

CLINITEK Status+ Analyzer

Installation and Setup



In-Service Training

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CLINITEK Status+ Analyzer Training Agenda

- System overview
- Setting up the analyzer
- Customizing setup

Note: This information applies only to the CLINITEK Status[®]+ analyzer with the latest version of software version 2.6.2. Sample interference notes features are not available in the U.S.



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 test strips, specialty kidney checks strips and hCG pregnancy rapid tests
- Auto-Checks® features identify test strip type, perform strip integrity check for humidity overexposure – prevents testing with unvalidated test strips and strips compromised by humidity over-exposure
- Interfaces uni-directionally to data management systems





System Overview

CLINITEK Status+ Analyzer 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



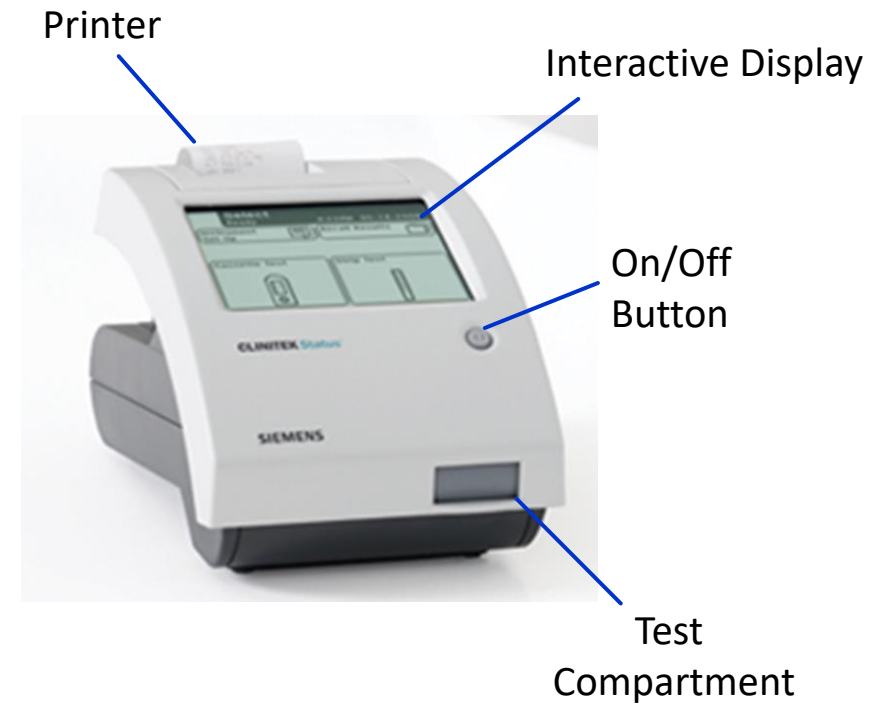


Setting up the Analyzer

CLINITEK Status+ Analyzer Overview



1. CLINITEK Status+ Analyzer
2. Power supply adaptor and AC power cord
3. Test table with calibration bar
4. Test table insert
5. Paper roll



Printer

Interactive Display

On/Off
Button

Test
Compartment

Test Table Overview and Set Up

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 is fed 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.



1 Paper holding arm

2 Printer paper

Powering Analyzer On/Off

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
 - 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 before being powered off again.





Customizing Setup

Customize Set-up – Select Test Mode

1. 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

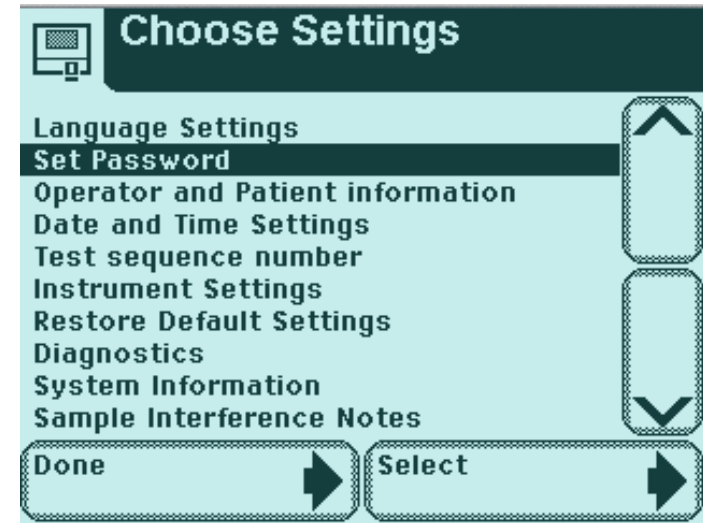
Input Settings
Select one of the options

