



cobas s 201 System

Operator's Manual for Use with Small Pools
(Pools of 1 and 6)

This manual is for use with Configuration C or Configuration C MR1 of the cobas s 201 system.

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Declaration of Conformity

The **cobas s 201** system is comprised of the following individual components, each of which complies with the requirements of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In-vitro Diagnostic Medical Devices. Compliance is provided by means of the following individual Declarations of Conformity:



Pooling and Data Management
 (PDM)



Roche Molecular Systems, Inc.
 Branchburg, NJ
 USA



Hamilton Microlab STAR IVD /
 STARlet IVD Pipettor



Hamilton Company
 Bonaduz
 Switzerland



COBAS® AmpliPrep Instrument



Roche Diagnostics Ltd.
 CH-6343 Rotkreuz
 Switzerland



COBAS® TaqMan® Analyzer



Roche Diagnostics Ltd.
 CH-6343 Rotkreuz
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Questions or comments regarding the contents of this manual can be directed to the address below or to your Roche representative.

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How to Use this Manual

Before operating the cobas s 201 system, it is essential that the warnings, cautions, and safety requirements contained in this manual are read and understood by the user.

Refer to the section titled *Symbols* on page 0.8 for a description of the warning symbols and caution symbols that appear in this manual.

Preface (*Preface*) summarizes safety precautions necessary when installing, operating, and servicing the system.

Section 1 (*Pooling Algorithms*) describes the Primary Pooling and Secondary Pooling methods and testing algorithms.

Section 2 (*Pipetting*) explains the batch concept and pipetting operations.

Section 3 (*Workflow*) describes routine workflow procedures.

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Conventions Used in This Manual










Text Conventions

To convey information readily and consistently, certain text conventions are used throughout this manual. These text conventions are as follows:

Text convention	Used for
Numbered lists	<p>Numbered procedures that should be implemented in order during an operation:</p> <ol style="list-style-type: none">1. Display the <i>Donor Review</i> tab.2. Select the desired status filter.
Bold typeface	<p>Emphasis of any term or component that is being described:</p> <p>The Library Plate is used to store samples for later testing.</p>
Italics	<p>Designating another section of this manual that should be consulted, or designating the name of a screen.</p> <p>Refer to the section titled <i>Symbols</i> on page 0.8 for a description of the warning symbols.</p>
>	<p>Separates command options in a multi-level command:</p> <p>Select File > Shut Down from the menu bar.</p>

Symbols

Certain symbols are used throughout this manual to provide a ready visual reference. These symbols are as follows:

Symbol	Used for
	Information note. Designates a note that provides additional information concerning the current topic or procedure.
	Important note. Designates an important note that must be reviewed and understood.
	Warning. Indicates a possible hazardous situation that, if not avoided, may result in death or serious injury.
	Caution. Indicates a possible hazardous situation which, if not avoided, may result in personal injury and/or in damage to the system.
	Warning Moving Parts. Indicates a possible hazardous situation. Keep hands away from moving parts.
	Warning Hot Surface. Designates the presence of a hot surface. Keep hands away from hot surfaces.
	Warning Laser Transmitter. Designates the presence of a laser transmitter. Do not stare into the laser transmitter.
	Warning Potentially Biohazardous Material. Indicates a possible hazardous situation due to biohazardous material that may result in death or serious injury.
	Electrical and electronic equipment marked with this symbol are covered by the European directive WEEE. This symbol denotes that the equipment must not be disposed of in the municipal waste system. (WEEE) Directive 2002/96/EC of the European Parliament and the Council of 27 January 2003 on waste electrical and electronic equipment

The following symbols appear on the system type plate:



Caution: Refer to accompanying documents. The triangular symbol on the back of an instrument is a general reminder that users read the safety information contained in this manual. Users must be able to identify specific hazards and take appropriate action to avoid them.



Manufacturer of device.

