ChloroChek®

Chloridometer®

Sweat Chloride Analyzer
Model 3400

USER'S MANUAL

57-2006-03D

01/18/2024

ELITechGroup

IVD CE

TABLE OF CONTENTS

SECTION 1
INTRODUCTION

1.1 ChloroChek Description

INDICATIONS FOR USE

The ChloroChek Chloridometer test system is intended for the quantitative in vitro diagnostic determination of chloride in human sweat using the principle of coulometric titration. Sweat chloride measurements are used in the diagnosis of Cystic Fibrosis. It is for use in clinical laboratory settings. The ChloroChek Chloridometer test system consists of the ChloroChek Chloridometer and the ChloroChek Reagent Set.

The ChloroChek Reagent Set (REF: SS-248) is to be used on the ChloroChek. It is used as the titration matrix during the titration process.

The 100 mmol/L NaCl/H_2O Standard Solution (REF: SS-251) is to be used on the ChloroChek. It is used as a calibration verifier, and quality control solution.

ELITechGroup Sweat Controls (REF: SS-150), levels #1, #2, and #3, are to be used on the ChloroChek. They are used as quality control solutions.

SAMPLE INFORMATION

Specimen

Human sweat collected with ELITechGroup's Macroduct® Collector or by other means (see CLSI C34 Sweat Testing Guideline 4th Edition for more information).

Storage

Sweat is stable for at least 72 hours across a reasonable temperature range, 25-77 ˚F (2-25˚C), without significant evaporation when stored in 0.2 mL microcentrifuge tubes with snugly fitting caps (see CLSI C34 Sweat Testing Guideline, 4th Edition, for more information).

Interferences

Any salts containing chloride or other halides (halogens) such as fluoride, bromide, or iodide will interfere and cause an elevated reading. CLSI states in C34-Sweat Testing Guideline 4th Edition, "In addition to chloride, other halides such as bromide and iodide are also detected using a Chloridometer®. Therefore, if a sweat sample contains other halides in addition to chloride, they will be detected and can falsely elevate the sweat chloride result." [(1)]. Halides including chloride may be present in lotions or creams, so it is important that the patient's skin is properly cleaned prior to collecting the sweat. Refer to the CLSI C34-Sweat Testing Guideline 4th Edition for cleaning the skin prior to pilocarpine iontophoresis. Improperly cleaned skin prior to sweat collection can lead to higher than normal results, thus leading to false intermediate or false positive results.

CAUTION!

It is critical that the skin is free of contamination before collecting a sweat sample to be used.

SPECIFICATION OF SAFE USE

Using this instrument in a manner not specified by ELITechGroup may impair the safety protection designed into the equipment and may lead to injury.

SAFE USE ENVIRONMENT

This device has been designed for indoor use only, between 41-104 °F (5-40 °C), maximum relative humidity 80%, at up to 87.8 °F (31 °C). For use at altitudes up to 2000 meters.
For use with a supply voltage of 85 to 264 Volts AC @ 50 to 60 Hz, ±10%. Transient Overvoltage Category II. Pollution Degree 2 in accordance with IEC 664 (non-conductive pollution).

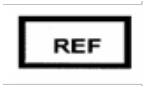
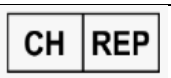
1.1 ChloroChek Description (continued)

PRECAUTIONS AND WARNINGS

- This equipment is for professional *in vitro* diagnostic use.
- Take standard precautions and adhere to good laboratory practices.
- To avoid contamination, clean the skin thoroughly and use clean or single use laboratory equipment while collecting the sweat sample.
- To avoid contamination, use clean or single use laboratory equipment during the analysis of the sweat sample on the ChloroChek.
- When opening the 100 mmol/L NaCl/H_2O Standard Solution (REF: SS-251) ampule, carefully break ampule at the correct location. The SS-251 ampule has a One Point Cut (OPC). Locate this point and break ampule by pushing the top of the ampule back while holding onto the base. It is recommended to use a plastic sleeve when breaking ampules. ELITechGroup provides two protective sleeves with each new box of sweat controls (SS-150).
- The reagent set contains acetic acid and nitric acid. If discharged in the plumbing system, rinse with plenty of water.

The symbols defined below may appear on the packaging material of the instrument or supplies, on the serial number label or in the operating instructions:

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	SYMBOL MEANING
	ISO 15223-1:2021 Reference no. 5.5.1.	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	In-vitro diagnostic medical device	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device
	This product conforms to EC Directive 98/79 for in-vitro diagnostic devices	REGULATION (EU) Directive 98/79 EEC	CE Marking	(43) 'CE marking of conformity' or 'CE marking' means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonization legislation providing for its affixing.
	ISO 15223-1: 2021 Reference no. 5.4.4. (ISO 7000-0434A)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	iso_grs_7010_WOO1	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	General warning sign	To signify a general warning
	ISO 15223-1: 2021 Reference no. 5.1.4. (ISO 7000-2607)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Use by date	Indicates the date after which the medical device is not to be used

	ISO 15223-1: 2021 Reference no. 5.1.5. (ISO 7000-2492)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified. Synonyms for “batch code” are “lot number”, “lot code” and “batch number”.
	ISO 15223-1: 2021 Reference no. 5.1.6. (ISO 7000-2493)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Catalogue number Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified ISO 15223 Catalogue number ISO 7000 Catalog number
	ISO 15223-1:2021 Reference no. 5.4.3. (ISO 7000-1641)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use
	ISO 15223-1: 2021 Reference no. 5.1.7. (ISO 7000-2498)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified
	N/A	Administrative Measure on the Control of Pollution Caused by Electronic Information Products (China)	Environment Friendly Use Period	Indicates the period of time before any RoHS substances are likely to leak out causing harm to the environment.
	ISO 15223-1: 2021 Reference no. 5.1.1. (ISO 7000-3082)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Manufacturer	Indicates the medical device manufacturer
	ISO 15223-1: 2021 Reference no. 5.1.2	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Authorized Representative in the European Community/ European Union	Indicates the authorized representative in the European Community / European Union
	MU600_00_016e V3.0	Information Sheet Obligations Economic Operators CH	Swiss Authorized Representative	Indicates the authorized representative in Switzerland

SECTION 1
INTRODUCTION

1.1 ChloroChek Description (continued)

Instrument Front

Touch Screen/
Display

Measurement Electrode

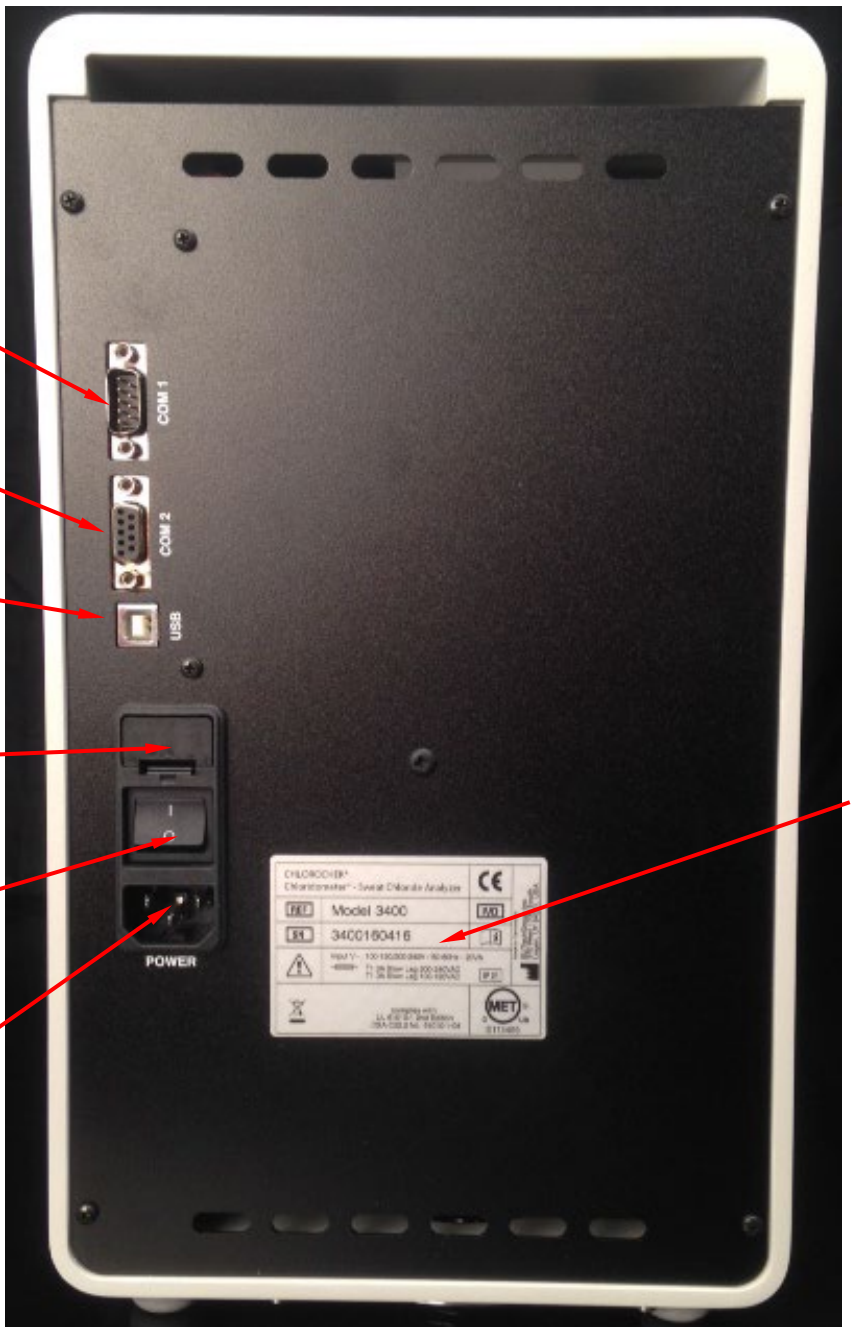
Titration Beaker
and Holder

Handle for lowering the electrode carriage into the titration beaker. Pipette guides are on the side of the handle.

Silver Electrodes
(Black housing = cathode
Red housing = anode)

1.1 ChloroChek® Description (continued)

Instrument Rear Panel



COM 1 – Serial data input port (not active in this model)

COM 2 – Serial data output port. RS232 port.

USB data output port.

Fuse holder for two-phase fuse protection of power supply

Power Switch I/on O/off

Power Entry Module

Product Model/Serial Number Label

SECTION 1
INTRODUCTION

1.1 ChloroChek Description (continued)

Unpacking the ChloroChek

After receipt of the shipment, the chloride meter should be immediately unpacked and checked for obvious signs of damage sustained during shipping. If any damage is found, notify the manufacturer or distributor (see appendix B for manufacturer contact information).

The packaging for this equipment was specially designed to ensure safe and hygienic transport. The packaging is reusable. Please save the packaging in case the unit needs to be shipped back to ELITechGroup for repairs or service.

Packaging Contents
Check to make sure the contents of the shipment are complete.

Accessories and consumables included in the shipment:

Reference Number	Item Description	Quantity
Model 3400	ChloroChek® Chloridometer®	1
RP-481	Silver Electrode, red housing (anode)	1
RP-482	Silver Electrode, black housing (cathode)	1
RP-483	Measurement Electrode	1
RP-484	Titration Beaker	2
RP-485	Magnetic Stir Bar	2
RP-486	Magnetic Stir Bar Retriever	1
RP-487	Silver Cleaning cloth	1
RP-535	Data Cable Set (RS232/USB)	1
SS-248	Reagent Set (37 x 10 mL of SS-248BS, 1 x 30 mL of SS-248GS)	1
SS-251	100 mmol/L NaCl/H_2O standard solution, 10 x 1.0 mL ampule	4
SS-150	Sweat Control Solutions, Tri-level 3 x 12 x 0.75 mL	1
AC-202	10 µL fixed volume pipette	1
SS-288	Pipette tips for ChloroChek® (box of 960 tips)	1
AC-071	Ampule Organizer	1
AC-180	Squirt Bottle for Water (500 mL)	1
	Power Cord	1
	Document Pack including User Manual	1

SECTION 2
SAFETY AND HANDLING INFORMATION

2.1 System Certification

The ChloroChek is an electronic laboratory measurement device. It should therefore be handled according to the safety provisions and precautions for electric measurement, control, and laboratory equipment.

Warning!
An apparatus with CLASS I construction shall be connected to a power outlet with a protective grounding connection. Where the power plug or an appliance coupler is used as the disconnect device, the disconnect device shall remain readily operable. To disconnect the equipment from the power remove the power plug from the power outlet.

