TITLE: Clinitek Status Operating Procedure	**Doc #:** 28089
Section: \\Management System\PLM\Point of Care Testing\Urinalysis\	**Version:** 1.0 Current
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Purpose

This procedure provides instructions for performing urine analysis testing using the Clinitek Status.

Materials

Reagents	Stability and Storage	Preparation (Y/N)
Multistix 10sg reagent strip for urinalysis, Siemens, 2300A	RT	**N**

Reagents stability and storage: Until expiry date at room temperature.

Supplies
Sterile urine container
Paper towel

Equipment
Clinitek Status

Sample

Sample type	Amount required	Transport and Storage	Stability
No preservatives random urine	10 mL	Room temperature	2-4 hours

Limitations: Ideally urine should be examined within 2-4 hours after collection. Some chemical and microscopic components begin to deteriorate after 4 hours. Specimens should be at room temperature before testing.

Note:

- The first morning urine is the preferred sample.
- Skin cleansers should not be used prior to collection as they may interfere with analysis.

Special Safety Precautions

To ensure patient and operator safety users must follow the CDHA infection prevention and control guidelines and policy.

Maintenance

1. **Daily Maintenance**

Step	Action
1.1	Clean sample table.
1.2	Complete QA Log
1.3	Record quality issues as required.
1.4	Retain all QA forms in a binder available for review.

2. **Monthly Maintenance**

Step	Action
2.1	Clean white calibration bar
2.2	Perform and record QC results. To be done monthly or when a new lot number of strips are to be used.

Quality Control

Control	Level	Stability	Frequency	Preparation (y/n)
qUAntify Plus control, Bilevel minipak, Biorad,	1, 2	Up to expiry date unopened at 2-8°C 30 days once opened at 2-25°C	Monthly and with each new lot number	None

Control preparation: Mix well and bring to room temperature before use.

Note: Follow step 2.0 Analyzing Urine Sample for processing Quality Control material.

Procedure

1 Collect urine sample

Step	Action
1.1	Label sterile urine container with: • Patient name, • Patient MRN and/or HCN number • Time and date of collection
1.2	Give labeled container to patient
1.3	Instruct patient on urine collection guidelines **Note:** Skin cleansers should not be used prior to collection as they may interfere with analysis
1.4	Obtain sample from patient and move to testing area

2 Analyzing urine sample

Step	Action
2.1	Press **Start** on the Status main screen.
2.2	Dip Multistix strip in the labeled urine container. **Note**: Immerse all pads.
2.3	Remove the strip from container by slowly run the edge of the strip against the side of the container to remove excess urine. Remove the excess urine by blotting the edge of the strip gently against a paper towel.
2.4	Place strip on the sample table.
2.5	Results will print automatically. Attach printout to patient chart.

Result Interpretation

If urine is bloody or intensely coloured, all tests except colour, appearance and specific gravity are INVALID.

Expected Values

Analyte	Normal result
Colour	Straw
Appearance	Clear
Leukocyte	Negative
Nitrite	Negative
pH	Diet dependant
Specific gravity	<1.005 to > 1.030
Protein	Negative to trace
Glucose	Negative
Ketone	Negative
Urobilinogen	3.2 to 16µmol/L
Bilirubin	Negative
Blood	Negative

Refer to package insert for urine chemistry sensitivity.

Limitations

Refer to Multistix 10sg reagent strip package insert.

Roles and Responsibilities

Role	Accountability
User	Healthcare providers
Inventory management	Supplies obtained from CDHA stores: • Unit staff receive, stock supplies (and discard outdated supplies) • All users must date supplies upon opening new container.
External Quality Assurance (EQA) management	All users may be requested to run EQA samples. These requests will be coordinated by laboratory and unit manager (or designate).
Troubleshooting	**All users** are trained in basic troubleshooting and shall: • Contact Technical Support if required • Record events on QA log or PSR/NCE • Contact laboratory (Biomed) if necessary

Principle

Refer to Multistix 10sg reagent strip package insert.

Clinical Utility

Refer to Multistix 10sg reagent strip package insert.

Training and Competency

Only operators who have completed the Clinitek Status training program and can demonstrate competence will be able to perform urine analysis testing.

Operator competency will be assessed and documented annually by two methods:

a) Successful performance of quality control (Performance Monitor).
b) One of the following:
   - Testing an unknown specimen
   - Having the qualified preceptor periodically observe routine work
   - Written quiz

Related Procedures and Documents

Document Name	Document #	Location
Clinitek Status QA Log	27982	[Paralink:<Clinitek Status QA Log>]
Clinitek Status Training Checklist	27993	[Paralink:]
Policy CH 70-110 *Point of Care Testing (POCT)*		Intranet

Reference

Clinitek Status Operators Manual
Multistix 10sg reagent strip package insert.