Multistix 10SG Tests
with CLINITEK Status+ Analyzer

In-Service Training

Maria Peluso-Lapsley, CDM Marketing
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Training Agenda

- System overview
- Multistix® 10SG Overview
- Performing testing:
  - Quality control testing
  - Patient testing
- Performing maintenance
- Ordering information
What is the CLINITEK Status+ Analyzer?

• Automated POC urinalysis analyzer with a broad testing menu
  ✓ Routine urinalysis, albumin-to-creatinine ratio, protein-to-creatinine ratio and hCG pregnancy test
• Automates the timing and result interpretation for routine urinalysis tests, kidney checks and hCG pregnancy tests
• Auto-Checks® features identify test strip type, perform strip integrity check for humidity overexposure – prevents testing with un-validated test strips and strips compromised by humidity over-exposure
CLINITEK Status+ Analyzer System Overview

The CLINITEK Status+ analyzer is a portable, easy to use analyzer. It is designed to read only Siemens Healthineers Urinalysis test strips and Clinitest® hCG tests.

- Measures the following in urine: Albumin, Bilirubin, Blood (Occult), Creatinine, Glucose, Ketone, Leukocytes, Nitrite, pH, Protein, Protein-to-Creatinine Ratio, Albumin-to-Creatinine Ratio, Specific Gravity, Urobilinogen, and human Chorionic Gonadotropin (hCG)

- These measurements are used to assist diagnosis in the following areas: Kidney function, Urinary tract infections, Metabolic disorders (such as diabetes mellitus), Liver function, and Pregnancy
Setting up the Analyzer
CLINITEK Status Analyzer – System Overview

Printer
Interactive Display
On/Off Button
Test Compartment
Serial Port
Power Cord
Inserting the test table is only done during set up or when cleaning the test table:

1. Insert the test table into the analyzer
2. Hold the tray by the Drip Tray end
3. Do not touch the calibration bar – careful not to scratch or soil as this will impact performance
4. With the calibration bar facing upwards push the test tray into the analyzer just over halfway
5. Do not force the tray table as it may become jammed (The analyzer will automatically pull in the tray when the power is turned on)
6. Place the Table Insert onto the Drip Tray
Loading the Printer Paper

To load the thermal printer paper or label roll, perform the following steps:

1. Turn the back of the analyzer to face you
2. Pull on the tab to open the printer cover
3. Open the paper roll compartment
4. Lift the paper holding arm into the open, upright position
5. Insert a new paper roll – it should unroll from underneath and roll toward the compartment wall
6. Feed the paper up along the wall and through the printer until 4 inches of paper feeds through
7. Feed the edge of the paper through the printer cover
8. Push the paper holding arm down in the closed position (if this step is missed the printer will not print)
9. Close both covers by clicking into place
If you power on the analyzer for the first time, the Start Up Wizard will guide the set-up procedure:

1. Press the on/off button on the front of the analyzer
   • Analyzer performs automatic checks when powered on

To power off the analyzer, perform the following steps:

1. Ensure that no strip or cassette is on the test table and that the table and insert are clean
2. Hold the on/off button down for at least 2 seconds
3. Analyzer pulls in the test table and will turn off
   ✓ If the test table hasn’t been cleared of test strips or cassettes, the analyzer will push tray back out and the analyzer will power off
   ✓ To power off, the analyzer must be powered back on, and the test strips or cassette must be cleared
Customize Set-Up

- Select the testing mode that best fits your site needs.
- There are three modes to select from:
  - Quick test – does not require any patient operator data to be entered
  - Full test – requires operator, patient and other fixed data to be entered
  - Custom

Path: Select Instrument Set Up > Operator and Patient Information
Customize Set-Up

• Instrument set up allows for customization and standardization of running your urinalysis program.
• Review each area to select your settings:
  ✓ Results format – units and flagging
  ✓ Connectivity – if you will be interfacing serially and uni-directionally
  ✓ Urinalysis test setting – handling of lot and expiration dating
  ✓ Authorized operators – to set up operator access and lock out
  ✓ Printer settings – define printing requirements
  ✓ QC settings – this will not be available for CLINITEK Status+ analyzer

Note: For more details on how to customize the analyzer refer to the analyzer in-service training tool.
Multistix 10SG Overview
Multistix® 10SG Test Overview