Provisions of Certification
CE compliance requires that the device, together with the buffer solution, gelatin solution, and standard solution and accessories, be used in the manner described in this manual. Any deviation from the specification or independent modification of the device, the buffer solution, gelatin solution, and standard solution or accessories without the express consent of the manufacturer may result in a violation of CE requirement. Such action invalidates the compliance statement and transfers responsibility to the originator of said actions.

NOTE:
If the equipment is to be decommissioned, make sure it is sufficiently disinfected. This will make sure the equipment has been decommissioned in accordance with local accident prevention guidelines.

ChloroChek does not emit harmful substances during operation or when switched off.

SECTION 2
SAFETY AND HANDLING INFORMATION

2.2 Buffer Solution, Gelatin Solution, and Standard Solution

SS-251 100 mmol/L NaCl/H_2O Standard Solution

Composition:	100 mmol/L sodium chloride in distilled water.
Container:	Clear glass One Point Cut (OPC) ampule.
Nominal Volume:	1 mL.
Storage and Shelf Life:	Up to the expiration date indicated on the packaging when stored in the ampule at 41-113°F (5˚ C to 45 ˚C). Do not use after expiration date. Once ampule has been opened the shelf life is up to ½ hour at 71.6°F (22˚ C).

The 100 mmol/l NaCl/H2O standard solution is not classified according to Regulation (EC) No. 1272/2008 (CLP) and is therefore not a hazardous substance within the meaning of the regulation.

NOTE: The 100 mmol/L NaCl/H_2O Standard Solution consists of chemicals. All precautionary measures and regulations must be followed (do not swallow, do not taste, always wear gloves, etc.).

The ampules have a blue dot colored breaking ring. The ampule can be opened manually by breaking it off at this point. Follow all safety precautions for the handling of glass (splintering, breakage, etc.).

Buffer Solution and Gelatin Solution (Working Solution)

The buffer solution and the gelatin solution are not classified according to Regulation (EC) No. 1272/2008 (CLP) and are therefore not hazardous substances within the meaning of the regulation.
Information of safety and handling can be found in the attached safety data sheets.
The shelf life of a fresh Working Solution (a vial of Buffer Solution plus 20 drops of Gelatin Solution), is maximum of 14 days when kept in a sealed opaque vessel and stored at 25-46.4°F (2˚C to 8˚C). Working Solution (which contains silver chloride) that is to be used for measuring purposes should be used as soon as possible since it can react photochemically with light (reduction of the precipitated silver chloride into elementary silver). It is recommended that a new working solution is prepared for each measurement series, or after 50 samples. The on-board stability of the working solution is 24 hours at room temperature.

SS-248BS Buffer Solution:

Composition:	Solution of: diluted acetic acid and nitric acid, pH 1.12.
Container:	Screw top plastic vials.
Nominal Volume:	10 mL.
Storage and Shelf Life:	Up to the expiration date indicated on the packaging when stored in the ampule at 41-113°F (5˚ C to 45 ˚C). Do not use after expiration date.

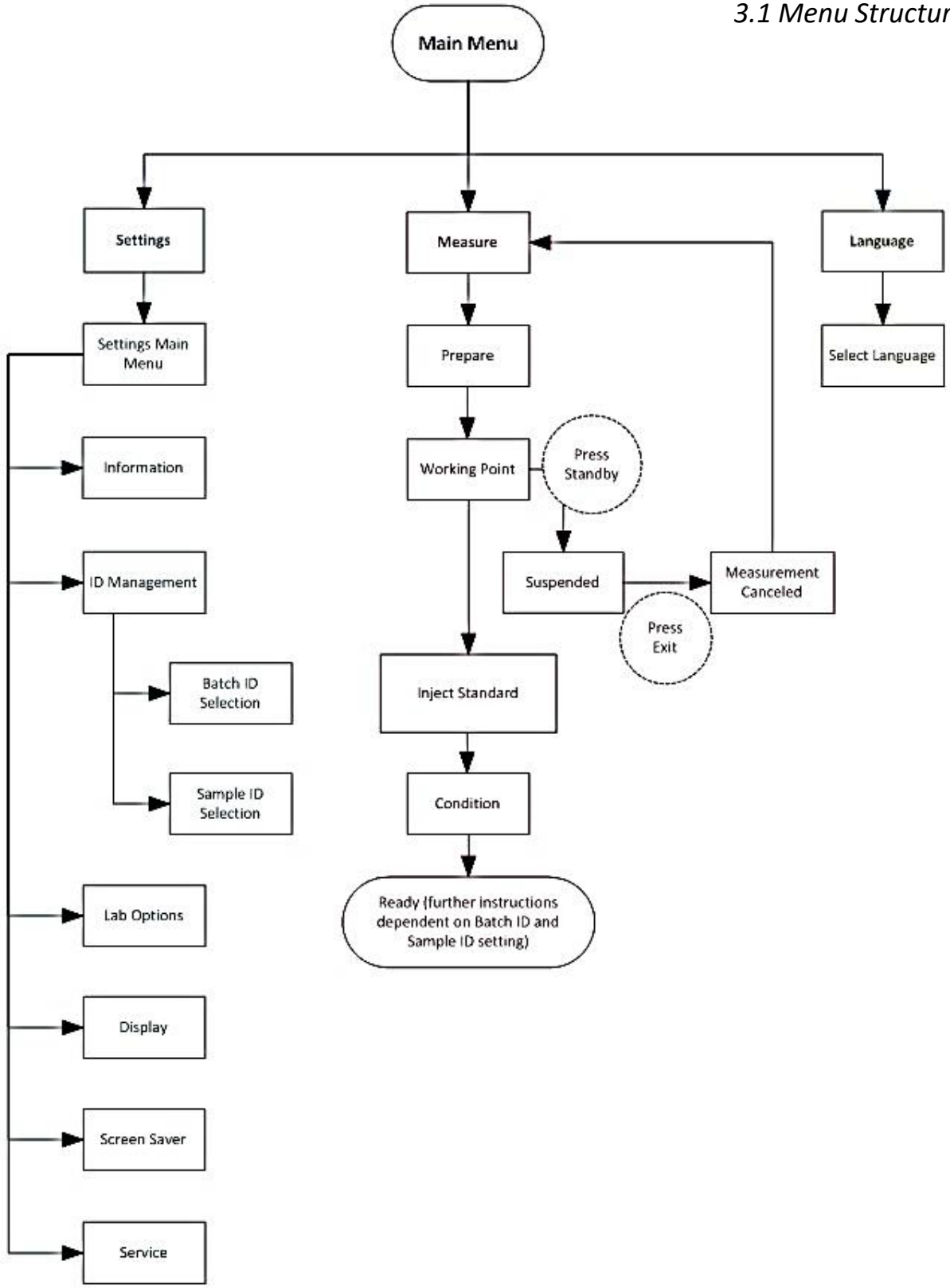
SS-248GS Gelatin Solution:

Composition:	Gelatin Solution with pH indicator, pH 5-7.
Container:	Screw top dropper bottle plastic vials.
Nominal Volume:	30 mL.
Storage and Shelf Life:	Up to the expiration date indicated on the packaging when stored in the ampule at 41-113°F (5˚ C to 45 ˚C). Do not use after expiration date.

Read the Safety Data Sheets (SDS) for Buffer Solution and Gelatin Solution.

CAUTION!
Disposal of all waste material should be in accordance with local, state and Federal regulatory requirements. The reagent set contains acetic acid and nitric acid. If discharged into the plumbing system, rinse with plenty of water.

3.1 Menu Structure



SECTION 3
OPERATING THE CHLOROCHEK®

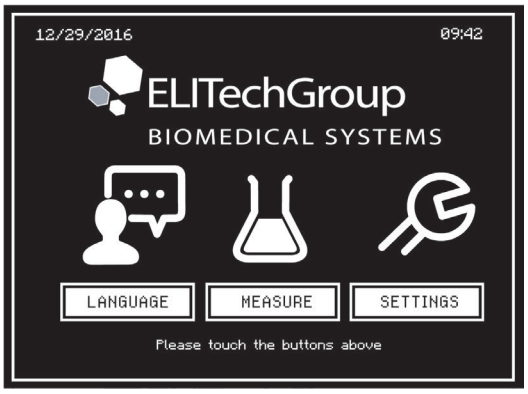
3.2 Initial Setup and Description

1 Place the instrument onto a flat and solid surface, such as a laboratory table. Avoid direct sunlight on the LCD screen for easier reading.

2 Use the provided power cord to connect power from an outlet to the power entry module.

NOTE:
Ensure that the line voltage matches the voltage indicated by the arrow on the power entry module of the instrument. If it does not, see Section 4.5 to change the voltage on the instrument.

3 Turn the power switch ON (I). After a short self-test the welcome screen appears on the display. This screen features three touch-sensitive buttons. This is the home screen:



4 Operating the ChloroChek is very easy using the touch screen display. Users can select between the menu items **LANGUAGE**, **MEASURE**, or **SETTINGS** by touching the corresponding button.

In the **LANGUAGE** menu, the user can select between German, English, Spanish, French, and Brazilian Portuguese.

In the **SETTINGS** menu, user can perform basic settings; to leave this menu press BACK. Setting options include Info (displays brief information about the system), Display (adjust contrast of the screen), Screen saver (select the amount of time until the screen saver activates, from 1 minute to 60 minutes). In order to avoid damage to the screen it is recommend that the screen saver be used.
The Settings menu contains the ID Management options. Users may select from automatic, numeric, alphanumeric, or none for ID type for a series of measurements (Batch ID) and individual samples (Sample ID). Automatic IDs will assign running numbers automatically, numeric IDs are assigned manually using the on-screen numeric keypad, alphanumeric IDs are assigned manually using the on-screen alphanumeric keypad, and selecting none will not assign any ID to batches or samples. Prompts during sample measurement are dependent on selection of ID type and will be discussed in section 3.7.
In the Settings menu there are also the Lab and Service menus. The date and time displayed on the ChloroChek is changed inside the Lab menu. The Lab menu can be password protected with a password set by the lab if they desire. The Service Menu is protected by a manufacturer generated password. Only trained personnel should access this Service menu.

In the **MEASURE** menu user can prepare the instrument for operation.

3.3 Installing Electrodes

Hands should be gloved so that the electrodes and beaker are not contaminated.

1 The electrode carriage must be in the up position.

2 Install the anode (red housing) and cathode (black housing) electrodes in the appropriate colored receptacle. The short side of the electrode goes into the receptacle leaving the long end exposed.

3 Install measurement electrode. The measurement electrode must be aligned to match the 3-pin connections without binding. Push the measurement electrode straight into the receptacle when the pins have been correctly aligned. The measurement electrode is not screwed into place.

SECTION 3
OPERATING THE CHLOROCHEK

3.4 Preparing the Working Solution (Reagents)

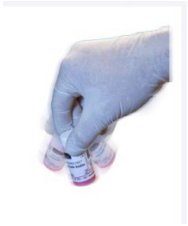
A fresh working solution must be prepared each day before using the ChloroChek or after 50 samples.

Appropriate good laboratory practices should be followed, including using appropriate personal protective equipment (PPEs). Refer to SDS.

The reagent set (SS-248) contains 1 bottle of SS-248GS and 37 flasks for SS-248BS. The 1 bottle of SS-248GS contains enough gelatin solution to prepare all 37 flasks of SS-248BS. Each flask of SS-248BS contains 10 mL of buffer solution.

1 Add 20 drops of Gelatin solution (SS-248GS) to one flask of buffer solution (SS-248BS).

2 Put the cap back on the flask and carefully swirl or invert it to mix it thoroughly. This forms the “working solution.”

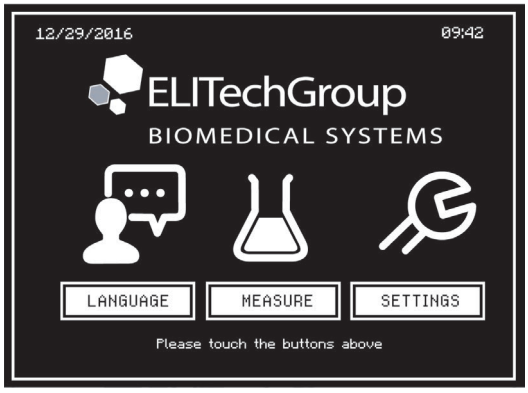


3 Place the magnetic stir bar (RP-485) in the titration beaker (RP-484). Pour the freshly prepared working solution into the titration beaker.

3.5 Conditioning

Conditioning must take place whenever a new working solution is prepared and used. A new working solution should be prepared and used each day, or after 50 samples.

1 With the instrument on, press MEASURE on the display.



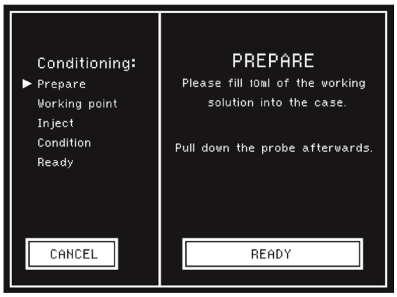
2 Place the filled titration beaker in the beaker receptacle.