Quick Test Permit test sequence without entering operator or patient information <input type="radio"/>	Full Test Permit test sequence after entering: - operator name - patient name - patient ID - sample appearance <input type="radio"/>
Custom Set Up <input checked="" type="radio"/>	Next

Path: Select Instrument Set Up >
Operator and Patient
Information

Customize Set-up – Set Password

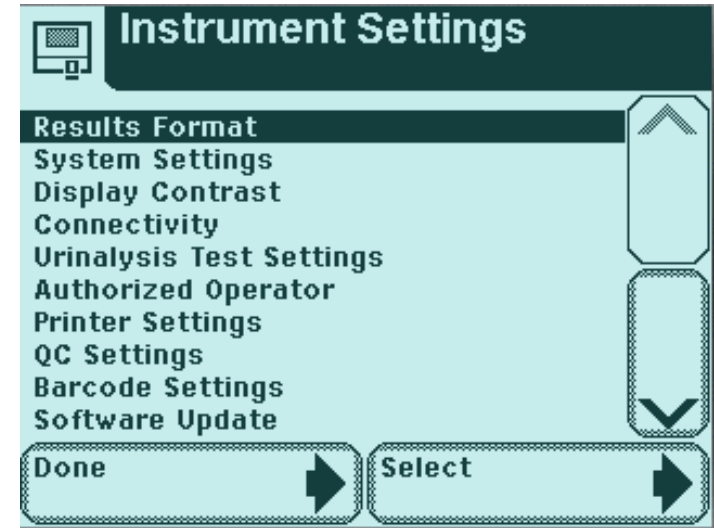
- If the site requires supervisor(s) to be the only ones who can modify system settings, a system password should be programmed.
- The analyzer defaults to not having a system password and is open for all to make system changes.
- The system password differs from the operator ID.
- Operator IDs can be added and supervisor can set individual operator access.



Path: Select Instrument Set Up >
Set Password

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 – define serial connectivity settings
 - ✓ Urinalysis test setting – handling of lot and expiration dating
 - ✓ Authorized operators – to set up operator access and lock out
 - ✓ Printer settings – define printing requirements
 - ✓ Barcode setting