The following symbols appear on the Hamilton Microlab STAR IVD / STARlet IVD Pipettor:

LASER LIGHT - DO NOT STARE INTO BEAM	
CLASS 2 LASER PRODUCT	
Maximum output:	1.3 mW
Pulse duration:	70 µs
Emitting wavelength:	650..690nm
EN 60825-1: 2001-11	
CLASS III LASER PRODUCT	
Maximum output:	1.3 mW
Pulse duration:	35 µs
Emitting wavelength:	650..690nm
Complies with 21 CFR 1040.10	

Warning Laser Transmitter. Situated on the barcode reader to designate the presence of a laser transmitter. Do not stare into the laser transmitter.



Caution. Situated on the paddles to indicate a possible hazardous situation. Keep paddles extended to avoid bumping into the loading deck.



Caution. Situated on the right hand side of the shield and on the pipettor arm to indicate a possible hazardous situation. Keep hands away from moving parts.



Warning Potentially Biohazardous Material. Situated on the left hand side of the shield and on the right hand side of the pipettor to indicate that donor samples and the waste bag may contain biohazardous material.

The following symbols appear on the COBAS® AmpliPrep Instrument:



Warning Laser Transmitter. Situated on Transfer Head 1 to designate the presence of a laser transmitter. Do not stare into the laser transmitter.



Caution. Situated behind the load panel to indicate the type of laser used. Do not stare into the laser transmitter.

IEC 825-1: 1993
Class 1 Laser Product
Appareil à laser de classe 1
1550 nm < 10 mW

Warning - Fire Hazard
For continued protection
replace only with same
type and rating of fuse.

Warning. Situated below the power supply.
Only replace a fuse with a fuse of the same
type and rating.



Warning Potentially Biohazardous Material.
Situated behind the load panel, on the left
hand side of the instrument, to indicate that
K-tubes, S-tubes, and SPUs may contain
biohazardous material.

The following symbols appear on the COBAS® TaqMan® Analyzer:



Warning Laser Transmitter. Situated on the barcode scanner to designate the presence of a laser transmitter. Do not stare into the laser transmitter.



Warning Moving Parts. Situated on each thermal cycler to indicate a possible hazardous situation. Keep hands away from moving parts.



Warning Hot Surface. Situated on each thermal cycler to designate the presence of a hot surface. Keep hands away from hot surfaces.



Warning Biohazard. Situated behind the load panel and on the service panel to indicate that K-tubes may contain biohazardous material.

Glossary

The terminology that is used with the **cobas s 201** system is generally the same as that used in clinical laboratories. Certain specific terms, however, are used for description of an operation or a component. A summary of these terms and their definitions is provided below.

AmpErase	AmpErase (Uracil-N-glycosylase) enzyme is incorporated into Master Mix to selectively destroy carryover products (containing deoxyuridine) from previous amplification reactions.
Amplification	The process of producing many DNA copies from a template DNA or RNA target region. Amplification occurs on the COBAS® TaqMan® Analyzer, where extracted samples are heated and cooled in thermal cyclers according to the Polymerase Chain Reaction profile for the selected test.
Anneal	The biochemical process of hybridizing or binding two segments of complementary nucleic acid by lowering temperature.
Denaturation	The biochemical process of separating double stranded DNA into single strands, by breaking the hydrogen bonds by raising temperature.
Detection	Obtaining measurements to determine whether a sample is reactive for the target analyte. Fluorescence measurements are made at selected temperatures and times during the amplification process. When the run is complete data are analyzed by the AMPLILINK software to determine the presence of the amplified products from the target and internal control nucleic acid sequences.

DNA	Deoxyribonucleic Acid (DNA) is the genetic material that is passed from parent to daughter cells and propagates the characteristics of the species in the form of genes it contains and the proteins for which it codes. DNA is built from the following four kinds of nucleotides: dATP, dCTP, dTTP, and dGTP.
Donor tube carrier	Reusable carrier that is used to load and unload donor tubes onto the Hamilton Microlab STAR IVD / STARlet IVD Pipettor.
Donor tube	A glass or plastic tube that contains a donor specimen.
Extension	Refers to the biological process of elongation of the DNA chain that is being synthesized by DNA polymerase using the parent DNA strand as the template for the synthesis of the daughter strand.
Extraction	The process of isolating DNA or RNA for subsequent molecular analysis. Pooled samples undergo extraction on the COBAS® AmpliPrep Instrument.
Internal control	A built-in nucleic acid sequence that is co-extracted and co-amplified with the sample to monitor sample recovery and amplification/detection inhibitions.
K-carrier	Reusable metallic holder that accommodates up to 24 K-tubes that contain PCR-ready samples for analysis on the COBAS® TaqMan® Analyzer.
K-tip	Kinetic Tip. Disposable tip that is used to resuspend and transfer a prepared sample to a K-tube.
K-tip rack	A prepackaged disposable rack that holds 36 K-tips.

