original value.

1. Select **Previous Screen** when editing is complete for that record to return to the Confirmatory Report.
2. Repeat Steps 2 through 4 above for each record.
3. When all editing is complete, select **Return to Ready/Run** to exit Confirmatory Report A.

**NOTE:** When you leave a Report, you are not able to edit the report any further.

1. Records for Confirmatory Report B display. Repeat Steps 2 through 4 above to edit these records.
2. When all Confirmatory Report editing is complete, select **Return to Ready/Run** to exit the Confirmatory Reports.

**NOTE:** When you leave the Edit routine, you are not able to edit the run any further.

# Reporting Results

RESULTING ANALYZER RUN:

A. RESULT TRANSMISSION

* 1. Log-on the Meditech system, select Laboratory, and Analyzer Desktop.
  2. Click on Clinitek Advantus analyzer from the analyzer list and select Process.
  3. Once the analyzer has completed the specimens, the appropriate information will be sent to the Meditech and can be viewed on the Process / Transmission screen.
  4. Use the up and down arrows on the keyboard to move to the specimen or use the mouse and click on the specimen. By holding down the CTRL key and using the mouse, you can highlight multiple specimens to be resulted.
  5. By holding down the CTRL key and using the mouse, you can highlight multiple specimens to be resulted.
  6. Match the analyzer printout to the specimen on the screen.
  7. Gross Blood and gross bile will always be pending and have to be manually resulted.
  8. Click on Comment to enter comments for test triggered reflex test.
  9. Watch for positive Bilirubin and/or 1+ protein with pH = or > than 8.5.
  10. Press F<12> or click on Save button to file, the computer will prompt you to “Verify All Results”. Press F<12> or click on Save button to verify all results.
  11. Once the chemical urinalysis results are filed and verified, the appropriate back-up test will be reflexed by the computer.
  12. Acknowledge the reflex tests by pressing F<12> or clicking on Save button.
  13. If a microscopic and/or culture has been reflexed forward original urine container to the main lab
  14. If a microscopic and or culture is not reflexed and no other testing (chemistry, etc) needs to be performed store the urine for 48 hours in the STAT Lab Urinalysis bucket.
  15. If other testing does exist on order forward to the main lab for processing.

B. REFLEX TESTS

URINE MICROSCOPIC EXAM

When “UA” (Urinalysis) is ordered, and the dipstick chemical analysis of the

urine does not meet the following listed criteria, computer will automatically

reflex a UA Microscopic.

\*\*If Microscopic examination is reflexed send original urine specimen to the hematology

department upon filing of macroscopic results. Place a red dot on the specimen.

CHEMICAL TEST RESULT

Turbidity Clear

Gross Blood Negative

Protein Trace/Negative

Occult Blood Negative

Leukocyte Esterase Negative

Nitrite Negative

**CULTURE REFLEX TEST**

When a “Urinalysis with Reflex to Culture” is ordered, a urine culture is performed based on one of the following criteria of test results: (Send specimen to hematology department with red dot on container with culture label and /or microscopic label).

-No reflex if “Many Squamous Epithelial Cells” are present.

-White Blood Cells (WBC): greater than 5/high power field with greater than trace bacteria

-Bacteria 3+ to 4+

-Nitrite: Positive

C. ENTER RESULT SPECIMEN:

1. Access Enter result by selecting Lab, Specimen desktop, Enter result.

“Enter/Edit Lab Results” screen appears for you to enter the result.

2. Enter the results at their corresponding result fields manually.

3. Press F<12> or click on Save button to save the result.

4. The computer will prompt you to “Verify All Results” or “Verify Edited result”.

5. Press F<12> or click on Save to verify all results or verify edited results.

6. Enter Result option is primarily used for entering all confirmatory tests.

Calculations

The operator is not required to perform any calculations.

Performance Parameters

Refer to the Siemens Diagnostics Reagent Strips product insert for specific performance characteristics. Refer to the section *Method* *Limitations*, in this document for possible interfering substances.