3 Lower the handle to bring the electrode set down into the working solution and the READY button will appear.

SECTION 3
OPERATING THE CHLOROCHEK

3.5 Conditioning (continued)

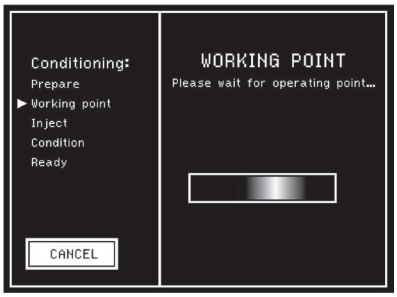
4 Press the READY button on the display.



NOTE:

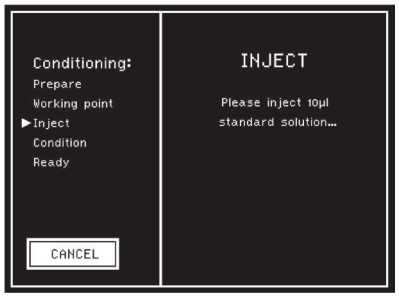
Pressing CANCEL ends the conditioning cycle and returns user to the main screen. If this is done, the working solution must be replaced.

5 In the following display, the user will be asked to wait until the system has reached its working point. A runtime display under the message visualizes this process. Proceed immediately to the next step.

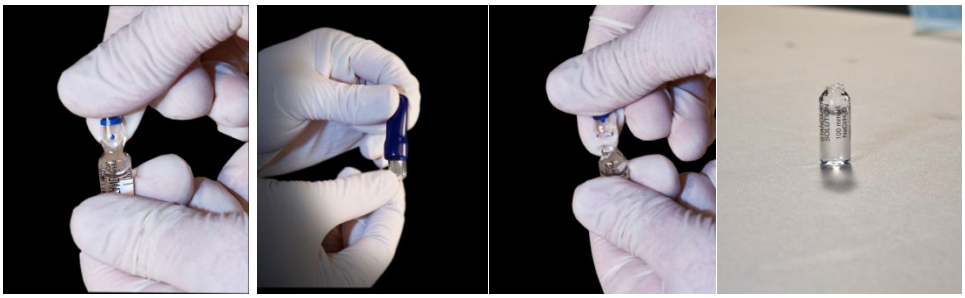


3.5 Conditioning (continued)

6 After the working point is reached, user will be instructed to pipette 10 µL of the 100 mmol/L NaCl/H_2O standard (SS-251) into the working solution.



To open the standard, first ensure that the fluid is in the bottom of the ampule. Hold the One Point Cut (OPC) ampule of SS-251 steady in one hand. With the other hand, carefully break off the head of the ampule with only slight pressure across the printed point (blue dot) on the neck of the ampule. Use a protective plastic sleeve when opening the ampule.



7 Place a correctly-sized pipette tip onto a 10 µL fixed-volume piston pipette. ELITechGroup provides a fixed volume pipette (AC-202) with each instrument. Use reference SS-288 for reordering pipette tips.

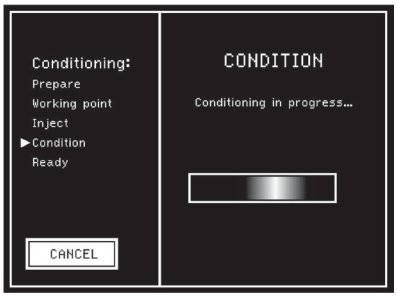
8 Place the pipette tip well into the 100 NaCl/H_2O mmol/L Standard Solution, holding the tip in the solution during the entire filling phase. Avoid drawing air into the pipette during the filling phase. Allow the piston to smoothly and slowly retract until it has returned to its initial position. Wait for about one second and then remove the pipette tip from the solution. If there are drops on the outside of the pipette tip, carefully remove them with a lint free tissue—do not draw out any solution from the pipette tip (through capillary forces of the paper tissue)—or if necessary, repeat the process with a new pipette tip.

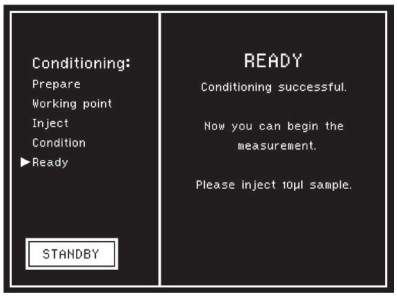
SECTION 3
OPERATING THE CHLOROCHEK

3.5 Conditioning (continued)

9 Using one of the pipette guides found on the sensor carriage, place the loaded pipette tip as near as possible in the center of the stirring working solution. Dispense the sample above the working solution, allowing the sample to drop into the working solution. Avoid dispensing the sample near the electrodes or the sides of the beaker. Press the pipette piston down to the second pressure point to completely eject the solution. Remove the pipette from pipette guide and discard the tip.

10 When the ChloroChek recognizes the added standard solution, the display will read: CONDITIONING.





11 When the conditioning is complete, the ChloroChek is ready to use.

NOTE:

- There may be a need to adjust the pipette calibration to account for minor variations in sample density and/or altitude. This calibration step could improve resolution.
- With the passage of time and with the use of the silver electrode of the anode (red shell), the electrode will be consumed as it precipitates with chloride ions. This electrode will need to be replaced periodically as it gets smaller. As long as the ChloroChek passes quality control, the anode can still be used for sample measurement.
- In cases where conditioning is not successful, user must clean the electrodes (Section 4.2), then prepare a new working solution. Contamination, such as dried buffer solution and/or sample debris, can cause electrodes to provide incorrect results or even cause an electric jump between the two electrode tips. With proper cleaning, users can be assured of success in conditioning, QC and specimen measurements.
- On rare occasions the ChloroChek may skip the conditioning step and move directly to the 'Conditioning Successful' screen. This usually happens when the electrodes are new or extremely clean. If this occurs and 'Conditioning Successful' appears on the screen, run the quality control solutions (Section 3.6). If quality control solutions produce the expected results, the ChloroChek is validated and ready to test unknown samples.

3.6 Quality Control

To ensure adequate quality control, the 100 mmol/L NaCl/H_2O Standard Solution (SS-251) should be assayed until it consistently reads within 100+/-2 mmol/L (Section 3.5, steps 6-9). Sweat Control Solution (SS-150) should be run at all three levels following the instructions for use. Both must be done at least once a day and after conditioning with a freshly prepared working solution and before running any patient samples.

The control frequency should be adapted to quality control procedures of each laboratory and any regulatory requirements. Results should be within the defined ranges.

If values fall outside of the defined ranges, then clean the measurement electrodes (Section 4.2) or check the accuracy of the pipette (Section 4.1). Quality control materials should be used in accordance with local, state, and/or federal guidelines.

NOTE:
Over time and use the anode (red housing) silver electrode will be used up as it precipitates with the chloride ions. This electrode will have to be replaced periodically as it gets smaller. As long as the ChloroChek passes quality control the anode is still usable for sample measurement.

QUALITY CONTROL PROGRAM

Navigate to www.elitechgroup.com/vqc for information on ELITechGroup's online, real time Quality Assurance Program.

SECTION 3
OPERATING THE CHLOROCHEK

3.7 Sample Measurement

PROCEDURE

After the Standard Solution (SS-251) consistently reads within 100+/-2 mmol/L and all three levels of Sweat Control Solution (SS-150) are in range, then the ChloroChek is ready to run patient samples.

1 Place a correctly-sized pipette tip onto a 10 µL fixed-volume piston pipette.

Place the pipette tip well into the sample, holding the tip in the sample during the entire filling phase. Avoid drawing air into the pipette during the filling phase. Allow the piston to smoothly and slowly retract until it has returned to its initial position. Wait for about one second and then remove the pipette from the solution. If there are drops on the outside of the pipette tip, carefully remove them with a lint free tissue—do not draw out any solution from the pipette tip (through capillary forces of the paper tissue)—or repeat the process with a new pipette tip.

2 Using one of the pipette guides found on the sensor carriage, place the loaded pipette tip as near as possible in the center of the stirring working solution. Avoid expressing solution near the electrodes or the sides of the beaker. Press the piston down to the second pressure point to completely eject the solution, and then remove the pipette tip with the piston still pressed.

3.7 Sample Measurement (continued)

Sample Measurement without ID Management

3 The ChloroChek recognizes the added sample and the display will count up from 0 until it reaches the final value. The final value remains on the screen until another sample is pipetted into the working solution, or until user presses STANDBY on the screen.

NOTE:
Test results must be interpreted by a qualified physician, according to the pertinent guideline. See Appendix F, Reference Intervals for Sweat Chloride.

4 After a final value is reached, the user can pipette another sample into the working solution following Steps 1-3 above. The ChloroChek automatically recognizes each sample when injected and the value for the last sample injection is displayed on the screen.

If the ChloroChek fails to automatically recognize the sample, the chloride concentration in the sample is less than 10 mmol/L. Verify this by adding 10 µL of the 100 mmol/L $NaCl/H_2O$ standard solution (SS-251). The reading will likely be above 100 mmol/L. Subtract 100 mmol/L from this final reading for the approximate final result of the sample. Keep in mind that this result is below the specified linearity range of the ChloroChek and should be recorded as <10 mmol/L.

NOTE:
If larger samples are used (>10 µL), take into account that the concentration is reported on the basis of the titration for a 10 µL sample. Adjust the reading according to the volume of pure sweat in the sample using a procedure validated by the laboratory.

Pressing STANDBY on the screen stops stirring the working solution, which conserves its functionality. Press STANDBY if there will be a break of at least 5 minutes between measuring samples. The ChloroChek will automatically go into STANDBY mode if no sample has been measured for at least 5 minutes. Press CONTINUE to restart stirring and continue with more measurements. Users should perform quality control with control samples before specimen samples are tested, to be sure that the ChloroChek is functioning correctly. In the STANDBY Menu, if CANCEL is pressed this will cancel the measurement sequence and the working solution should be discarded.

NOTE:
If ChloroChek has been in “Standby” mode with the electrodes in the working solution for an extended period (> 1 hour), an unexpected measurement (ghost reading) may occur. This is due to excess chloride becoming unbound from the silver electrodes or silver chloride precipitate.

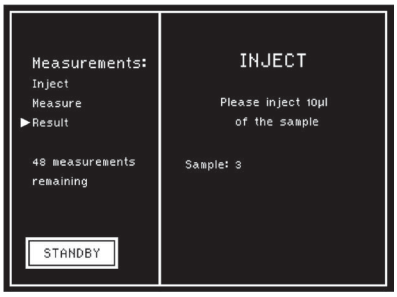
SECTION 3
OPERATING THE CHLOROCHEK

3.7 Sample Measurement (continued)

Sample Measurement with ID Management

Screen prompts are dependent on ID type selected in the ID Management settings menu. Flow charts describing screen prompts during sample measurement are provided in Appendix D.

1 After conditioning is finished, the READY screen will contain sample or batch options, depending on the ID types selected. Press the SINGLE SAMPLE button on the touch screen and follow the prompts (if any) for entering a sample ID. When the INJECT screen appears, the ChloroChek is ready for samples.



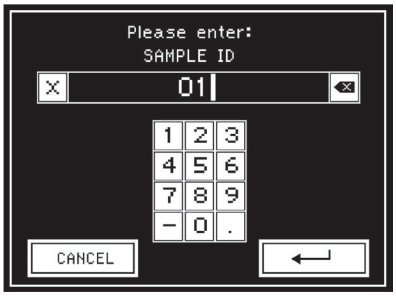
2 Place a correctly-sized pipette tip onto a 10 µL fixed-volume piston pipette.

Place the pipette tip well into the sample, holding the tip in the sample during the entire filling phase. Avoid drawing air into the pipette during the filling phase. Allow the piston to smoothly and slowly retract until it has returned to its initial position. Wait for about one second and then remove the pipette from the solution. If there are drops on the outside of the pipette tip, carefully remove them with a lint free tissue—do not draw out any solution from the pipette tip (through capillary forces of the paper tissue)—or repeat the process with a new pipette tip.

3 Using one of the pipette guides found on the sensor carriage, place the loaded pipette tip as near as possible in the center of the stirring working solution. Avoid expressing solution near the electrodes or the sides of the beaker. Press the piston down to the second pressure point to completely eject the solution, and then remove the pipette tip with the piston still pressed.

4 The ChloroChek recognizes the added sample and the display will count up from 0 until it reaches the final value. The final value remains on the RESULT screen until another sample is pipetted into the working solution, begin/end batch is selected, single sample is selected, or until user presses STANDBY on the screen.

All prompts and on screen buttons are dependent on ID type selection. For example, if automatic Batch ID type and numeric Sample ID type were selected, the scenario described in step 3 would result in a prompt to enter a sample ID using the on-screen numeric key pad upon selecting SINGLE SAMPLE from the READY screen.