- For professional in vitro diagnostic use in near patient (point of care) and centralized laboratory locations
- The 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
  - measure physical characteristics, including acid-base
- For use on CLINITEK Status® family of analyzers
- Results reported in 1 minute
- CLIA-waived when tested on the CLINITEK Status® family of analyzers

For measuring protein, blood, leukocytes, nitrite, glucose, ketone (acetoacetic acid), pH, specific gravity, bilirubin and urobilinogen.
Multistix 10SG Configuration

- Urine test strip bottle:
  - 100 test strips
  - desiccant to prevent moisture
- Instructions for use can be downloaded from the internet
Test Bottle Storage and Stability

• All unused strips must remain in the original bottle

• Transfer to any other container may cause reagent strips to deteriorate and become unreactive

• Store at temperatures between 15–30°C (59–86°F)

• Do not use the strips after their expiration date (Note: analyzer can be programmed to prevent use of expired test strips)

• Do not store the bottle in direct sunlight and do not remove the desiccant from the bottle
Getting Ready for Testing
Supplies Needed to Conduct Testing

Analyzer and Tests
(supplied by Siemens Healthineers or authorized distributor):
- CLINITEK Status+ Analyzers
- Multistix 10 SG Test Strips
- Chek-Stix Quality Control Materials

Recommended Supplies:
(non Siemens Healthineers items):
- Urine specimen collection containers
Performing Quality Control Testing
Quality Control Testing Modes

• Control samples are treated and stored as patient samples. User must enter control name or ID to distinguish results.

• Control results must be manually compared to the values assigned by the control manufacturer.

• If the control results are not favorable, do not test patient samples until quality control is passed.
Quality Control Testing Recommendations

• Test positive and negative quality controls with new lots, new shipments of reagents, and when you open a new bottle of reagent strips
• Test reagents monthly that are stored for more than 30 days
• Run QC tests to ensure reagent strips integrity; train new users; confirm test performance; and when patients’ clinical conditions or symptoms do not match
• Run QC tests per your laboratory procedures
• Liquid ready-to-use controls are available
• Do not use water as a negative control
Quality Control Materials

- Some urinalysis commercial controls tend to be very dark in color because of added analytes
- See below the commercial controls that are compatible with MULTISTIX 10SG tests:

<table>
<thead>
<tr>
<th>Dipper-Style, Liquid-Ready Quality Controls</th>
<th>Dropper-Style, Liquid-Ready Quality Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product Name</strong></td>
<td><strong>Product Name</strong></td>
</tr>
<tr>
<td>Quantimatrix Dipper Dipstick Control</td>
<td>Quantimatrix Dropper Plus POC Urine Dipstick Control Set</td>
</tr>
<tr>
<td>Quantimatrix Dipper POC Liquid Urinalysis Control</td>
<td>Yes</td>
</tr>
<tr>
<td>KOVA International KOVA POC Control</td>
<td>KOVA International KOVA POC Dropper Control</td>
</tr>
<tr>
<td>Bio-Rad qUAntify Plus Control, Bi-Level</td>
<td>Alta Diagnostics, Inc., Liquid Urine Dipstick Control</td>
</tr>
<tr>
<td>Bio-Rad qUAntify Control, Bi-Level</td>
<td>Kenlar Liquid Urine Dipstick Control</td>
</tr>
<tr>
<td>MAS Urinalysis Liquid Assayed Urinalysis Control</td>
<td>StanBio hCG Bi-Level Urine Control</td>
</tr>
<tr>
<td>CLINIQA Liquid QC DipStrip Urinalysis Control</td>
<td>CLINIQA Liquid QC DropStrip Urinalysis Control</td>
</tr>
<tr>
<td>Cardinal Health UA Control Tube</td>
<td>Cardinal Health UA Control Dropper</td>
</tr>
</tbody>
</table>

*NOTE: MAS UA Urine Chemistry Control is a different product that has been shown to cause errors when used with the CLINITEK Status Family of Analyzers and the CLINITEK Advantus Analyzer.*
Chek-Stix Storage and Stability

- Store Chek-Stix® control strips in the original, tightly capped bottle at temperatures between 15–30°C
- Do not store the bottle in direct sunlight.
- Do not remove the desiccant from bottle
- Control strips are stable until the expiration date shown on the bottle label

Reconstitution Stability

- Reconstituted controls are stable for 8 hours at 18–23°C (64–73°F) – except for bilirubin in the Positive Control, which is stable for 3 hours
- If your laboratory operates outside of this temperature range, reconstituted solution should be refrigerated at 2–8°C (34–46°F) to maintain the 8 hour stability
- Allow refrigerated control solutions to equilibrate to ambient temperature prior to use
Prepare Chek-Stix Quality Controls