Reference Interval:

|  |  |
| --- | --- |
| Protein | Negative |
| Blood | Negative |
| Leukocytes | Negative |
| Nitrite | Negative |
| Glucose | Negative |
| Ketone | Negative |
| pH | 4.5 – 8.0 |
| Specific Gravity | 1.001 – 1.035 |
| Bilirubin | Negative |
| Urobilinogen | ≤ 1.0 mg/dL |
| Color | Yellow |
| Clarity | Clear |

Units for Reporting Results

The Clinitek Advantus is reporting results Conventional units:

|  |  |
| --- | --- |
| Test | Reporting Unit |
| Protein | NEGATIVE, TRACE, 1+, 2+, 3+ |
| Blood | NEG, TRACE, 1+, 2+, 3+ |
| Leukocytes | NEG, TRACE, 1+, 2+, 3+ |
| ***Test*** | ***Reporting Unit*** |
| Nitrite | NEGATIVE, POSITIVE |
| Glucose | NEG, TRACE, 1+, 2+, 3+ |
| Ketone | NEG, TRACE, 1+, 2+, 3+ |
| pH | 5.0, 6.0, 6.5, 7.0, 7.5, 8.0, ≥ 8.5 |
| Specific Gravity | 1.000, 1.005, 1.010, 1.015, 1.020, 1.025, ≥ 1.030 (in 0.005 increments) |
| Bilirubin | NEG, 1+, 2+, 3+ |
| Urobilinogen | 0.2, 1.0, 2.0, 4.0, 8.0 |
| Color | No color, Straw, Yellow, Dark yellow, Amber, Orange, Red, Green, Brown, Interfere, Other |
| Appearance / Clarity | Clear, SL Cloudy / SL Hazy, Cloudy/Hazy, Turbid, Opaque, Bloody/Red, Other |

# Procedure Notes

* Refer to your *Clinitek Advantus Operator’s Guide* for:
* Setup Information in *Section 8,* *System Configuration*
* Maintenance in *Section 5*
* Troubleshooting in *Section 6*
* Service in *Appendix G, Warranty and Support Information*
* Empty the waste bin as it starts to fill to prevent problems with strips jamming as they leave the readheads.
* If a strip should become jammed, select **Stop Run** and follow the directions in your *Clinitek Advantus Operator’s Guide*, *Section 6, Troubleshooting*.
* Thermal print from the internal printer fades with time, especially when exposed to light. The print also fades if covered with transparent tape or when exposed to extremes in temperature or humidity.
* The analyzer detects when the internal printer is out of paper and retains the results until the printer paper roll is replaced. The last meter of paper on the roll has a pink edge. Change the roll when the pink edge displays. Refer to your *Clinitek Advantus Operator’s Guide*, *Section* 5, *Maintenance, Changing the Paper*.
* False positives and negatives may occur in the presence of interfering substances; refer to Interfering Substances table in the section *Method Limitations* of this document.
* Contamination of the urine specimen with skin cleansers containing chlorohexidine may affect protein and to a lesser extent specific gravity and bilirubin test results.

# Method Limitations

# Clinitek Advantus optical system

The analyzer can only determine color if the Siemens Diagnostics Reagent Strip used contains the leukocyte test. Results reported by the analyzer may be different from the color seen visually. This is because of the inherent differences between the human eye and the optical system of the analyzer.

Detectable Range

|  |  |
| --- | --- |
| Reagent Area | Sensitivity |
| Protein | 15 – 30 mg/dL albumin |
| Blood | 0.015 – 0.062 mg/dL hemoglobin |
| Leukocytes | 5 – 15 white blood cells/hpf in clinical urine |
| Nitrite | 0.06 – 0.1 mg/dL nitrite ion |
| Glucose | 75 – 125 mg/dL glucose |
| Ketone | 5 – 10 mg/dL acetoacetic acid |
| Bilirubin | 0.4 – 0.8 mg/dL bilirubin |

Interfering Substances

Substances that cause abnormal urine color may affect the readability of test pads on urinalysis reagent strips. These substances include: (These specimens can be referred to the Hematology Department for testing).

