

Reagent Strip Testing:

Performing a Quick Test on the Clinitek Status Analyzer

READ THIS GUIDE BEFORE PERFORMING A TEST

Note information regarding CLIA waiver on reverse side.

Test fresh urine samples within 2 hours of collection. Refrigerated urine samples must be brought to room temperature before testing (15-30°C). Do not test visibly bloody or unusually colored urine.

STEP 1 GETTING STARTED

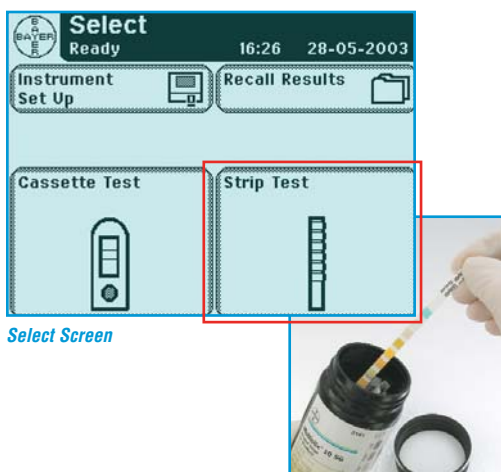
- Turn ON (ⓘ) Clinitek Status analyzer.
- Turn table insert so reagent strip holder is facing upwards.
- Be sure test table and table insert are clean.



STEP 2

- When the “Select” screen appears, touch the **Strip Test** screen button.

- To begin testing, **Remove** a reagent strip from the bottle.
- Immediately **replace** the bottle cap.
- **Read** Steps 3 and 4 and then proceed with Step 3.

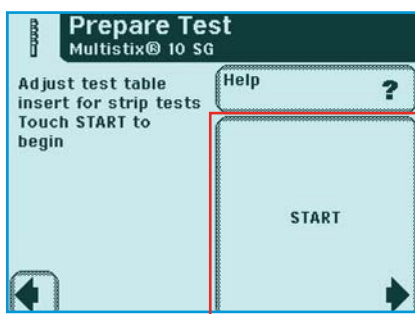


Select Screen

STEP 3

- Touch **START** on the “Prepare Test” screen.

- Now complete Step 4 in 8 seconds.



Prepare Test Screen

Abnormal results marked by “+”

Refer to reagent package insert for product limitations, interferences, storage and expiration date. Do not use a reagent strip past the expiration date.

If error occurs, follow screen prompts or consult the Clinitek Status Operator's Manual.

For questions or comments call (877) 229-3711.

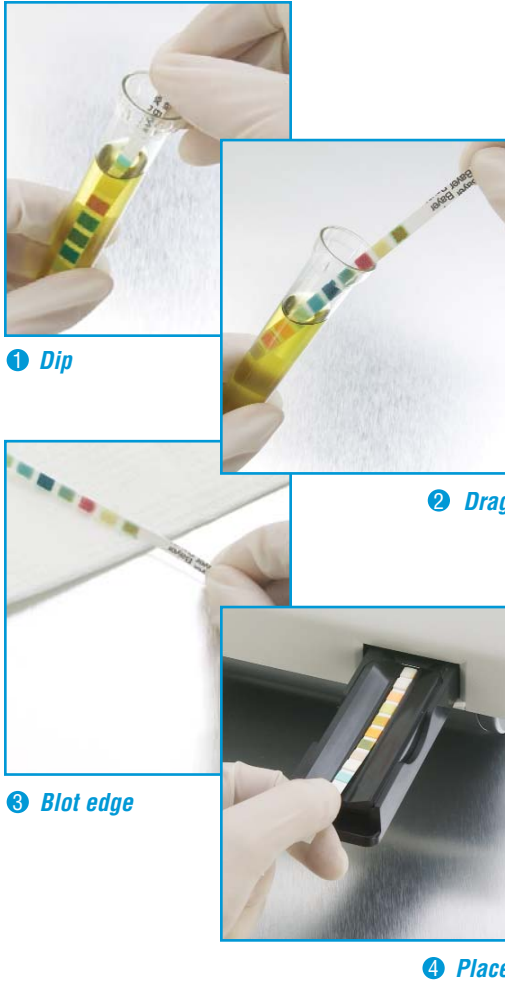


BIOHAZARD

Wear personal protective equipment. Use universal precautions. Refer to your Clinitek Status Operator's Guide *Appendix H* for recommended precautions when working with biohazardous materials.