Directions:

1. Place 12 mL of distilled or deionized water in an appropriately labeled specimen tube. **Do not use tap water.**

2. Remove a Chek-Stix Control Strip from the bottle and replace the cap immediately and tightly.

3. Place the strip into the tube. Cap tightly.

4. Repeat Steps 1–3 if using a second control.

5. Gently invert the tube(s) back and forth for 2 minutes.

6. Allow the tube(s) to stand for 30 minutes at room temperature.

7. Invert one more time, then remove and discard the strip(s), according to your standard laboratory procedures.
Run QC Testing – Optional Set Up Customization

1. In order to record QC level with QC test, set up analyzer to add the patient name and ID.
2. Use the patient name field to record the QC name and level, use the ID field to enter the lot control lot number.
3. You will need to manually check to ensure that QC has passed or failed.
4. If QC mode and lock out is required, you will need to upgrade to the CLINITEK Status Connect system.
Running a Quality Control Test

- Press Strip Test to begin testing,
- Enter information as prompted
- Touch Start first, then dip the test strip

• Dip ① strip in urine sample. Wet all pads.
• Quickly remove strip from urine.
• Drag ② the edge of the strip against the side of the sample container as you remove it.
• Eject ③ by touching the edge of the strip to a paper towel to remove excess urine.
• Place ④ strip in channel of table with pads facing up.
• Slide or push strip to end of the channel. Do not touch the pads on the test strip.
Performing Patient Testing
Specimen Collection and Handling

• Collect urine into a clean, dry container
• First morning or random collections are acceptable
• Test fresh urine samples within 2 hours of collection
• If cannot be tested within 2 hours, refrigerate specimens at 2°C to 8°C (36° to 46°F) for up to 72 hours, if the testing is not performed immediately
• If samples are refrigerated, bring them to room temperature 15°C to 30°C (59° to 86°F) before testing
• The use of urine preservatives is not recommended
• Do not use urine that looks bloody or is not a normal color
### Performing a Test

#### STEP 1

**Getting Started**
- Turn ON the Clinitek Status®+ analyzer.
- Turn the table insert so reagent strip holder is facing up.
- Be sure the test table, the table insert, and the calibration bar are clean.

#### STEP 2

- Select Strip Test from Select Ready screen.
- Remove a reagent strip from the bottle and quickly replace the cap.
Performing a Test

**STEP 3**
- Select Enter New Patient from Patient Information screen.
- Read Steps 5 and 6 and then proceed with Step 4.

**STEP 4**
Bar code entry (with Clinitek Status Connect System only)
- 1. Enter patient information with bar code scanner. 2. The name automatically appears. 3. Select Enter.

**NOTE:** You can also enter patient information using the keyboard screen.

To avoid errors, follow the process and do not dip the tests strip early.
Performing a Test

STEP 5

- Select Start from Prepare Test screen.
- Complete Step 6 in 8 seconds.

STEP 6

- Dip 1 strip in urine sample. Wet all pads.
- Quickly 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 the strip to a paper towel to remove excess urine.
- Place 4 strip in channel of table with pads facing up.
- Slide or push strip to end of the channel. Do not touch the pads on the test strip.

To avoid errors, follow the process. Do not dip the tests strip until after pressing the start button.

Once you press the start button, you will have 8 seconds to dip, drag, blot and place test strip on tray.
Performing a Test

**STEP 7**

- After 8 seconds, the instrument pulls in the test table.
- When test completes, the Results screen displays.
- Select More to view the second screen of Results.
- Select Print to print the Results.
- Select Done to return to the Select Ready screen.

**STEP 8**

When Test Is Finished

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

If interfaced, results will be automatically transmitted to the DMS/LIS.
# Interpretation of Test Results