Path: Select Instrument Set Up >
Instrument Settings

Customized Setup Review

**Result
Format**

Connectivity

**Urinalysis
Test
Setting**

**Authorized
Operator**

**Printer
Setting**

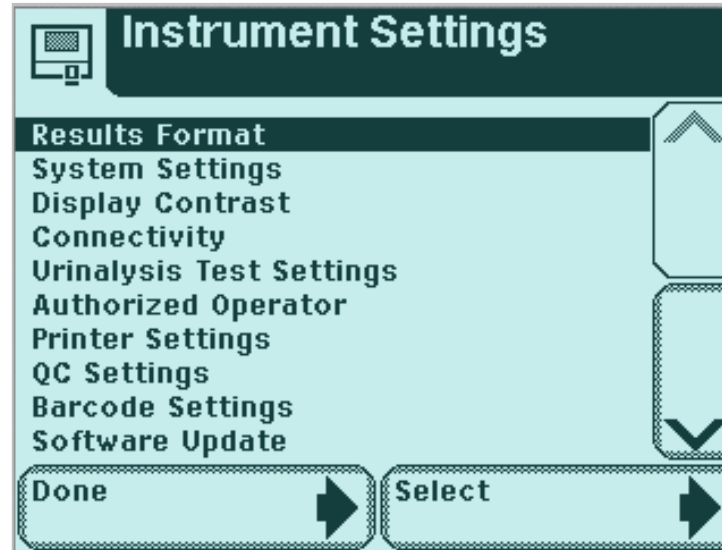
**QC
Setting**

**Barcode
Setting**

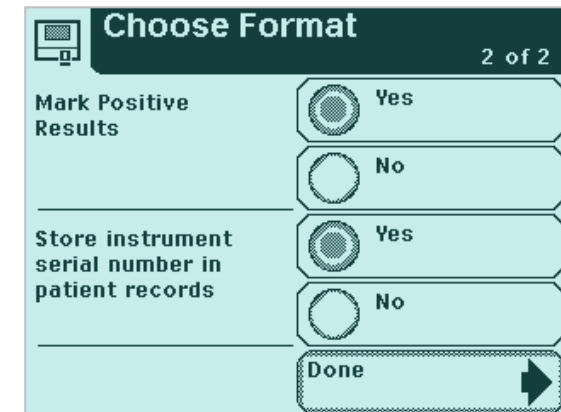
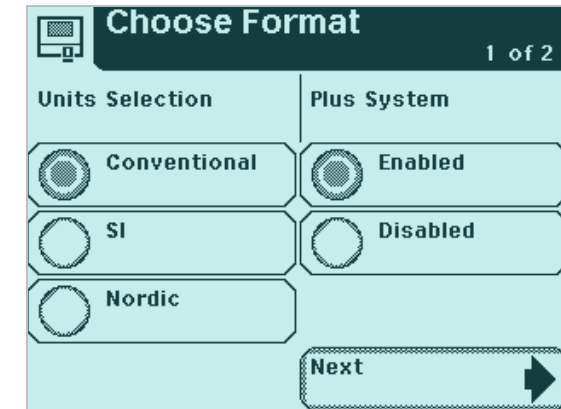
**Click to
Go to End**

Select Results Format

- Select units for reported results
- Determine if Plus system for results are required
- Determine if positive results should be flagged
- Determine if analyzer serial number should be recorded with each result

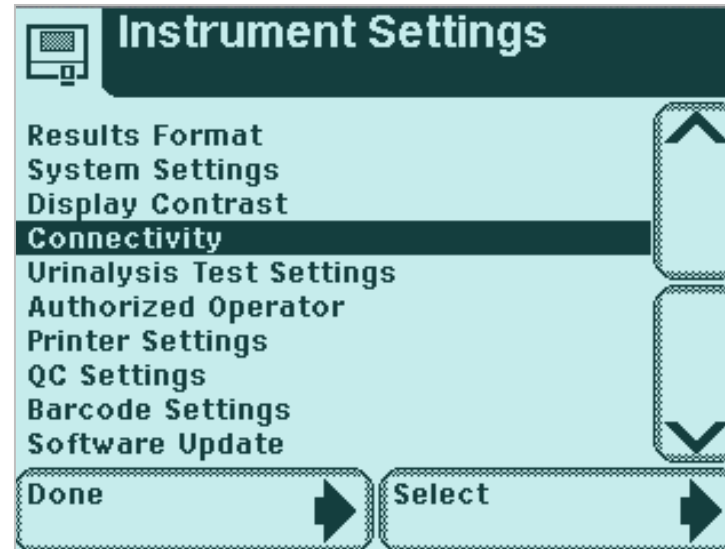


Path: Select Instrument Set Up > Instrument Settings > Results Format

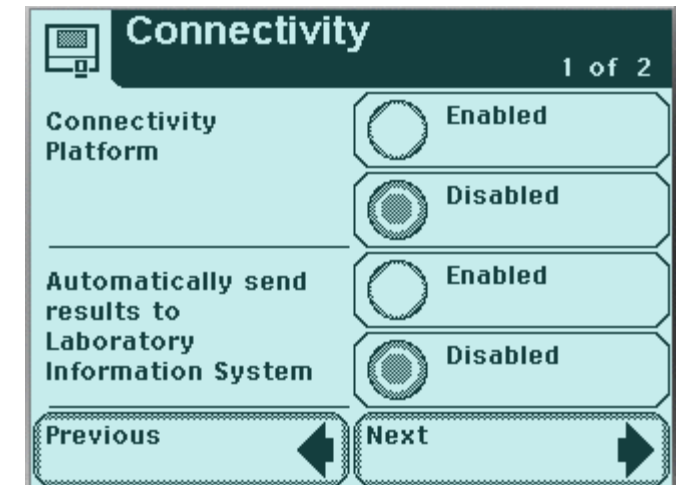


Select Connectivity Set Up

- If using the CLINITEK Status+ analyzer as a standalone, connectivity platform selection will not be available
- Determine if results need to be automatically transmitted after testing