K-tube	Kinetic tube. The disposable sample tube that is used to amplify a prepared sample with Master Mix. K-tubes come prepackaged in a covered K-tube rack.
K-tube rack	A prepackaged disposable rack that holds 96 K-tubes.
Library Plate	A 12 x 8 deep well plate used to store aliquots of donor samples in the event that testing needs to be repeated.
LIS	Laboratory Information System. A computerized system for entering, managing, and reporting laboratory information. Information includes but is not limited to donor demographics, test data, and consumable inventory.
Magnetic glass particles	Small magnetic particles, suspended in liquid, used in combination with other reagents to bind nucleic acids using positive charge on the surface, allowing nucleic acids to be separated from other sample components by a magnet during washing.
MGP	<i>see Magnetic glass particles.</i>
MPX	A multiplexed set of targets that may include HCV, HIV-1 Group M, HIV-1 Group O, HIV-2, and HBV.
PCR	Polymerase Chain Reaction. The <i>in vitro</i> biochemical process used to amplify short specific target nucleic acid sequences. PCR is performed by cycling the temperature of the amplification mixture according to a set profile. The profile generally consists of 1) denaturation, 2) annealing, and 3) extension.
PDM	Pooling and Data Management.
Plate carrier	Reusable carrier used to load and unload up to five plates onto the Hamilton Microlab STAR IVD / STARlet IVD Pipettor.

Primary Pool	A pool prepared by combining equal aliquots from a specified number of donor tubes into one S-tube. Once a sample has been successfully aspirated by the system, that sample is no longer eligible for Primary Pooling.
Repeat Pool	A pool prepared by combining equal aliquots from either donor tubes or a Library Plate to retest specimens from a Primary Pool with testing results that are invalid.
Resolution Pool	A single-specimen pool prepared from either donor tubes or a Library Plate to retest specimens with testing results that are either reactive or invalid.
RF	Radio frequency.
RMEC	Roche-manufactured external control. RMECs are mandatory for each batch.
Secondary Pooling	Follow-up pooling performed to resolve invalid or reactive initial test results.
S-tube	Disposable sample tube. Empty, uncapped, S-tubes are placed in barcode clips in an SK24 rack and loaded onto the Hamilton Microlab STAR IVD / STARlet IVD Pipettor. After pipetting is complete the S-tubes contain pooled samples. The S-tubes are unloaded from the Hamilton Microlab STAR IVD / STARlet IVD Pipettor, capped, and loaded onto the COBAS® AmpliPrep Instrument for sample preparation. S-tubes are supplied in bags of 24.
S-tube carrier	Reusable carrier that is used to load and unload SK24 racks from the Hamilton Microlab STAR IVD / STARlet IVD Pipettor.
Sample	Refers generically to a donor specimen, control reagents, or input sample (any pooled or individual donor pipetted into an S-tube).

Sample processing unit	<p>Disposable device that contains the sample and reagent mixture during sample preparation. The SPU consists of two processing chambers, the waste chamber, and the sample tip chamber.</p> <p>One SPU is used for each sample that is processed.</p>
SK24 rack	<p>Reusable rack that holds S-tubes or K-tubes in barcode clips. The SK24 rack loads and unloads samples throughout the pipetting, sample preparation, and amplification/detection process.</p>
Specimen	<p>Refers to a sample obtained from a donor.</p>
SPU	<p><i>see Sample processing unit.</i></p>
SPU rack	<p>Reusable rack used to load 24 SPUs onto the COBAS® AmpliPrep Instrument.</p> <p>When sample preparation is complete, the SPU rack contains the input S-tube and the used SPUs. The SPUs contain the used K-tips and all of the potentially biohazardous waste in a chamber sealed by the used S-tip.</p>
System	<p>Refers generically to the reagents, hardware, and software for the cobas s 201 system.</p>
Test definition file	<p>File containing all the processing steps required for sample preparation, amplification, and detection. Test definition files are provided by Roche on CD-ROM and are loaded into AMPLILINK software.</p>
Thermal cycler	<p>Programmable temperature block in the COBAS® TaqMan® Analyzer. The thermal cycler rapidly changes temperature according to the amplification profile defined in the test definition files.</p>