<table>
<thead>
<tr>
<th>Test</th>
<th>Units</th>
<th>Results (Normal System)</th>
<th>Results (Plus System)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose</td>
<td>GLU</td>
<td>mg/dL</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td></td>
<td>100</td>
<td>Trace</td>
</tr>
<tr>
<td></td>
<td></td>
<td>250</td>
<td>1+</td>
</tr>
<tr>
<td></td>
<td></td>
<td>500</td>
<td>2+</td>
</tr>
<tr>
<td></td>
<td></td>
<td>≥ 1000</td>
<td>3+</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>BIL</td>
<td>mg/dL</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Small</td>
<td>1+</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Moderate</td>
<td>2+</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Large</td>
<td>3+</td>
</tr>
<tr>
<td>Ketone</td>
<td>KET</td>
<td>mg/dL</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Trace</td>
<td>Trace</td>
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<tr>
<td></td>
<td></td>
<td>15</td>
<td>1+</td>
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<td>80</td>
<td>3+</td>
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<tr>
<td></td>
<td></td>
<td>≥ 160</td>
<td>4+</td>
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</table>

## Interpretation of Test Results

<table>
<thead>
<tr>
<th>Test</th>
<th>Units</th>
<th>Results (Normal System)</th>
<th>Results (Plus System)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific Gravity</td>
<td>SG</td>
<td>n/a</td>
<td>≤ 1.005</td>
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<td></td>
<td></td>
<td></td>
<td>1.010</td>
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<td>1.025</td>
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<td></td>
<td></td>
<td></td>
<td>≥1.030</td>
</tr>
<tr>
<td>Occult Blood</td>
<td>BLO</td>
<td>n/a</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Trace-lysed</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Trace-intact</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Small</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Large</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Negative</td>
</tr>
<tr>
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<td></td>
<td></td>
<td>Trace-lysed</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Trace-Intact</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>1+</td>
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<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>3+</td>
</tr>
<tr>
<td>pH</td>
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<td>8.5</td>
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<tr>
<td></td>
<td></td>
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<td>No difference</td>
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</table>

## Interpretation of Test Results

<table>
<thead>
<tr>
<th>Test</th>
<th>Units</th>
<th>Results (Normal System)</th>
<th>Results (Plus System)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein</td>
<td>PRO</td>
<td>mg/dL</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Trace</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>100</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>250</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>≥300</td>
</tr>
<tr>
<td>Urobilinogen</td>
<td>URO</td>
<td>E.U./dL</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1.0</td>
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<td>2.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4.0</td>
</tr>
<tr>
<td>Nitrite</td>
<td>NIT</td>
<td>n/a</td>
<td>Negative, Positive</td>
</tr>
<tr>
<td>Leukocytes</td>
<td>LEU</td>
<td>n/a</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Trace</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Small</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Large</td>
</tr>
</tbody>
</table>

Avoiding Errors

• 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

• Discoloration or darkening of the test pads may indicate deterioration:
  1. Auto-Checks technology will detect overexposure to humidity for urine test strips and prevent patient testing.
  2. Analyzer automatically detects if test strips, cassette materials or QC materials are expired and prevent patient testing.

• Do not touch the test areas of the strip

• Contamination of the urine specimen with skin cleansers containing chlorhexidine may affect protein (and to a lesser extent specific gravity and bilirubin) test results

• The user should determine whether the use of such skin cleansers is warranted

• It is especially important to use fresh urine to obtain optimal results with the tests for bilirubin and urobilinogen, as these compounds are very unstable when exposed to room temperature and light
Performing Routine Maintenance/Cleaning
• Clean the test table at least once a week to remove any build up. The test table can be soaked in 5% hypochlorite and rinsed thoroughly – do not use solvents.
• Check that the calibration strip on the instrument is clean every day. If not, clean with a cotton swab or soft cloth and water only, ensuring that you do not scratch it.
Replacing the Printer Paper

1. Paper Holding Arm
2. Printer Cover
3. Printer
4. Paper Roll
5. Paper Roll Compartment Cover
6. Printer Paper Compartment
Ordering Information
## Ordering Information