NOTE:
Test results must be interpreted by a qualified physician, according to the pertinent guideline. See Appendix F, Reference Intervals for Sweat Chloride.

5 After a final value is reached, the user can pipette another sample into the working solution following Steps 1-3 above. The ChloroChek will automatically recognize each sample when injected and the value for the last sample injection will be displayed on the screen. The user may also select begin/end batch or single sample (dependent upon ID management settings) and follow prompts to continue testing a batch or single sample. See Appendix D for detailed flow charts of screen displays based on ID management settings.

SECTION 3
OPERATING THE CHLOROCHEK

3.8 Ending a Measurement Series

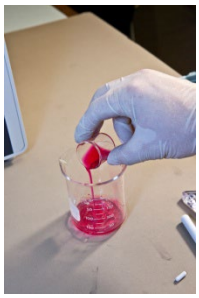
Once all samples are measured, press STANDBY and then CANCEL. This will end the measurement sequence.

Users can run up to 50 samples in each series before needing a fresh working solution. A freshly prepared working solution should be a transparent red color. As a working solution is used it will appear cloudy. If a freshly prepared working solution appears cloudy it should be discarded. The titration beaker should then be carefully cleaned and a new working solution prepared.

1 Raise the handle to lift the electrode set out of the working solution.

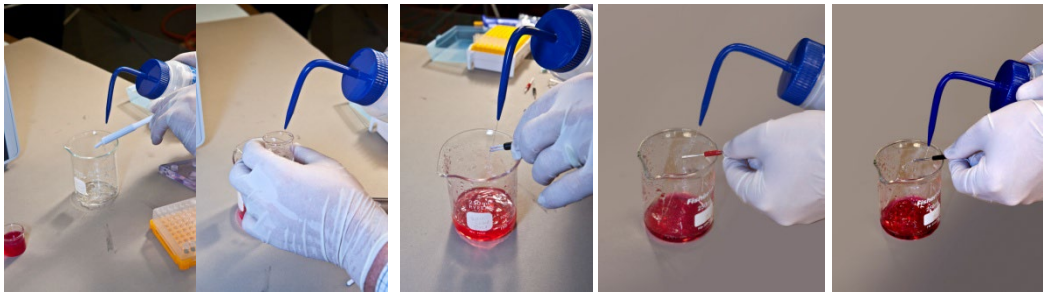
2 Remove the stir bar from the working solution by using the magnetic stir bar retriever (RP-486).

3 Discard the Working Solution.

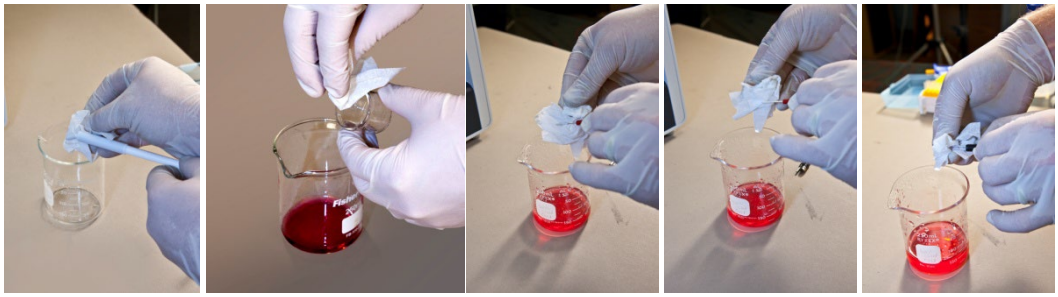


3.8 Ending a Measurement Series (continued)

4 Rinse the titration beaker, stir bar, and electrodes with deionized water. Remove the electrodes from the electrode carriage for easy rinsing and drying.



5 Dry the titration beaker, stir bar, and electrodes with lint-free tissue. To prevent oxidation, store cleaned and well dried electrodes in their individual plastic containers.



6 The ChloroChek is now ready for use again with a freshly prepared working solution.

SECTION 4
MAINTENANCE AND TROUBLESHOOTING

4.1 Error Messages and Troubleshooting

The following is an overview of the individual component groups, identifying the function of each component, its potential malfunctions, the effects of the malfunctions on the measurement system, and the possible causes of the malfunction and the procedure for correcting each malfunction. Conditioning cannot help minimize damage in this case. It is thus of no consequence whether these malfunctions occur during conditioning or during a sample measurement. Some errors can be remedied directly by the user or an in-house medical equipment technician; other errors require return of the unit to the manufacturer.

Component Groups function	**Malfunction**	**Effect**	**Possible Cause**	**Solution**
Titration electrode Anode or Cathode	- Fluctuating measurement values during measurement of the standard solution or controls.	- No plausible measurement values.	- Contaminated electrodes. - Mechanically defective electrodes.	- Clean electrodes with silver cleaning cloth and rinse with distilled water. - Replace electrodes and working solution.
Measurement electrode	- Conditioning not successful.	- Unable to begin the measurement series.	- Contaminated electrode. - Mechanically defective electrode.	- Clean the measurement electrode with the silver cleaning cloth and then rinse with distilled water. - Replace the measurement electrode.
Working Solution	- Conditioning not successful.	- Unable to begin the measurement series.	- Incorrect or used solution.	- Use new working solution.
Pipette	- Fluctuating measurement values during measurement of the standard solution or controls.	- No plausible measurement values.	- Pipette defective or incorrect use of the pipette.	- Inspect the pipette and/or assess pipetting technique for errors. - A sequence of 10 µL water samples pipetted into a container on a precision scale can help assess pipetting accuracy and consistency.

4.2 Cleaning the Electrodes

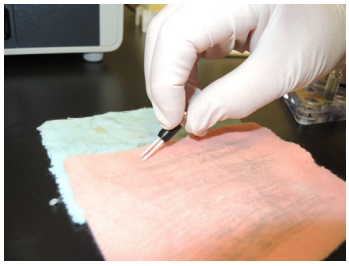
The measurement electrode, silver anode, and silver cathode must be cleaned weekly and a new working solution prepared. The measurement electrode must be replaced if conditioning fails after multiple cleaning attempts.

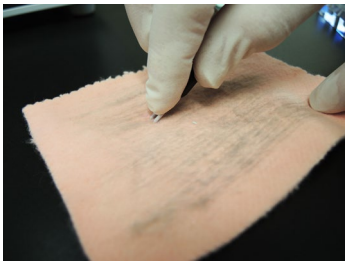
Equipment needed: Deionized water, catch beaker, silver cleaning cloth and microfiber cloth (silver cleaning cloth and microfiber cloth is provided as RP-487).

1 Place the small pink or green microfiber cloth and the large blue or orange silver polishing cloth near each other on a lab bench or other hard surface.

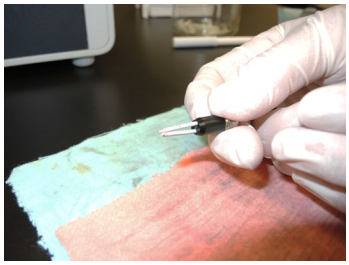
2 Remove the electrodes from the ChloroChek.

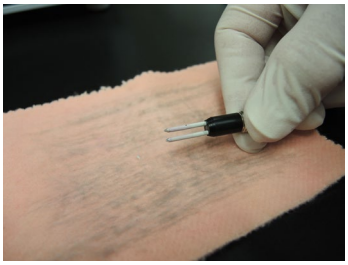
3 Observe the angle of the measurement electrode tip demonstrated below. When the correct angle has been achieved, aggressively pull the tips of the measurement electrode across the microfiber cloth with heavy downward pressure against the cloth. Repeat on all sides of the electrode. If done correctly, dark marks should appear on the cloth.





4 Electrodes may bend; straighten to be parallel if needed.

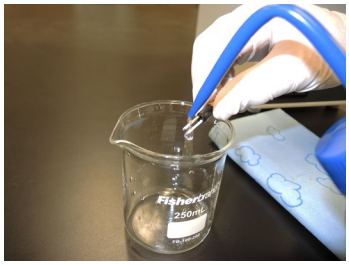


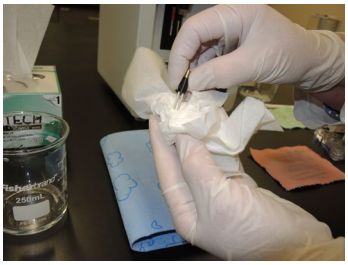


4.2 Cleaning the Electrodes (continued)

5 Dampen the large silver polishing cloth with deionized water. Clean all four sides of the electrode on the dampened cloth.

6 Rinse the electrode with deionized water.
7. Dry with lint free tissue, i.e. Kimwipes.
8. Again, straighten the electrodes if needed.





9. Install the measurement electrode into the ChloroChek.
10. Prepare a fresh working solution.
11. Lower probes into the working solution.
12. Press MEASURE; then READY.
13. Add 10uL of 100mmol/L NaCl standard. If 'conditioning successful' appears, continue to check instrument prior to use as described in Section 3.4.
14. At the end of the session, press STANDY, then EXIT.
15. Remove the electrodes: measurement electrode, silver anode, and silver cathode.
16. Rinse with deionized water.
17. Dry very well with lint free tissue, i.e. Kimwipes.

18. Store all three electrodes in individual plastic containers to prevent oxidation.

4.3 Calibration and Meter Check

The ChloroChek is factory calibrated. Calibration is not required by the user. Return the ChloroChek for service if the following occurs:

- ChloroChek not able to condition even after electrodes have been cleaned and or replaced.
- Correct quality control values while using Sweat Control Solutions (SS-150) are not achieved, after verification that the pipette is delivering the correct volume.

Calibration is checked during a maintenance check or meter check by the manufacturer or service agency and, if necessary, recalibration is performed.

SECTION 4
MAINTENANCE AND TROUBLESHOOTING

4.4 Cleaning the ChloroChek

Under normal clinical use the ChloroChek poses very little risk of biological infection to laboratory workers. The ChloroChek is essentially an environmental surface, which should be kept clean. Only low-level disinfection is required.

WARNING!
Make sure the instrument is OFF and unplugged before cleaning.

1 Use standard laboratory cleaning agents such as 10% bleach (0.5% sodium hypochlorite) to wipe down the instrument surfaces.

CAUTION!
Do not contact the instrument with excessive moisture. This can seep into the interior and cause damage to the instrument. Use a *damp* cloth only.

2 Rinse surfaces thoroughly with a cloth dampened with tap water.

3 Dry surfaces with a dry cloth or allow to air dry.

Other commonly used detergents, such as Mikrozid® AF Liquid, Bacillol® plus, 3% Korsolex® plus, 4% or similar can be used. REF: SS-133 (Decontamination Solution, Concentrate) can also be used.

NOTE:
These cleaning procedures are for routine use only. If shipping the instrument to ELITechGroup for repair or service, refer to Appendix G, Returning Product for Warranty Repair or Credit.

4.5 Changing the Power Fuses or Voltage Setting

WARNING!
Risk of electrical shock: Unplug the unit from the power supply before attempting to replace the fuses.

If screen is blank while unit is powered on, then the fuses may need to be replaced. To replace the fuses or to change the voltage setting to the local output, follow the instructions below.

1 To replace the fuses, use a small screwdriver to remove the fuse holder on the rear of the unit.

2 Remove and replace the two fuses. The device has two-phase protection. Only HBC fuses with a switching capacity of 1500 A are to be used:

200-240 VAC power supply: 1 A slow/LAG
100-120 VAC power supply: 1 A slow/LAG

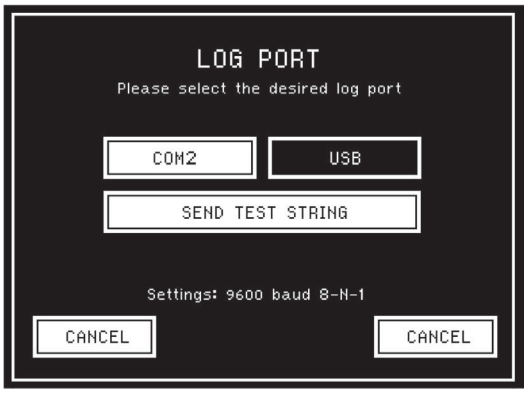
NOTE:
When inserting the fuse holder, return it to its original position (with the correct voltage setting directly below the power input socket). The arrow should point up to the correct line voltage indicated on the fuse holder.

SECTION 5
DIGITAL DATA MANAGEMENT

5.1 Digital Data Output

If digital data output is installed, three digital data ports are located on the back of the ChloroChek.

The ChloroChek can output the recorded measurement results to a PC via the COM2 (RS232) serial data port or the USB port. To select the data port, select LOG PORT in the SETTINGS menu. The following screen lets the user select COM2 or USB:



If using the RS232 Serial port then select COM2 and press OK.