STEP 4

- **Dip** (1) strip in urine sample, wetting all pads.
- **Immediately remove strip** from urine.
- **Drag** (2) the edge of the strip against the side of the sample container as you remove it.
- **Blot** (3) by touching the edge of strip to paper towel to remove excess urine.
- **Place** (4) reagent strip in channel of table, with test pads facing up.
- **Slide or push** strip to end of channel. Do not touch the reagent pads on the test strip.

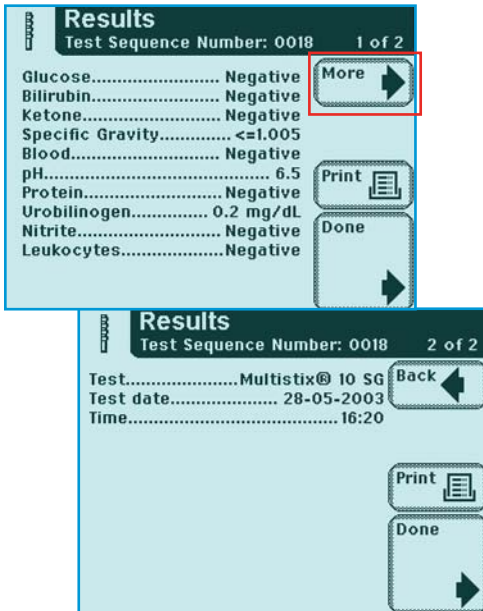


STEP 5

- After 8 seconds, test table will automatically be pulled into the instrument.
- When analysis is complete, the "Results" screen will be displayed.
- **Touch More** to view the second "Results" screen.

STEP 6 WHEN TEST IS FINISHED

- **Discard reagent strip.**
- **Wipe table insert** with damp tissue between tests to remove any urine residue, if needed.
- **Record or print result, and report** with Patient ID, as per laboratory practice.



Results Screens

Quality Control

Test negative and positive controls whenever a new reagent bottle is first opened.

Liquid, ready-to-use controls should be used. Water should not be used as a negative control.

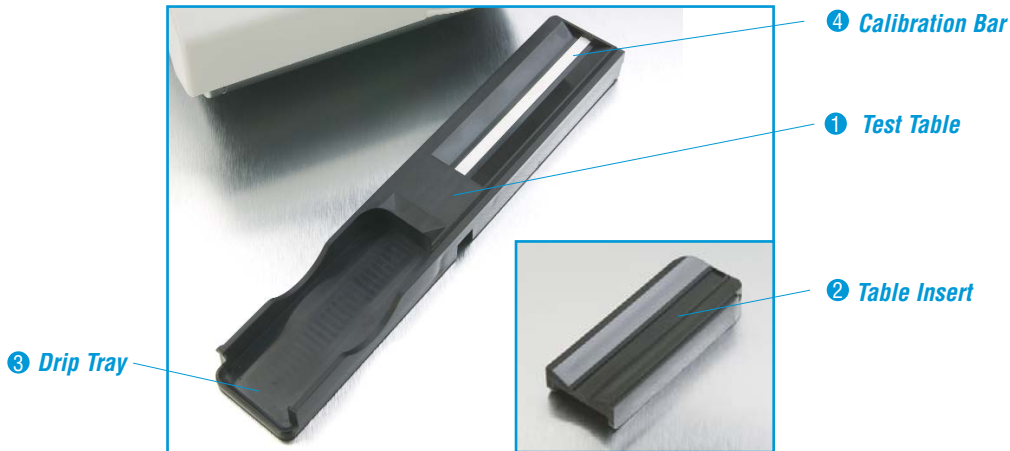
Compare control results to those listed as acceptable by the manufacturer of the control material.