Path: Select Instrument Set Up > Instrument Settings > Connectivity

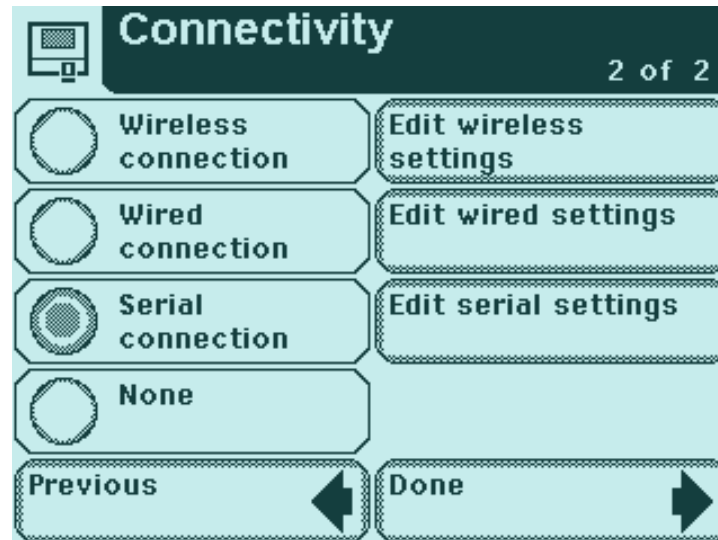


Select Connectivity Options - Serial Connection Set Up

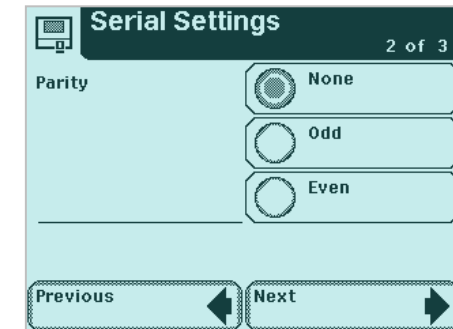
- For connecting the analyzer serially, follow these steps.

Note: serial connections will be uni-directionally only.

- Wireless and Wired Ethernet connectivity will not be available with the standalone analyzer.



Path: Select Instrument Set Up > Instrument Settings > Connectivity > Serial connection > Edit serial settings

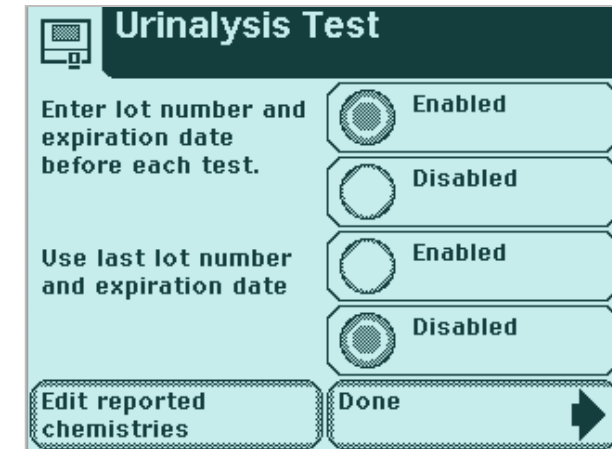


Select Urinalysis Testing Options

- Determine if lot and expiration dating for test strips is required to be recorded with each patient test and enable function.
- Determine if last lot number is acceptable or if site will require this information to be scanned in with each test.



Path: Select Instrument Set Up > Instrument Settings > Urinalysis Test Settings



Select Reported Chemistries

- System default is to report all chemistries.
- System can be customized to select chemistries to repress or not report.

Urinalysis Test

Enter lot number and expiration date before each test.