Tip rack	Disposable RNase-free pipette tips are used for sample and control pipetting on the Hamilton Microlab STAR IVD / STARlet IVD Pipettor. Pipette tips are packaged in disposable tip racks. Each rack holds 96 pipette tips.
Tip carrier	A carrier used to load and unload up to five tip racks onto the Hamilton Microlab STAR IVD / STARlet IVD Pipettor.
UDEC	User-defined external control that can be included in a batch. UDEC test results are not included in the batch analysis.
UPS	Uninterruptible power supply.
Viability time	<p>The elapsed time between initial pipetting and assignment of final results.</p> <p>If a result is not accepted within the viability time limit, the sample is automatically assigned a status of Complete, Unresolved, unless the sample tested reactive in an individual pool (Primary Pool of 1 or Resolution Pool). In that case, the sample is automatically assigned a status of Complete, Reactive.</p>
WNV	West Nile virus. The West Nile virus belongs to the Japanese Encephalitis Virus group of the family <i>Flaviviridae</i> .

Units

The following measurement abbreviations are used:

kg	Kilogram
mL	Milliliters (10^{-3} liters)
V	Volts

Precautions

Safety Requirements

The safety precautions that are necessary when installing, operating, and servicing the instruments are summarized in the following section of this manual. It is important that you carefully read and understand the statements regarding safety contained in these sections. This information should also be made available to new employees and for future reference.

For reasons of data security and integrity, it is required to use the system with an uninterrupted power supply (UPS) as a loss of power may cause data corruption or loss.

General Instrument Warnings



User should keep hands away from hot surfaces.



User should not stare into the laser transmitter when the barcode readers are exposed.



User should keep hands away from moving parts.



Warning

Never remove the middle grounding prong from the power cable or defeat its purpose by using an ungrounded adapter.

Disposal Recommendations

All electrical and electronic products should be disposed of separately from the municipal waste system. Proper disposal of your old appliance prevents potential negative consequences for the environment and human health.

Disposal of the Instrument



The instrument must be treated as biologically contaminated-hazardous waste. Decontamination (i.e., a combination of processes, including cleaning, disinfection and/or sterilization) is required before reuse, recycling or disposal.

Dispose the instrument according to local and/or labor regulations. For more information, contact your local Roche Support personnel.

Disposal of Control Unit Components



Components of your control unit such as the computer, monitor, keyboard, etc. which are marked with the crossed-out wheeled bin symbol are covered by the European Directive 2002/96/EC (WEEE).

These items must be disposed of via designated collection facilities appointed by government or local authorities.

For more information about disposal of your old product, please contact your city office, waste disposal service or your local Roche Support personnel.

Constraint

It is left to the responsible laboratory organization to determine whether control unit components are contaminated or not. If contaminated, treat in the same way as the instrument.

Hamilton Microlab STAR IVD / STARlet IVD Pipettor



The Hamilton Microlab STAR IVD / STARlet IVD Pipettor conforms to European norms as regards interference immunity. However, if the Hamilton Microlab STAR IVD / STARlet IVD Pipettor is subjected to electromagnetic RF fields, or if static electricity is discharged directly onto the Hamilton Microlab STAR IVD / STARlet IVD Pipettor, its liquid level detection ability may be negatively affected. It is therefore recommended that the Hamilton Microlab STAR IVD / STARlet IVD Pipettor be kept away from other equipment that emits electromagnetic RF fields in the laboratory, and that static electricity be minimized in its immediate environment.