If using the USB port then select USB and press OK.

To send a test string to a connected device, select SEND TEST STRING and the text “TEST” should appear in the connected output.

A software driver is required to use the USB port. Connect the ChloroChek to the PC using the USB cable and switch it on. The operating system of the PC detects the interface, automatically installs the required software driver, and notifies the user that installation was successful. The USB port can now be used as an additional COM interface.

A serial port program such as PuTTY or HyperTerminal must be installed on the computer that is interfacing with the ChloroChek.

Printer AC-177 is available for use with this instrument. It can be connected to the RS232 Port and provide human readable printouts, without being connected to a computer, using the Legacy CSV format.

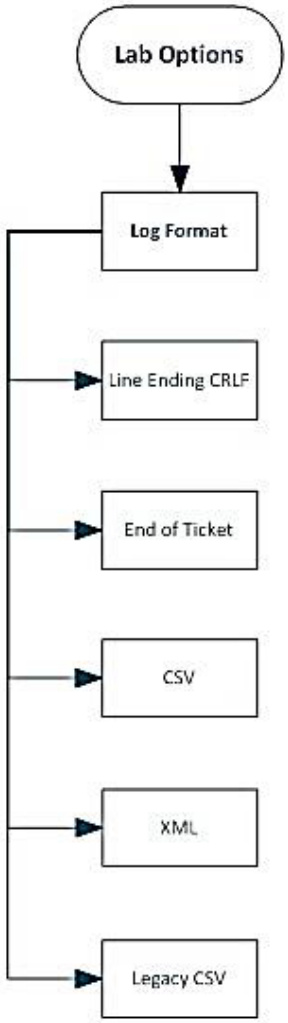
WARNING!
To protect life and equipment: Devices and accessories connected to the RS232 or USB connectors must meet the applicable safety standards for medical lab equipment.

5.1 Digital Data Output (continued)

The following data format will be used for output:

Formatting:	ASCII	A comma character (ASCII 0x2C ","), is used to separate the data columns and the carriage return character (ASCII 0x0d <CR>) to separate lines.
Baud Rate:	Transfer speed is 9600 Bits/s.	
Data Format:	8 data bits no parity 1 stop bit	

5.2 Lab Options Menu Structure



5.3 Log Format Options

Log Formats

Format	Description	Advantages	Disadvantages
CSV	• Line by line • Comma-separated values • Placed within quotation marks	• Compact • Can be uploaded into spreadsheets (e.g. Excel) • Easily human-readable • Checksum acts as a backup	• RFC4180: Not a formally released and controlled standard
XML	• Standardized extensible markup language	• Standardized • Compatible with large number of APIs • Human-readable • Checksum acts as backup	• Not very compact
Legacy CSV	• CSV format from previous generations of devices	• Compatible with legacy devices and interfaces	• Syntax not always clear • May cause data to be misinterpreted • Works best with AC-191 Printer • For reasons of security, it is strongly advised not to use this format with a networked computer

End of Line Markers

Name	Description	ASC11
CR	Carriage return	0x0D
CRLF	Carriage return and line feed	0x0D 0x0A

End of Ticket Markers

An “end of ticket” marker can be implemented to display the text “EndOfTicket” after each individual sample measurement of after the end of each batch.

5.4 CSV Format

If CSV format is selected, the log is displayed line by line. Each line is separated by the end of line symbol selected in the Lab Options. There are three types of line content:

Type	Purpose
Intro	Message showing version numbers of the instrument
Title	Column title of the next table of result lines
Result	Measurement result or error message

Line Group

Every line within the CSV format contains several semicolon-separated values (ASCII:0x3B), which may be contained within quotation marks (ASCII:0x22). Whether or not quotations marks are used depends on the value format; they are not used for measurements or times, but are used for text values.

Intro Line

When the instrument is started, a line is published with version information to prevent future compatibility problems. This line contains the short name of the device type followed by the version numbers of the mainboard and the components connected to it. A typical intro line looks like the following:

CM20; Main:V1.80; COM:V1.7; D:V1.10

NOTE:
Software driver must be open when powering on the machine or when changing the Log Format to CSV in order to generate the intro line and the title line. Changing the settings restarts the logbook and also publishes a new intro and title line.

Title Line

The intro line is followed by a line with title names for the values of the next result lines. This line helps to make the text human-readable and generates practical column titles when imported into a spreadsheet. The title line looks like the following:

“charge”; “sample”; date; value; “dimension; “device-no”; “check”; “message”

5.4 CSV Format (continued)

Output Content

After each measurement a result line is published, which contains the following semicolon-separated values in a fixed order:

charge	Batch ID appears if entered manually or set to automatic. A minus sign "-" is displayed if Batch ID type is none or Single Sample is selected during measurement. (The term “charge” is synonymous with the term “batch”.)
sample	Sample ID appears if entered manually or set to automatic. Void if Sample ID type is none.
date	Date and time in combined ISO 8601 format (e.g. 2015-12-31T13:45).
value	Measurement result without decimal places (regardless of language setting).
dimension	Unit of the measurement value published in quotation marks “mmol/l” (regardless of language setting).
device-no	Serial Number of ChloroChek® (alphanumeric).
check	Checksum of previous values in this line (see Checksum section).
message	Human-readable message in selected language (not present if there is no notification).

5.5 XML Format

The XML format is published line by line, but a single record will generally extend across several lines. Each record is imported as a ticket and multiple measurements for one batch are combined into one ticket. Records are allocated to tickets in the same way as they are published; each printed record corresponds to one ticket in the XML log. There are two types of tickets:

Type	**Description**
Sample	Contains exactly one result from a single measurement
Batch	Contains several results from a batch measurement

Ticket

A ticket consists of an XML tag, which corresponds to one published ticket. If it relates to a single measurement, it contains an additional XML tag called MEASUREMENT, which contains the measurement and the associated metadata. If it relates to a batch measurement, one ticket may contain several measurements. A ticket has the following attributes in addition to the measurements contained in it:

Attribute	**Description**
Class	Ticket type (sample or batch)
Serial-no	Serial number of the device
Versions	Version info on the device and connected components (similar to the Intro Line in the CSV format)

5.5 XML Format (continued)

Measurement

A measurement or mismeasurement is described in a ticket in an XML tag called MEASUREMENT, which contains the following values:

BatchID	Batch ID appears if entered manually or set to automatic. A minus sign "-" is displayed if Batch ID type is none, Single Sample is selected during measurement, or if it is a mismeasurement.
SampleID	Sample ID appears if entered manually or set to automatic. Void if Sample ID type is none and will not be present if it is a mismeasurement.
DateTime	Date and time in combined ISO 8601 format (e.g. 2015-12-31T13:45).
Value	Measurement result with floating point number with a point as decimal separator (regardless of language setting). Value will not be present if it is a mismeasurement.
Unit	Unit of measurement in mmol/l (regardless of language setting). Will not be present if it is a mismeasurement.
Failure	Error identifier (see Error messages section).
DeviceNo	Serial Number of ChloroChek® (alphanumeric).
CheckSum	Checksum of previous values in this line (see Checksum section).
Message	Human-readable message in selected language (not present if there is no notification).

Example of a Single Measurement

In the case of a single measurement the entire ticket is published in one piece when the measurement has been completed; the value BatchID does not apply.

```
<Ticket class=”SAMPLE” serialno=”3400140127” versions=”CHLOROCHEK®;Main:V1.80;COM:V1.6”>
<Measurement>
        <SampleId>01</sampleId>
        <DateTime>2016-12-22T12:51:30</DateTime>
        <Value>21</Value>
        <Unit>mmol/l</Unit>
<DeviceCode>3400140127</DeviceCode>
        <CheckSum>1fe1219fa897b340c91407c191af319d</CheckSum>
</Measurement>
</Ticket>
```

SECTION 5
DIGITAL DATA MANAGEMENT

5.5 XML Format (continued)

Example of a Batch Measurement

If a new batch is initiated, a section is published that opens the ticket as an XML tag in the log and measurements are then implemented within that batch:

```
<Ticket class="BATCH"  serialno="3400140127"  versions="CHLOROCHEK®;Main:V1.80;COM:V1.6">
<Measurement>
        <BatchId>BATCH01</sampleId>
        <SampleId>01</sampleId>
        <DateTime>2016-12-22T12:55:30</DateTime>
        <Value>21</Value>
        <Unit>mmol/l</Unit>
<DeviceCode>3400140127</DeviceCode>
        <CheckSum>1fe1219fa897b340c91407c191af319d</CheckSum>
</Measurement>
```

Ending the batch also closes the ticket:

```
</Ticket>
```

5.6 Legacy CSV Format

If Legacy CSV format is selected, the following header will be transferred before any data output at the beginning of a charge or a single sample measurement:

charge, sample, date, time, value, device, device-no <CR>

Then, the following output will be transferred after every successful measurement:

<charge>,<sample>,<date>,<time>,<value>,<device>,<deviceno> <CR>

Output Content

Output content is very similar to CSV format, but the text is more human-readable when printing:

charge	Batch ID appears if entered manually or set to automatic. A minus sign "-" is displayed if Batch ID type is none or Single Sample is selected during measurement. (The term “charge” is synonymous with the term “batch”.)		
sample	Sample ID appears if entered manually or set to automatic. Void if Sample ID type is none.		
date	Date of the measurement in English notation "mm/dd/yyyy".		
	mm	Month, two digits	[01..12]
	dd	Day, two digits	[1..31]
	yyyy	Year, four digits	[0000..9999]
time	Time of measurement in English notation "HH:MM".		
	HH	Hour, [00..23]	
	MM	Minute, [00..59]	
value	Measurement result without decimal places (in mmol/l, regardless of language setting).		
device	Alphanumeric device description (e.g. "Wescor ChloroChek®").		
device-no	Serial Number of ChloroChek® (alphanumeric).		

5.7 Error Messages

The following error messages may be used to diagnose an operating error or device failure:

Notification	**Meaning**
ABORT	User cancels by pressing the exit key
LIFT	User cancels by lifting the sensor
MFAIL	Measurement could not be completed successfully
CFAIL	Conditioning could not be completed successfully
MABORT	Measurement was canceled
IFAIL	Unexpected injection of sample
EXHAUST	Working solution has been used up

5.8 Checksums

The checksum for each result line is calculated from the values from the columns BatchID, SampleID, DateTime, Measurement, Unit, and Device number. A possible result line is as follows:

```
<Measurement>
    <SampleId>01</SampleId>
    <DateTime>2016-12-22T12:55:30</DateTime>
    <Value>21</Value>
    <Unit>mmol/l</Unit>
    <DeviceNo>3400140127</DeviceNo>
    <CheckSum>a173e3f754290e77f1b5ac689d3d2486</CheckSum>
</Measurement>
```

Or:

```
; “01”; 2016-12-22T12:55:30; 21; “mmol/l”; “3400140127”; “a173e3f754290e77f1b5ac689d3d2486”;
```

And the above contents are strung together to form:

```
012016-12-22T12:55:30mmol/l3400140127
```

The MD5 checksum for this string is:

```
A1 73 e3 f7 54 29 0e 77 f1 b5 ac 68 9d 3d 24 86
```

5.9 Using a Barcode Scanner for ID Input

A barcode reader can be attached to the COM1 port and allows for scanned barcodes to be used in ID management. Barcode reader AC-192 is available for purchase and necessary cables are included.

1 To use a barcode for ID management, the batch and/or sample ID Management type must first be set to numeric or alphanumeric from the ID Management settings menu.

2 Plug barcode reader into the COM1 RS232 port and attach power cable. Plug unit into power source and ensure a green light appears on the top of the barcode reader.

3 Enter the measurement screen and condition the working solution. Once the Ready screen appears, follow the instructions in section 3.7 for sample measurement with ID management or refer to flow charts using ID management in Appendix D.

4 Screens are dependent upon ID Management type selections. Whenever the on screen keypad appears for entering a batch or sample ID, a barcode may be scanned using the barcode reader and will be entered into the screen. The keypad is still accessible and the barcode can be deleted or modified.

APPENDIX A
SPECIFICATIONS
ChloroChek Chloridometer Model 3400

Sample Volume	10 µL
Measurement Duration	Approximately 20 Seconds
Reproducibility*	CV of 1.02% at 100 mmol/L
Measurement Display	0 - 999 mmol/L
Linearity Measuring Range	10 - 160 mmol/L
Resolution	1 mmol/L over the entire measurement range
Integrated Stir Bar	PTFE coated magnetic cylindrical stir bar
Data Output	Serial RS232/USB
Environment operating temperature	Indoor use; no direct sunlight
Operating temperature (ambient)	50 ˚F to 95 ˚F / 10 ˚C to 35 ˚C
Storage temperature	-40 ˚F to 158 ˚F / -40 ˚C to 70 ˚C
Room humidity	5-80% (non-condensing)
Altitude	up to 2000 m /6562 feet
Electrical Voltage	100-120 VAC / 200-240 VAC
Frequency	50-60 Hz
Power	20 VA
Electrical connection	Detachable power supply cord
Fuses (2): HBC breaking capacity 1500 A	1.0 A for 100-120 VAC 1.0 A for 200-240 VAC
Memory backup	integral lithium cell: 10 years typical
Dimensions: (W x D x H)	20.5 x 22.0 x 36.0 cm (8.0 x 8.1 x 14.2 inches)
Weight	Approximately 5.7 kg (12.54 lbs.)