* visible levels of blood or bilirubin
* drugs containing dyes
* nitrofurantoin
* riboflavin

| Test Name | False Positive or  Increased values | False Negative or  Decreased values |
| --- | --- | --- |
| Protein | Visibly bloody urine | Capoten® (Captopril) |
| Blood | * Oxidizing contaminants (e.g. hypochlorite) * Microbial peroxidase from urinary tract infections |  |
| Leukocytes | Vaginal discharge | Elevated glucose (≥ 3 g/dL)   * Cephalexin (Keflex®) * Cephalothin (Keflin®) * High concentrations of oxalic acid * Tetracycline |
| Nitrite | Pink spots or pink edges should not be interpreted as a positive result | A negative result does not rule out significant bacteriuria  False negatives may occur with:   * Shortened bladder incubation of the urine * Absence of dietary nitrate * Presence of nonreductive pathological microbes |
| Glucose |  | Ketones (≥ 40mg/dL) may affect a 75 to 125 mg/dL glucose level |
| Ketone | Highly pigmented urines  Large amounts of levodopa metabolites  Compound that contain sulfhydryl groups |  |
| pH | Bacterial growth that converts urea to ammonia |  |
| Specific Gravity | Moderate quantities of protein  (100 – 750 mg/dL) | Highly buffered alkaline urines |
| Bilirubin | Indican (indoxyl sulfate) may impart a yellow-orange to red color on the pad   * Metabolites of Lodine® (etodolac) | * A typical colors may indicate bile pigment abnormalities and further testing is required * Unfresh urine specimen (instability of bilirubin) |
| Urobilinogen | Temperature > 26°C (79°F)   * Interfering substances known to react with Ehrlich’s reagent, such as ρ-aminosalicylic acid and sulfonamides * ρ-aminobenzoic acid may cause atypical color development | Temperature < 22°C (72°F)   * Formalin |
| Color | Concentration   * Food Pigments * Dyes * Blood * Various pathological conditions | These all can affect negatively as well  Bacterial growth that converts urea to ammonia |

# Daily Maintenance:

# Daily function verification to be performed in the morning:

* Daily Cleaning of the Clinitek Advantus:
  1. Fixed platform
  2. Inspect Calibration bars for scratches / discoloration, clean if needed
  3. Moving table
  4. Reagent strip plate
  5. Push bar
  6. Display screen
  7. Liner
  8. Replace liner if cracked
  9. Verify calibration confirmation

* Check paper supply
* Check UA reagent supply and expiration date
* Disinfect UA bench
* Perform UA Chemical on two levels of QC samples after the daily maintenance. Results of the controls must be within their reference before performing any patient samples.
* Check off maintenance performed on the Clinitek Advantus Maintenance log and initial

Notes:

1. Use only DI H2O \*\*\* to gently clean the two white calibration bars on the platform.
2. Use warm water and mild soap to clean all parts except white calibration bars.
3. Do not use isopropyl alcohol or any product containing phenol (such as Amphyl), as these will cause damage to the calibration bars.
4. Do not use bleach or other solvents on the display screen.

# Supplies

* Siemens Healthcare Diagnostics Reagent Strips: Siemens Multistix 10 SG
* Distilled Water
* Kova tubes and Kova tube caps or equivalents

# References

1. Clinitek Advantus Operator’s Guide, V.1.0, 2009. Siemens Healthcare Diagnostics, Tarrytown, NY 10591-5097 USA.
2. Siemens Healthcare Diagnostics Multistix 10 SG Reagent Strips for Urinalysis package insert, revised 2010. Siemens Healthcare Diagnostics, Tarrytown, NY 10591-5097 USA.
3. Clinical and Laboratory Standards Institute. Laboratory Documents: Development and Control; Approved Guideline⎯Fifth Edition. CLSI document GP2-A5 [ISBN 1-56238-600-X]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2006.

# Technical Assistance

Siemens Healthcare Diagnostics Technical Care Center: 1-877-229-3711

Clinitek Advantus Serial Number: KPS 48011144

Updated by : Jessica Mercer, MT (ASCP) Date: 02/16/2016