During operation, the Hamilton Microlab STAR IVD / STARlet IVD Pipettor should be shielded from direct sunlight and intense artificial light. The instrument should be positioned in the laboratory in such a way that personnel have access at the front and sides of the instrument, for operation, maintenance, opening and removal of protective covers, and so on. Accordingly, to calculate how much room is needed, consider the dimensions of the instrument plus room for a person to move and work comfortably.

Never lift a fully installed instrument from one place to another. It must be reinstalled in the new work location by an authorized service technician. The instrument weighs in excess of 150 kg. Necessary precautions should be taken when transporting the instrument.

Never disable any security measure.



When using the Hamilton Microlab STAR IVD / STARlet IVD Pipettor, Good Laboratory Practices (GLP) must be observed. Suitable protective clothing, safety glasses, and protective gloves must be worn, particularly when dealing with a malfunction of the instrument where the risk of contamination from spilled liquids exists. Smoking and eating in the vicinity of the instrument and in rooms in which samples or reagents are handled is forbidden.

If working with contaminated samples, the operator need not touch them. The Hamilton Microlab STAR IVD / STARlet IVD Pipettor will drop its used tips by means of a tip waste chute into a laboratory-supplied waste container that should be emptied as soon as it is full.

During Hamilton Microlab STAR IVD / STARlet IVD Pipettor operation, do not place hands in the way of moving parts or on the working deck. Keep your head and hands away from the work surface of the Hamilton Microlab STAR IVD / STARlet IVD Pipettor when it is in operation – the pipetting arm and channels move fast and it is possible to sustain an injury. In general, never lean over the Hamilton Microlab STAR IVD / STARlet IVD Pipettor when working with it.



Do not try to open the locked front cover of the Hamilton Microlab STAR IVD / STARlet IVD Pipettor during a run, as the system will abort and this may cause the loss of data.

User access to the cabinets underneath the instruments during a run may interfere with automatic loading and unloading of carriers (the carriers protrude).

If the system is paused, do not wait too long before resuming the run. Loss of liquid from a full tip may result in invalid data.

Do not re-use tips.

Do not leave tips on the pipetting channels for a long period of time (for example, overnight). This may cause damage to the CO-RE O-rings. A daily maintenance procedure will remove the tips.



Cleaning, maintenance, and calibration of the Hamilton Microlab STAR IVD / STARlet IVD Pipettor must be performed at the specified intervals for accurate operations.



The Pooling Management workstation and Data Management workstation cannot be used for running any other software or programs other than the PDM applications. Only the Roche PDM Pooling Wizard software and firmware protocol may be used to control the Hamilton Microlab STAR IVD / STARlet IVD Pipettor.

Hamilton Microlab STAR IVD / STARlet IVD Pipettor, COBAS® AmpliPrep Instrument, and COBAS® TaqMan® Analyzer

Electrical safety



If the power cable becomes cracked, frayed, broken, or otherwise damaged, it must be replaced immediately with the equivalent part from Roche Diagnostics.



The Hamilton Microlab STAR IVD / STARlet IVD Pipettor, COBAS® AmpliPrep Instrument, and the COBAS® TaqMan® Analyzer are electromechanical devices that can cause electrical shock or physical injury to the operator if not operated in accordance with the procedures outlined in this manual.



The COBAS® AmpliPrep Instrument and the COBAS® TaqMan® Analyzer are designed in accordance with safety standard EN/IEC 61010-1. Grounding of the instruments and those surfaces the user can come into contact with are provided by grounded cables in accordance with Protection Class I (IEC). For protection against electrical shock hazards, each instrument must be directly connected to an approved power source such as a 3-wire grounded receptacle for the 120 V or 230 V line. Where an ungrounded receptacle is encountered, a qualified electrician must replace it with a properly grounded receptacle in accordance with the local electrical code. An extension cord must not be used.



Keep the side panels closed while the instruments are connected to the main power supply.



Any break in the electrical ground path, whether inside or outside the instruments, may create a hazardous condition. Under no circumstances should the user attempt to modify or deliberately defeat the safety features of the instrument.