<table>
<thead>
<tr>
<th>#</th>
<th>Code</th>
<th>Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>10379675</td>
<td>1780</td>
<td>CLINITEK Status+ Analyzer</td>
<td></td>
</tr>
<tr>
<td>10376323</td>
<td>1790</td>
<td>CLINITEK Status Connector</td>
<td></td>
</tr>
<tr>
<td>10484591</td>
<td>1782</td>
<td>CLINITEK Status Upgrade Kit (includes Status Connector, Bar-code Reader, and most recent software kit)</td>
<td></td>
</tr>
<tr>
<td>10282579</td>
<td>6502880</td>
<td>Bar-code Scanner (CLINITEK Status Connect and DCA Vantage® Analyzers)</td>
<td></td>
</tr>
<tr>
<td>10470849</td>
<td>1797</td>
<td>CLINITEK Status Connect System (includes CLINITEK Status+ Analyzer, Status Connector, and Bar-code Reader)</td>
<td></td>
</tr>
<tr>
<td>11046800</td>
<td>N/A</td>
<td>CLINITEK Status+ V2.62/2.4.2.0 SW UPG KIT U.S. USB (for instruments with connector base)</td>
<td></td>
</tr>
<tr>
<td>11046802</td>
<td>N/A</td>
<td>CLINITEK Status+ V2.62/2.4.2.0 SW UPG KIT U.S. MMC (for instruments without connector base)</td>
<td></td>
</tr>
<tr>
<td>10376825</td>
<td>1795</td>
<td>CLINITEK Status Wireless Adapter</td>
<td></td>
</tr>
<tr>
<td>10328736</td>
<td>5773</td>
<td>Thermal Printer Paper (CLINITEK Advantus®, CLINITEK Status, and DCA Vantage Analyzers)</td>
<td>5/pk</td>
</tr>
<tr>
<td>10324219</td>
<td>1759</td>
<td>Label Printer Paper (CLINITEK Status and DCA Vantage Analyzers)</td>
<td>5/pk</td>
</tr>
</tbody>
</table>
## Ordering Information

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>103147839</td>
<td>CLINITEK® Microalbumin 2 Reagent Test Strips (test for semiquantitative determination of microalbumin and creatinine in urine)</td>
<td>–</td>
</tr>
<tr>
<td>10331147</td>
<td>Multistix PRO® 10 LS Reagent Strips* (dip-and-read test for protein, creatinine, P/C ratio, ketone, specific gravity, glucose, blood, pH, nitrite, and leukocytes in urine)</td>
<td>–</td>
</tr>
<tr>
<td>10332782</td>
<td>Multistix PRO 10 LS Reagent Strips* (dip-and-read test for protein, creatinine, P/C ratio, ketone, specific gravity, glucose, blood, pH, nitrite, and leukocytes in urine)</td>
<td>–</td>
</tr>
<tr>
<td>10336425</td>
<td>Multistix® 10 SG Reagent Strips (dip-and-read test for glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, and leukocytes in urine)</td>
<td>–</td>
</tr>
<tr>
<td>10337913</td>
<td>Multistix® 8 SG Reagent Strips (dip-and-read test for glucose, ketone, specific gravity, blood, pH, protein, nitrite, and leukocytes in urine)</td>
<td>–</td>
</tr>
<tr>
<td>10356145</td>
<td>Multistix® 7 Reagent Strips (dip-and-read test for glucose, ketone, blood, pH, protein, nitrite, and leukocytes in urine)</td>
<td>–</td>
</tr>
<tr>
<td>10337415</td>
<td>Multistix® 5 Reagent Strips (dip-and-read test for glucose, blood, protein, nitrite, and leukocytes in urine)</td>
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<tr>
<td>10339953</td>
<td>Multistix® Reagent Strips (dip-and-read test for pH, glucose, ketone, bilirubin, blood, and urobilinogen in urine)</td>
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<td>10334851</td>
<td>Albustix® Reagent Strips (dip-and-read test for protein in urine)</td>
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<td>10324600</td>
<td>Azostix® Reagent Strips (60-second test for blood urea nitrogen)</td>
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<td>10312568</td>
<td>Hemastix® Reagent Strips (dip-and-read test for blood in urine)</td>
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<td>Hema-Combistix® Reagent Strips (dip-and-read test for glucose, pH, protein, and blood in urine)</td>
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<td>Lacobstix® Reagent Strips (dip-and-read test for blood, ketone, glucose, protein, and pH in urine)</td>
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<td>Uristix® Reagent Strips (dip-and-read test for protein and glucose in urine)</td>
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<tr>
<td>10312569</td>
<td>Uristix® 4 Reagent Strips (dip-and-read test for glucose, protein, nitrite, and leukocytes in urine)</td>
<td>–</td>
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</tbody>
</table>

*Multistix PRO products sold through authorized Multistix PRO distributors only.
How to change paragraph levels

- All levels font Calibri 26 pt.
- Level 1 is subtitle, Bold, no bullet.
- Level 2 is bulleted: Regular, no indent.
- Level 3 is bulleted: Regular, indent 7.5 mm.
- Level 4 is bulleted: Regular, indent 15 mm.
- Level 5 is bulleted: Regular, indent 2.25 mm.

Switch between Text and bullet levels:

- click

Thank you!

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