If control results are not acceptable, do not test patient samples until the problem is resolved and repeat control results are acceptable. For assistance, call the Bayer Technical Care Center (in the U.S.: 877-229-3711).



(01)00630414485089(240)06317349

Cleaning: Clean the table weekly or more often if buildup is seen.



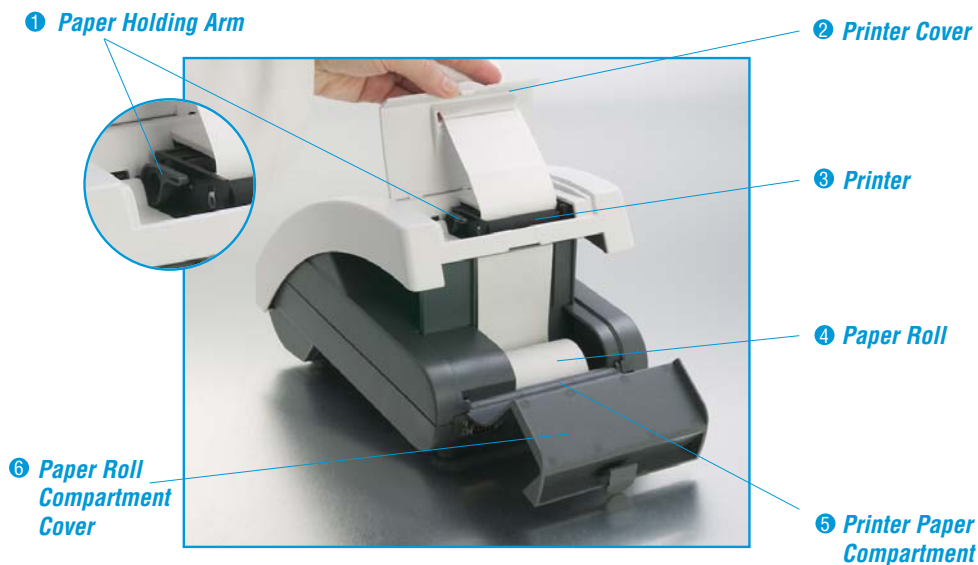
- Remove test table (①) by pulling straight out.
- Lift the table insert (②) to remove it from the test table (①), draining the drip tray (③) if required.

CAUTION: Do not touch or scratch the white calibration bar (④) during cleaning.

- Wet a cotton-tipped stick with water and thoroughly scrub test table (①) and table insert (②) [except for white calibration bar (④)]
- Rinse both sides of table insert (②) and test table (①) under running water.
- Dry thoroughly [except for white calibration bar (④)] with a soft cloth or lint-free tissue.
- Check white calibration bar (④) for dust, marks or scratches. If dirty, gently clean with a new wet cotton-tipped stick. Do not use solvent.
- Allow to air dry and check again. If scratched or scuffed, or if it cannot be cleaned, obtain a new test table (①).
- Re-insert the test table (①) to the instrument, pushing it in more than halfway.

CAUTION: Do not push the test table fully into the analyzer. The test table may jam.

Changing the Printer Paper or Label Roll



- Open the printer cover (2) and paper roll compartment cover (6).
- Lift paper holding arm (1).
- Place new paper roll (4) into printer paper compartment (5).
- Insert paper or labels under printer (3).
- Pull the end of the paper gently through the printer.
- Push paper holding arm (1) back into position.
- Feed the paper through the printer cover (2).
- Close the printer cover (2) and paper roll compartment cover (6).

Information Regarding CLIA Waiver

The Clinitek Status system is CLIA-waived only when used with Bayer branded urinalysis reagent strips.

A certificate of CLIA waiver is required to perform the test in a waived setting.

To obtain a Certificate of Waiver, contact your state department of health or visit the CMS website for an application, Form CMS-116.

Failure to adhere to the instructions for use, including instructions for limitations or intended use, and for performing QC testing, is considered as off-label use, resulting in the test being categorized as high complexity and subject to all CLIA regulations.



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