*Generally limited by the sample dispensing system (pipette accuracy)

APPENDIX B
CUSTOMER SERVICE INFORMATION

ELITechGroup is ready to help you resolve any problems with your ChloroChek Chloridometer. If you cannot solve a problem using the procedures in this manual please contact us.

Customers within the United States and Canada are encouraged to contact us by telephone. Contact ELITechGroup by mail, telephone, fax or e-mail at the address and numbers listed below.

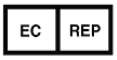
ELITechGroup, Inc.
370 West 1700 South
Logan, Utah 84321-8212 USA

Telephone:
1-435-752-6011
1-800-453-2725 *(United States & Canada)*

Fax:
1-435-752-4127 *(US)*

Email:
Service_EBS@elitechgroup.com *(Service)*
Sales_EBS@elitechgroup.com *(Sales)*

Web Page:
www.elitechgroup.com



European Authorized Representative:
MT-Promedt Consulting GmbH
Ernst-Heckel-Straße 7
66386 St. Ingbert
Germany

Telephone: +49(0)68 94-58 10 20
Fax: +49(0)68 94-58 10 21
Email: info@mt-procons.com

Swiss Authorized Representative
Decomplix AG
Freiburgstrasse 3
3010 Bern
Switzerland
Telephone: +41-32-365-33-33
Email: sar@decomplix.com

APPENDIX C
CONSUMABLES, ACCESSORIES, AND REPLACEMENT PARTS

ChloroChek Accessories

Item	Reference Number
Reagent Set (37 x 10 mL of SS-248BS, 1 x 30 mL of SS-248GS)	SS-248
100 mmol/L NaCl/H_2O Standard Solution, 10 x 1.0 mL ampule	SS-251
Sweat Control Solutions, Tri-level, 3 x 12 x 0.75 mL	SS-150

ChloroChek Supplies

Item	Reference Number
Pipette tips for ChloroChek (box of 960 tips)	SS-288
10 µL Fixed Volume Pipette	AC-202
Ampule Organizer for Sweat Controls	AC-071
Squirt Bottle for Water (500 mL)	AC-180
Serial Printer	AC-177
ChloroChek Barcode Reader	AC-192

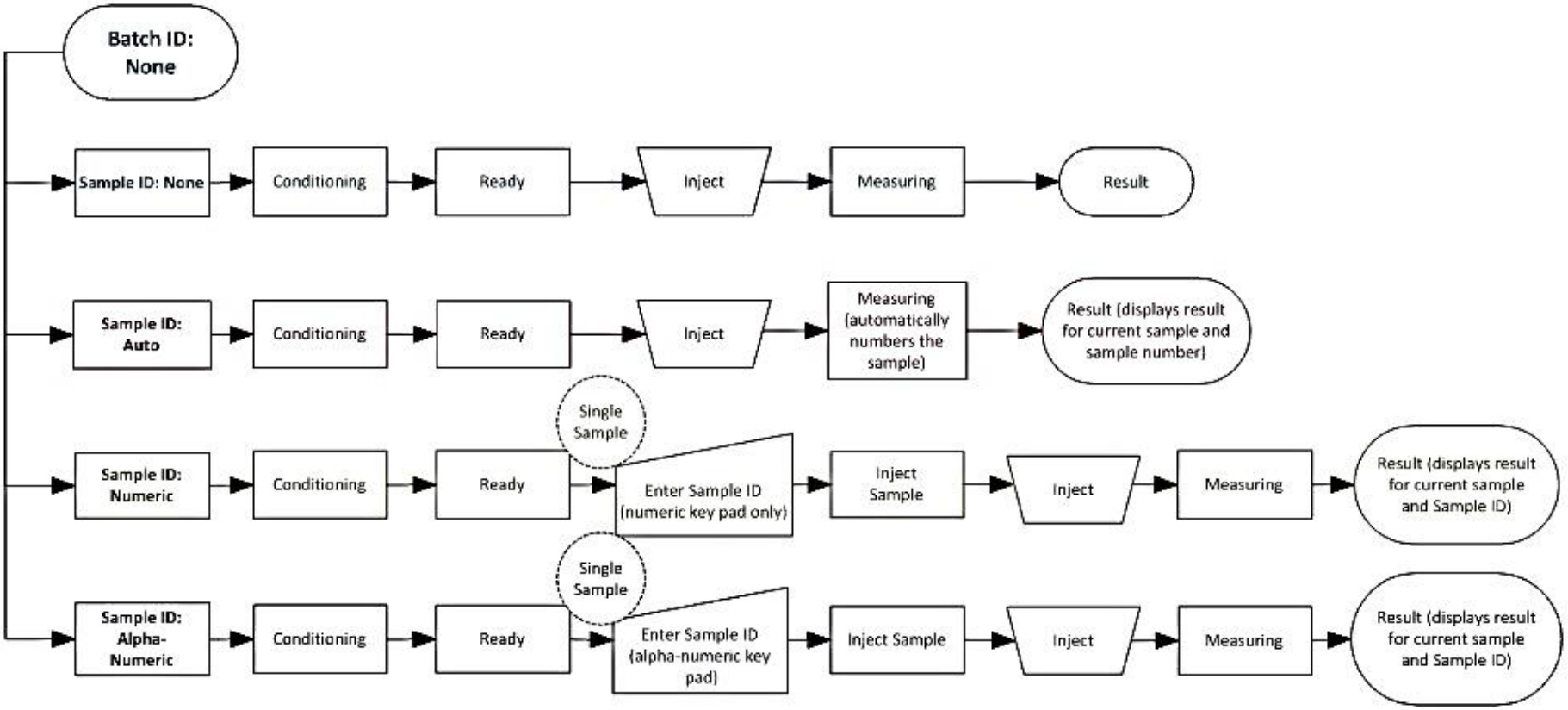
ChloroChek Replacement Parts

Item	Reference Number
Silver Electrode, red housing (anode)	RP-481
Silver Electrode, black housing (cathode)	RP-482
Measurement Electrode	RP-483
Titration Beaker	RP-484
Magnetic Stir Bar	RP-485
Magnetic Stir Bar Retriever	RP-486
Silver Cleaning Cloth	RP-487
ChloroChek User's Manual	RP-497