Enabled
 Disabled

Use last lot number and expiration date

Enabled
 Disabled

Edit reported chemistries Done

Path: Select Instrument Set Up > Instrument Settings > Urinalysis Test Settings

Reported Chemistries 1 of 2

Choose which to include in reported results

GLU BIL
 KET SG
 BLO pH

Previous Next

Reported Chemistries 2 of 2

Choose which to include in reported results

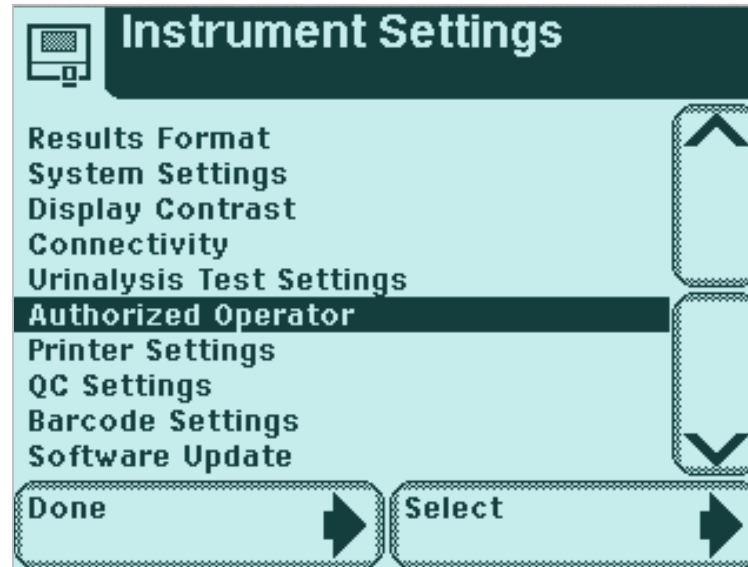
PRO URO
 NIT LEU
 ALB CRE

Previous Done



Set Up Authorized Operators

- Set up authorized operators.
- For each operator, set up:
 - ✓ operator ID
 - ✓ access level
- 700 operators can be defined and stored
- Operator ID length can be up to 13 characters



Path: Select Instrument Set Up > Instrument Settings > Authorized Operator



Set Up Authorized Operator Access

- Set up authorized operators.
- For each operator, set up:
 - ✓ operator ID
 - ✓ access level