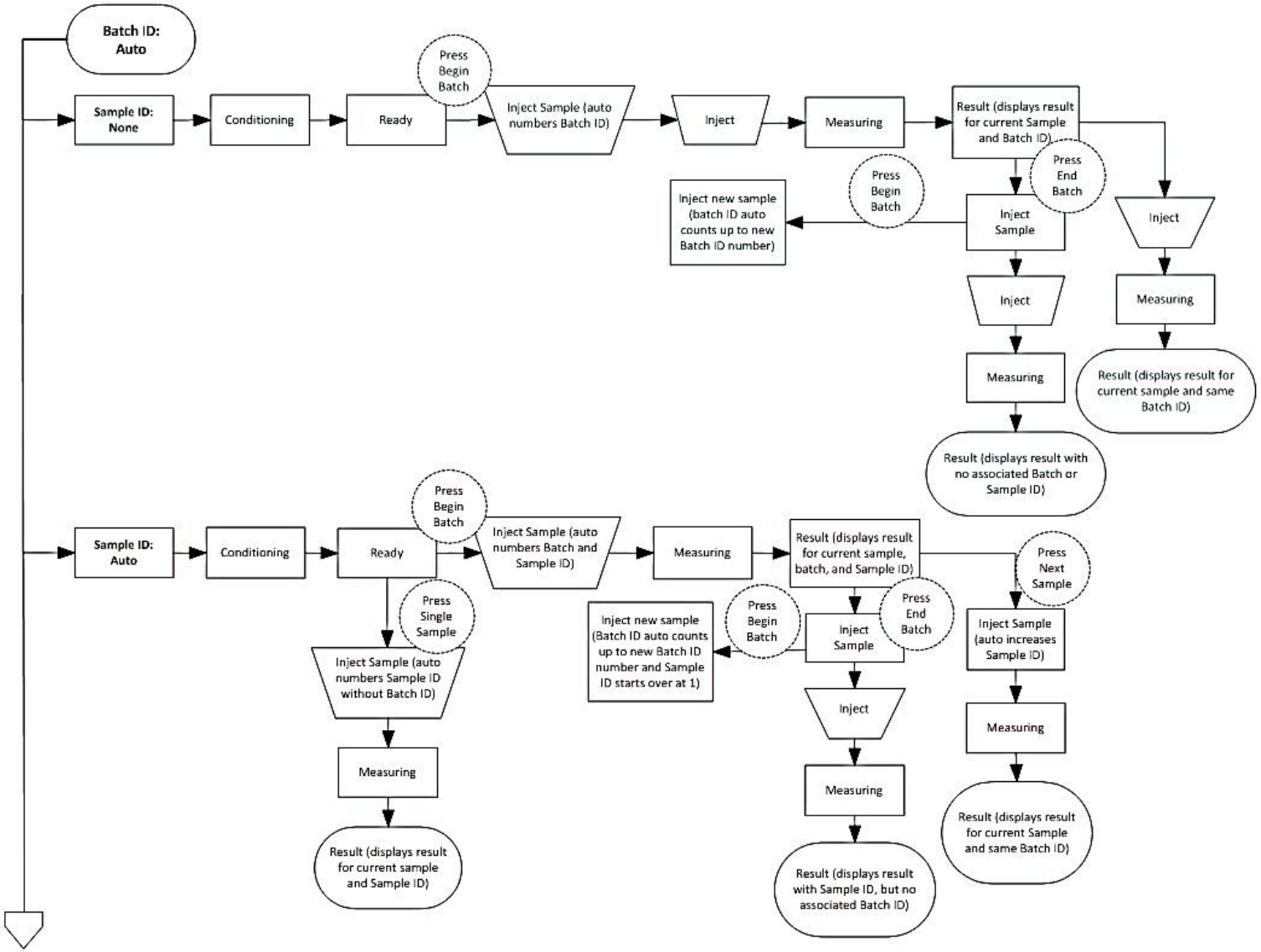
APPENDIX D

FLOW CHARTS FOR SAMPLE MEASUREMENT USING ID MANAGEMENT

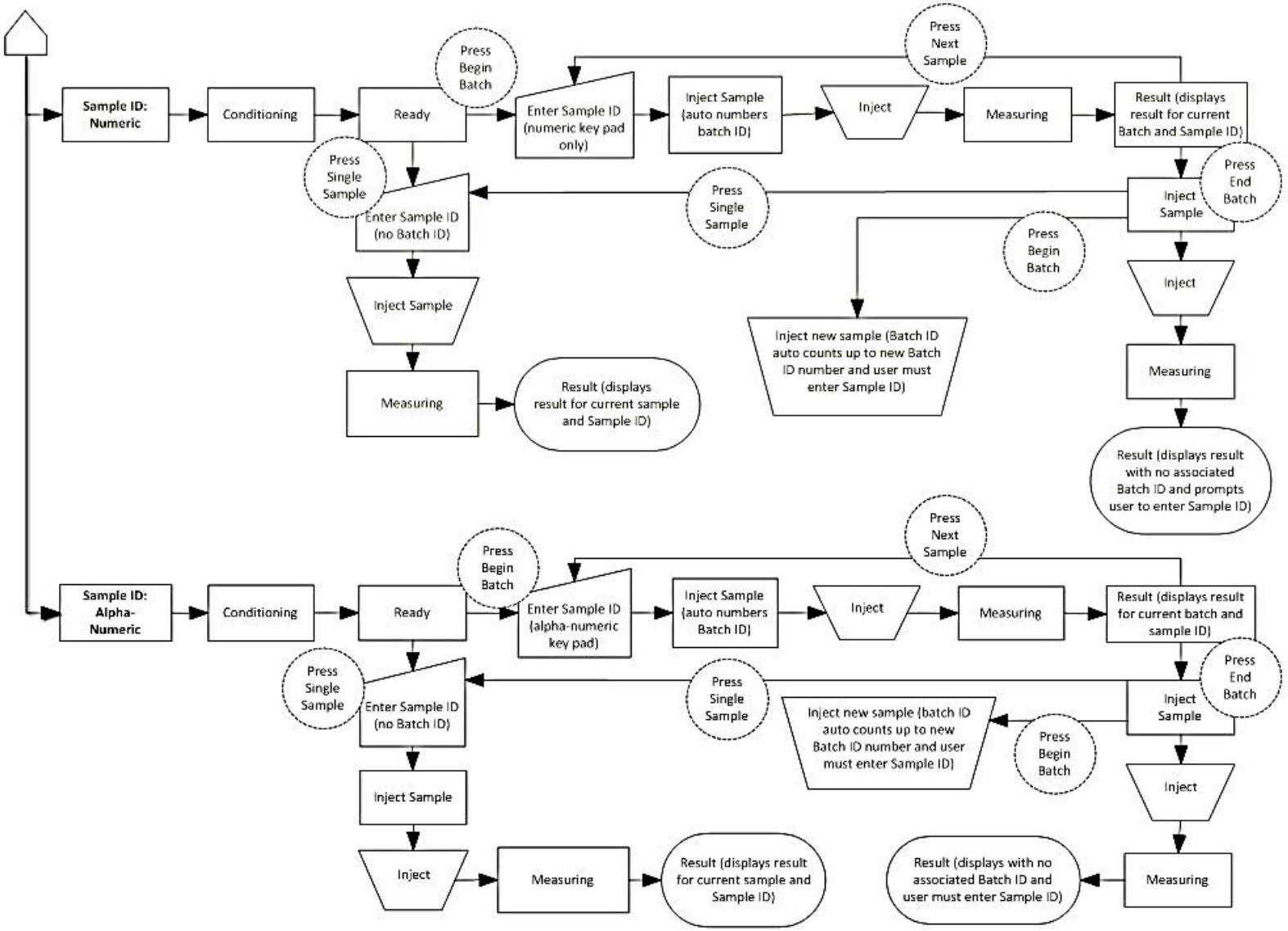
Screen Cascade for Batch ID Type None



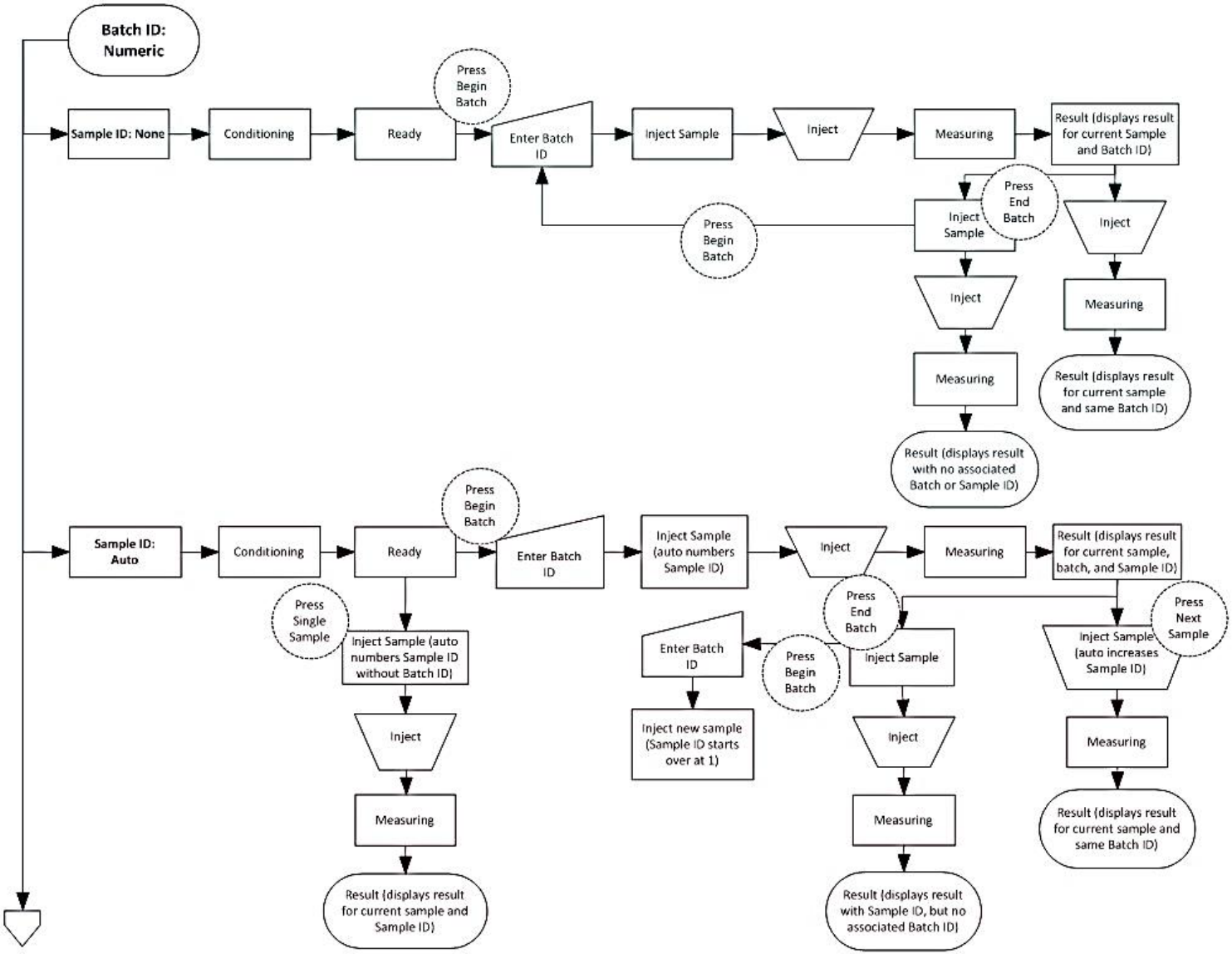
APPENDIX D
FLOW CHARTS (CONTINUED)
Screen Cascade for Batch ID Type Auto



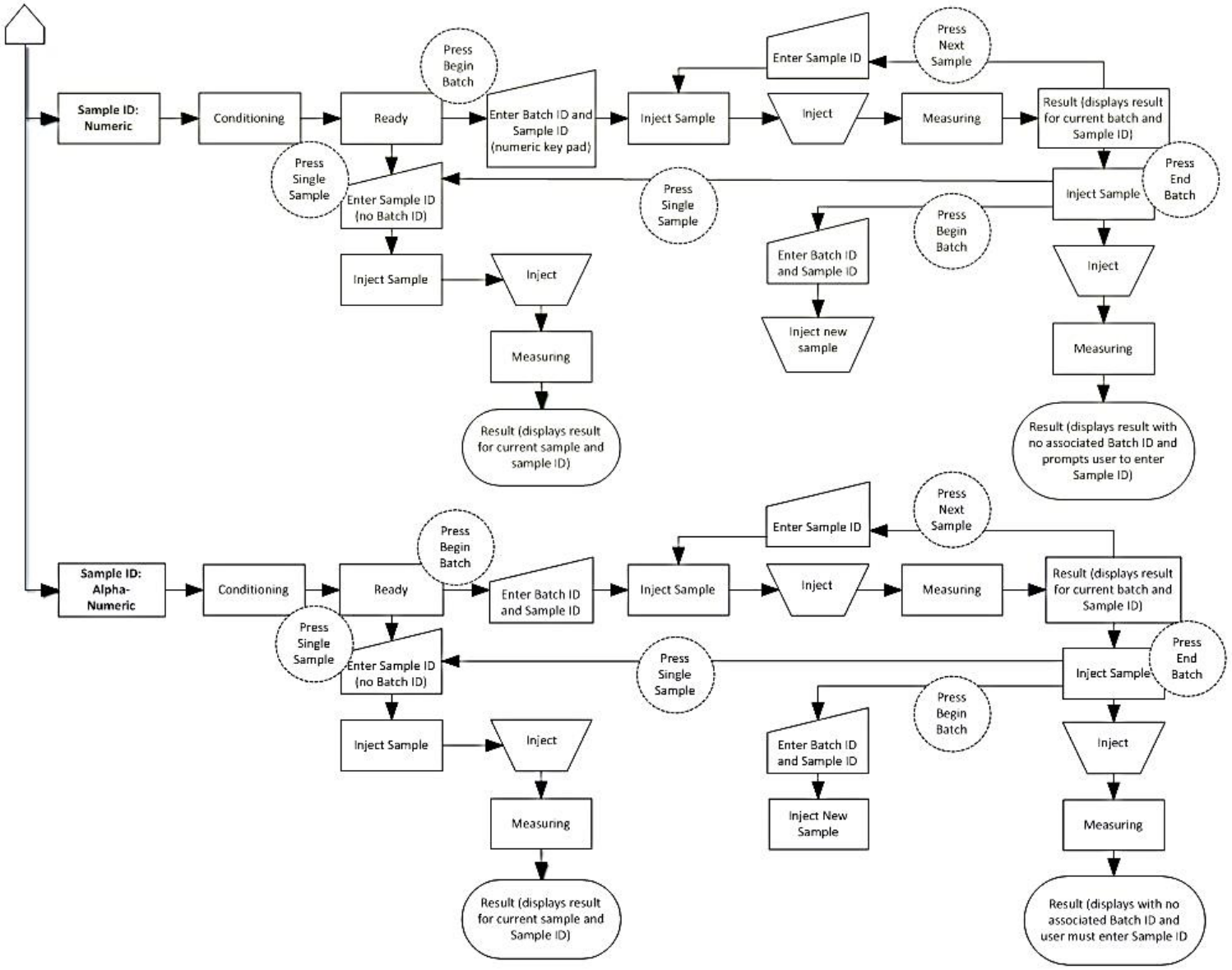
APPENDIX D
FLOW CHARTS (CONTINUED)
Screen Cascade for Batch ID Type Auto (Continued)



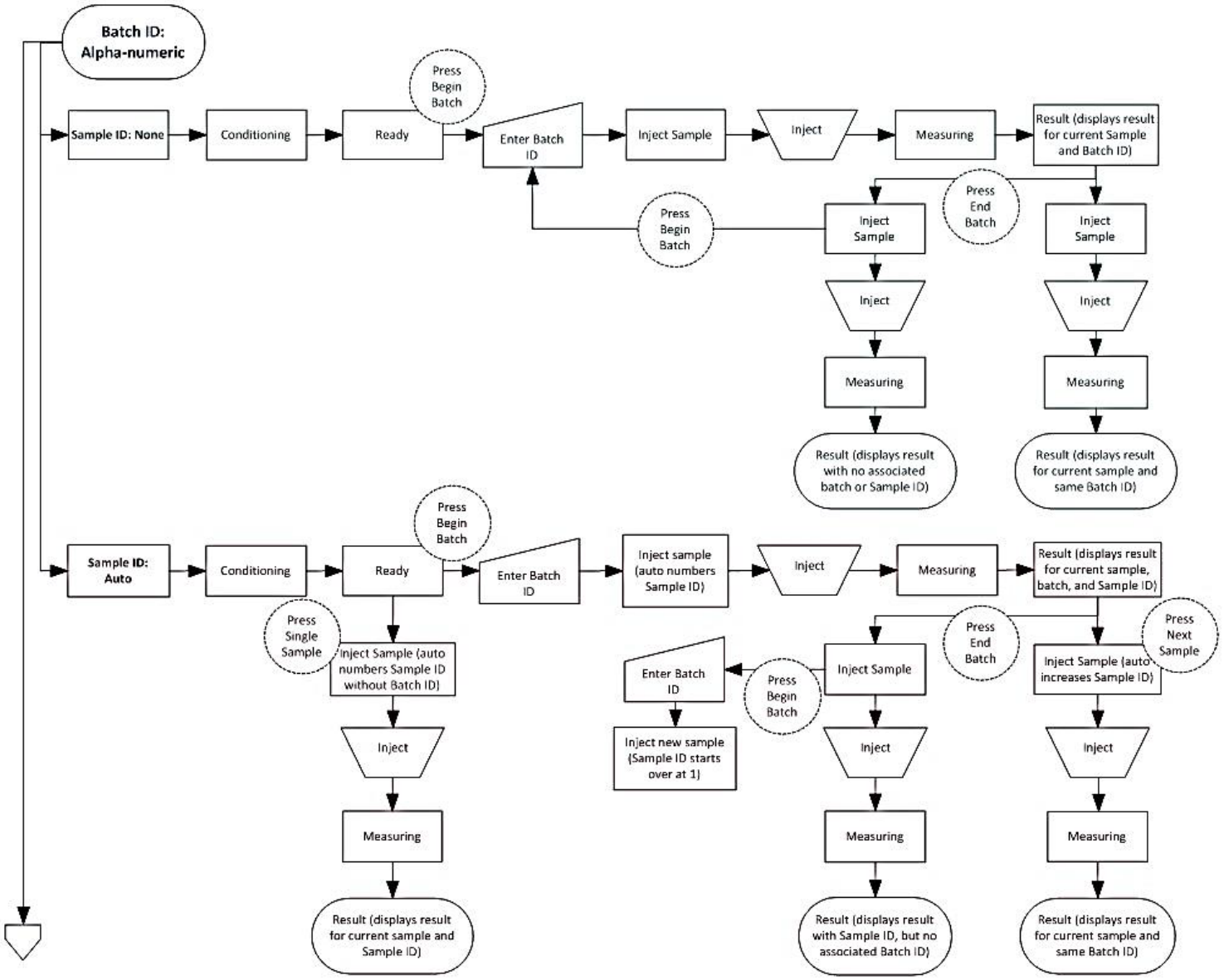
APPENDIX D
FLOW CHARTS (CONTINUED)
Screen Cascade for Batch ID Type Numeric



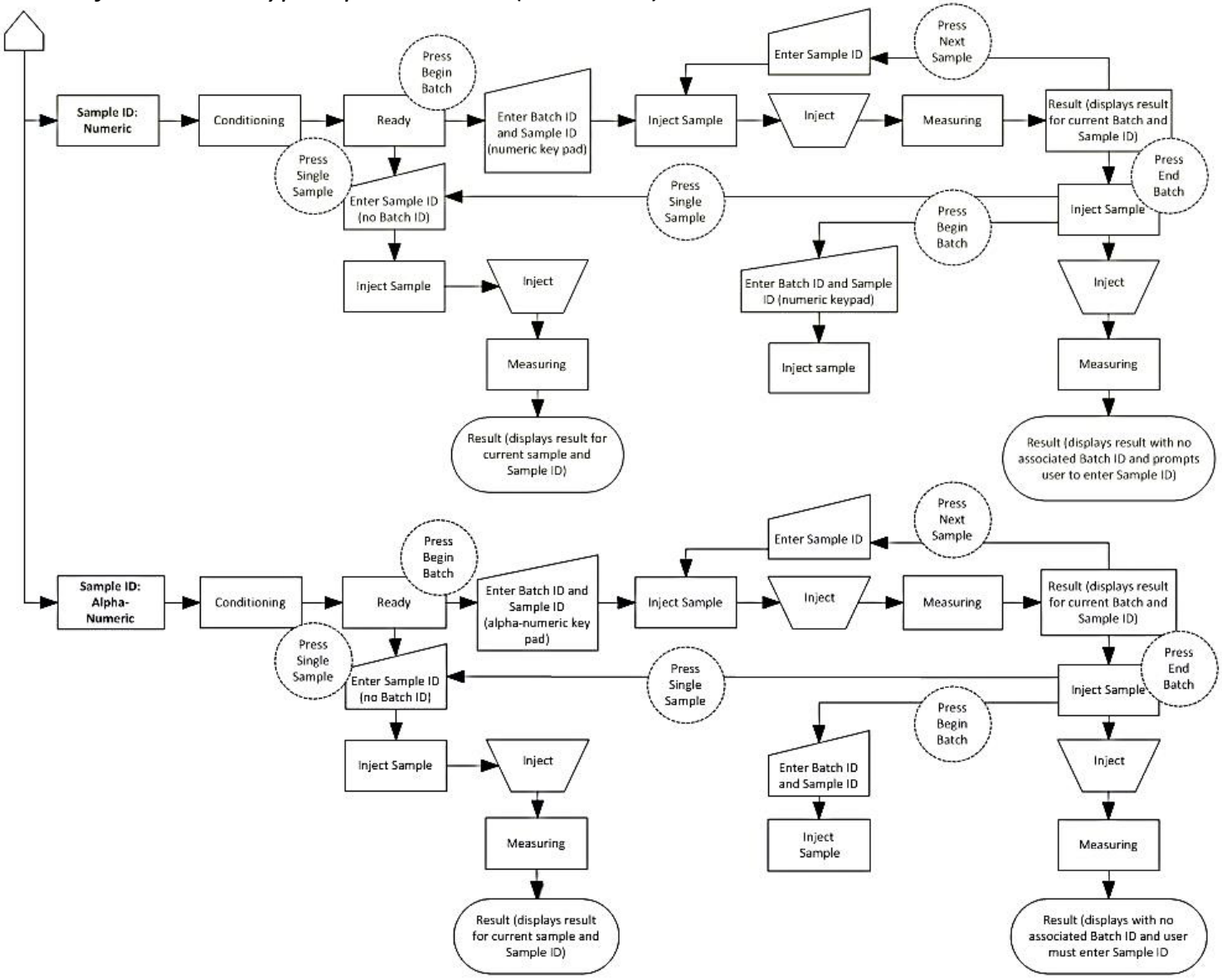
APPENDIX D
FLOW CHARTS (CONTINUED)
Screen Cascade for Batch ID Type Numeric (Continued)



APPENDIX D
FLOW CHARTS (CONTINUED)
Screen Cascade for Batch ID Type Alpha-Numeric



APPENDIX D
FLOW CHARTS (CONTINUED)
Screen Cascade for Batch ID Type Alpha-Numeric (Continued)



APPENDIX E
THEORY OF OPERATION

INTENDED USE

The ChloroChek® Chloridometer® test system is intended for the quantitative *in vitro* diagnostic determination of chloride in human sweat using the principle of coulometric titration. Sweat chloride measurements are used in the diagnosis of Cystic Fibrosis. It is for use in clinical laboratory settings. The ChloroChek Chloridometer test system consists of the ChloroChek Chloridometer and the ChloroChek Reagent Set.

The ChloroChek Reagent Set (SS-248) is to be used on the ChloroChek. It is used as the titration matrix during the titration process.

The 100 mmol/L NaCl/H_2O Standard Solution (SS-251) is to be used on the ChloroChek. It is used as a calibration verifier, and quality control solution.

ELITechGroup Sweat Controls (SS-150), Tri-level, are to be used on the ChloroChek. They are used as quality control solutions.

CLINICAL SIGNIFICANCE [(1)]

The quantitative measurement of the chloride in sweat (commonly called the "sweat test") is used to confirm the diagnosis of cystic fibrosis (CF). With an approximate incidence of 1:3200 in Western Europe and the USA, CF is the most common life-threatening genetic disease within the Caucasian population. It is an autosomal recessive disorder characterized by viscous secretions that affect the exocrine glands, primarily in the lungs and pancreas. Patients with CF have an increased concentration of sodium, chloride, and potassium in their sweat. The criteria for the diagnosis of CF include the presence of one or more characteristic phenotypic features, a history of CF in a sibling, or a positive newborn screening result; and an increased sweat chloride concentration by pilocarpine iontophoresis on two or more occasions, or identification of two CF-causing mutations or demonstration of abnormal nasal epithelial ion transport.

METHOD [(1)]

Based on CLSI recommendations. C34-Sweat Testing Guideline 4th Edition (2019): Coulometric titration.

PRINCIPLE

ChloroChek operates according to the principle of coulometric titration. Two silver electrodes—the generator electrodes (anode and cathode) –are dipped into a measuring vessel filled with working solution. The working solution consists of a buffer and a colloid stabilizer that keeps the silver chloride, which arises later on, in suspension.

Since the buffer does not contain any silver ions, the silver ion concentration, and thus the indicator current (see below) is brought to a specific end point. By means of a constant current (generator current) between the two silver electrodes, a constant amount of silver ions is released at the anode. The silver ion concentration is maintained by the measurement electrodes (indicator electrodes), which are dipped into the solution. By adding a chloride sample, the free silver ions form a non-soluble silver chloride precipitate together with the free chloride ions of the sample.

$$Ag^+ + Cl^- \rightarrow AgCl\downarrow$$

The indicator current drops, and by controlling the generator current, silver ions are released until all chloride ions are precipitated as silver chloride. This restores the original silver ion concentration (end point).
The period of flow of the generator current is measured during the titration process and is proportional to the chloride ion concentration.

Depending on the type of sample, no more than 50 measurements should be carried out using one batch of working solution.

APPENDIX F
REFERENCE INTERVALS FOR SWEAT CHLORIDE [1]

Age	Normal Range	Intermediate Range	Indicative of CF Range
All age groups*	Cl^- ≤ 29 mmol/L	Cl^- 30-59 mmol/L	Cl^- ≥ 60 mmol/L

* Refer to CLSI C34 4th Edition for more information.

APPENDIX G
RETURNING PRODUCTS FOR WARRANTY, SERVICE, OR REPAIR

All products returned for repair or credit must be prepared as follows:

1 Call or write (see Appendix B, Customer Service Information) to request a Return Materials Authorization (RMA) number, hazard free certification, and decontamination instructions for equipment that is being returned for warranty repair or credit.

2 You may also request a return order for equipment that is being returned for non-warranty repair, but you will be liable for the cost of the repairs.

3 Clean the equipment before returning it to ELITechGroup.

NOTE:
Shipping costs are paid by the customer.

APPENDIX H
PERFORMANCE DATA

Measuring Range (Linearity)

Determined according to CLSI[2] EP6-A protocol, the measuring range is from 10 – 160 mmol/L. Some samples below 10 mmol/L can be and are read on the ChloroChek. If a result <10mmol/L is obtained, the user should follow the procedure in Section 3.6, step 4 Note of this Manual. See Appendix E, Reference Intervals for Sweat Chloride, for more details. Samples below 10 mmol/L were not evaluated for linearity.

Precision

Determined according to CLSI[3] EP5-A2 protocol, two ChloroChek units, three operators, two reagent lots, over 10 days.

Sample	n	Mean	Standard Deviation	CV (%)
10 mmol/L NaCl Standard	240	10	0.6	5.6
Sweat Control Level #1	240	22	0.9	4.0
Sweat Control Level #2	240	49	0.8	1.7
Sweat Control Level #3	240	98	1.0	1.0
100 mmol/L NaCl Standard	240	100	1.0	1.0

Repeatability

Determined with one ChloroChek® unit and one operator.

Sample	n	Mean	Standard Deviation	CV (%)
10 mmol/L NaCl Standard	40	10.1	0.5	4.7
Sweat Control Level #1	40	22.5	0.8	3.5
Sweat Control Level #2	40	49.3	0.8	1.7
Sweat Control Level #3	40	98.6	0.8	0.9
100 mmol/L NaCl Standard	40	100.1	0.9	0.9

Correlation

Two comparative studies have been performed between ChloroChek and another FDA cleared system (Buchler Instruments, K760394) (Coulometric titration), according to CLSI[4] EP9-A3 protocol.

Study #1:
Number of samples: 89 (80 samples were natural sweat samples, 9 samples were spiked with NaCl.)
The sample concentrations were between <10 and 160 mmol/L.

The parameters of the linear regression for the 89 samples were as follows:

	Regression Parameters	Lower 95% CI	Upper 95% CI
Intercept	0.875	-0.659	2.410
Slope	0.999	0.976	1.022

Correlation coefficient (r): = 0.99

Correlation

Study #1 (continued)

		Predicate Device			Total
		+	±	-	
ChloroChek®	+	21	0	0	21
	±	0	6	0	6
	-	0	0	53	53
	Total	21	6	53	80

Where '+' = Indicative of CF, '±' = Intermediate (Equivocal), '-' = Normal
The nine spiked samples were not included in this comparison table.

Study #2:
Number of samples: 90 (All 90 samples were natural sweat samples.)
The sample concentrations were between <10 and >119 mmol/L.

The parameters of the linear regression for the 90 samples were as follows:

	Regression Parameters	Lower 95% CI	Upper 95% CI
Intercept	-0.979	-1.879	-0.082
Slope	1.060	1.043	1.089

Correlation coefficient (r): = 0.99

		Predicate Device			Total
		+	±	-	
ChloroChek®	+	8	0	0	8
	±	0	3	1*	4
	-	0	0	78	78
	Total	8	3	79	90

Where '+' = Indicative of CF, '±' = Intermediate (Equivocal), '-' = Normal

*The result on the predicate device was 38 mmoL/L and was 41 mmoL/L on the new device. This sample was from an individual older than 6 months old and was borderline for the intermediate category (40-59 mmoL/L). CLSI C34-Sweat Testing Guideline 4th Edition recommends repeating intermediate results.

APPENDIX I
BIBLIOGRAPHY

1 CLSI. *Sweat Testing: Specimen Collection and Quantitative Chloride Analysis*. 4th ed. CLSI guideline C34. Wayne, PA: Clinical and Laboratory Standards Institute; 2019.

2 Evaluation of the Linearity of the Measurement of Quantitative Procedure: a Statistical Approach; Approved Guideline. CLSI (NCCLS) document EP6-A (2003), **23** (16).

3 Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition. CLSI (NCCLS) document EP5-A2 (2004), **24** (25).

4 Method Comparison and Bias estimation Using Patient Samples; Approved Guideline—Second Edition. CLSI (NCCLS) document EP9-A2 (2002), **22** (19).