Authorized Operator

Operator ID: MPL Edit

Patient test..... Enabled Edit

QC test..... Enabled

Recall results..... Enabled

Instrument set up..... Enabled

Delete entry Done

Path: Select Instrument Set Up > Instrument Settings > Authorized Operator

Authorized Operator
Operator access 1 of 2

Patient test Enabled Disabled

QC test Enabled Disabled

Previous Next

Authorized Operator
Operator access 2 of 2

Recall results Enabled Disabled

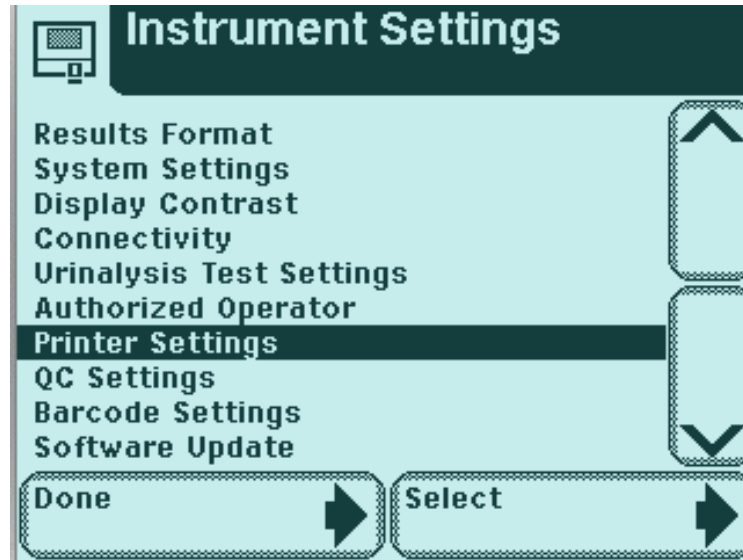
Instrument set up Enabled Disabled

Previous Done

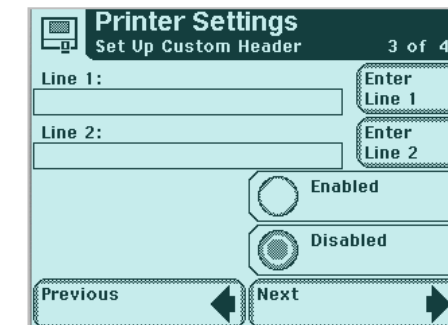
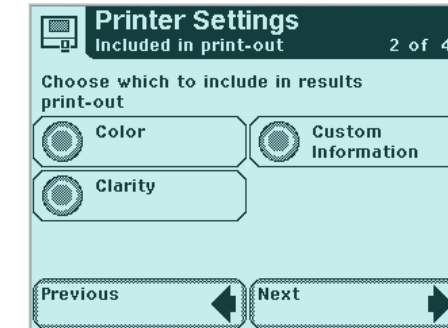
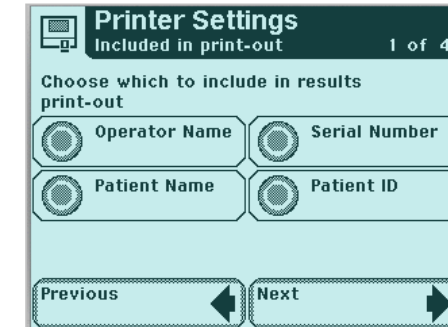


Select On-board Printer Settings

- Select information to include on print-out with each test result:
 - ✓ Operator name
 - ✓ Patient name
 - ✓ Patient ID
 - ✓ Serial number
 - ✓ Color
 - ✓ Clarity
 - ✓ Custom information
 - ✓ Customer headers



Path: Select Instrument Set Up > Instrument Settings > Printer Settings



Define Printer Options

- Select printer type – internal or external.
- If customer notes to be printed with each result, select Enabled.

The screenshot shows a 'Printer Settings' screen with the following elements:

- Printer Settings** (Title)
- Printer options** (Subtitle)
- 4 of 4** (Page indicator)
- External printer** (Radio button, currently unselected)
- Internal printer** (Radio button, currently selected)
- Print notes on internal printer** (Text label)
- Enabled** (Radio button, currently selected)
- Disabled** (Radio button, currently unselected)
- Previous** (Navigation button with left arrow)
- Done** (Navigation button with right arrow)

Path: Select Instrument Set Up >
Instrument Settings > Printer
Settings



Customize – Quality Control (QC) Set Up

- QC Settings will be disabled and not programmable with the standalone analyzer.
- If QC management and QC lock out functionality is a requirement, as about upgrading to the CLINITEK Connect System to enable these important features.

If using the CLINITEK Status+ analyzer in stand-alone mode:

- QC tests will be run as patient samples. Use the patient ID or patient name field to identify the control name and control level.
- You will need to manually check the test results against the control documentation to determine if the QC test has passed or failed.

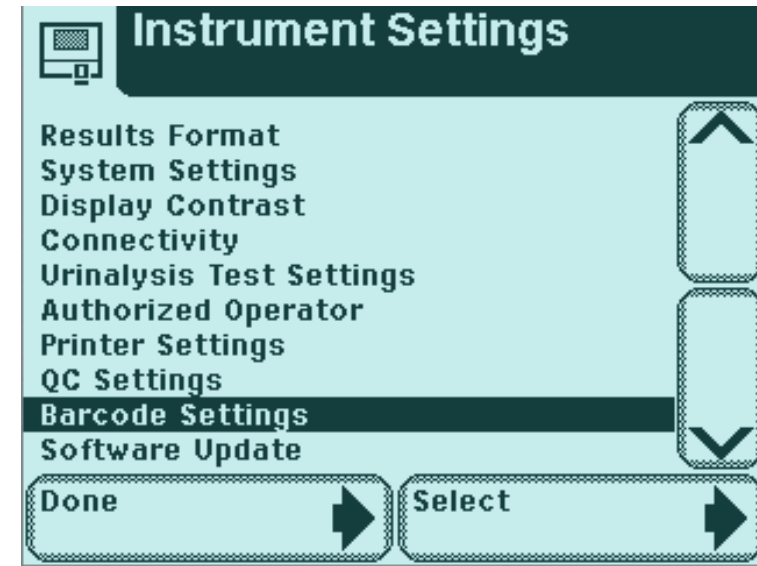


Path: Select Instrument Set Up >
Instrument Settings > QC Settings



Define Barcode Settings

- Barcode settings will be disabled.
- If barcode functionality is a requirement, consider upgrading with the connector base to add optional barcode scanning capabilities.



Path: Select Instrument Set Up >
Instrument Settings > Barcode
Settings



This training is a subset of the major custom features that can be set up.

Refer to the operators manual for more complete instructions and information.



Thank you!

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