Never clean the instruments without turning the power switch off and disconnecting the power cable.

General



When any indication of potential sources of contamination is seen (e.g., spilled samples, etc.), preventative service must be performed.



The COBAS® AmpliPrep Instrument and the COBAS® TaqMan® Analyzer surfaces may be cleaned with isopropanol, 70% ethanol, or any acceptable PCR laboratory cleaner. For sample cleanup, use a 1:10 dilution (0.5% sodium hypochlorite) of household bleach followed by 70% ethanol.

Turn the analyzer power switch off and disconnect the power cord before cleaning the analyzer.



User should not perform any servicing except as specifically stated in this manual.

Biological safety



Use good laboratory practices when handling donor sample tubes, S-tubes, K-tubes, and Library Plates that contain donor samples. Avoid splashing and spilling containers in order to prevent cross-contamination.



Samples analyzed with this instrument are treated to inactivate potentially biohazardous material. However, as with all human-derived specimens, universal safety precautions should be taken when handling and processing samples.

Wear clean, disposable laboratory gloves when performing any procedure with the **cobas s 201** system.

Dispose of waste in accordance with country, federal, state, and local regulations.



Universal safety precautions should be taken when handling and processing samples. Spills should be immediately disinfected with an appropriate disinfectant solution to avoid spreading contamination to laboratory personnel or equipment.

Analyzer and Reagent Performance

Each laboratory is responsible for performance qualification testing to verify that all instruments perform as expected.

The new quality regulations (GLP/cGMP), concerning test kit supervision, require that the instrument should be calibrated after each repair or service. This confirms that the specifications defined by the manufacturer, with respect to accuracy and precision, are reached.






Validated System Configuration

The **cobas s 201** system must be installed and used as a complete system. Individual **cobas s 201** system components cannot be used as stand-alone devices, nor may other components be substituted.

Software Precautions



Virus protection software is not installed on the PDM workstations or the Data Station for AMPLILINK software. Therefore, it is essential to follow these recommendations:

-  Check all external storage devices with an anti-virus program (on another PC) before using them on any **cobas s 201** system workstation.
-  Do not load any other software on instrument workstations or data stations.
-  Keep all external storage devices in a secure place so that they can be accessed only by authorized personnel.
-  Use the remote services modem only for contacting Roche Service or for authorized usage.
-  Make sure there are no other computers on the **cobas s 201** system network.

Failure to observe these recommendations may result in data loss or the unavailability of the system, which may put patients at risk.

WARNING WINDOWS DISPLAY SETTINGS



Roche loads the Windows and AMPLILINK software and enters default configuration settings during manufacturing.

Do not change the Windows display setting. *Windows Classic style* must be selected for proper viewing of AMPLILINK software screens.

Pooling Algorithms

Overview

The cobas s 201 system offers the flexibility of testing single donor samples or combining aliquots from multiple samples and testing the samples in pools of 6.

The selected pooling method depends on the analyte being tested and the population of samples under test.

Primary Pooling

The following Primary Pooling options are available for small pools:

- **Primary Pools of 1:** Single-specimen pools to test donor samples for either WNV or MPX target
- **Primary Pools of 6:** Six-specimen pools to test donor samples for either WNV or MPX target
- **Simultaneous Pools of 6:** Two six-specimen pools to test donor samples for WNV and MPX target

Secondary Pooling

Follow-up (secondary) testing is required if initial (primary) testing on a multi-specimen pool is reactive or if a test result is invalid. The following Secondary Pooling options are available:

- **Repeat Pools of 6:** Six-specimen pools to retest donors from Primary Pools of 6 with testing results that are invalid
- **Resolution Pooling:** Single-specimen pools to individually test samples from invalid or reactive pools

Primary Pools of 1

Primary Pools of 1 are tested for the presence of the screening analyte(s) (Figure 1.1).

- The donor sample is reported as non-reactive if the Primary Pool of 1 is non-reactive.
- The donor sample is reported as reactive if the Primary Pool of 1 is reactive.
- Resolution Pooling is scheduled (Figure 1.4) if test results are invalid.

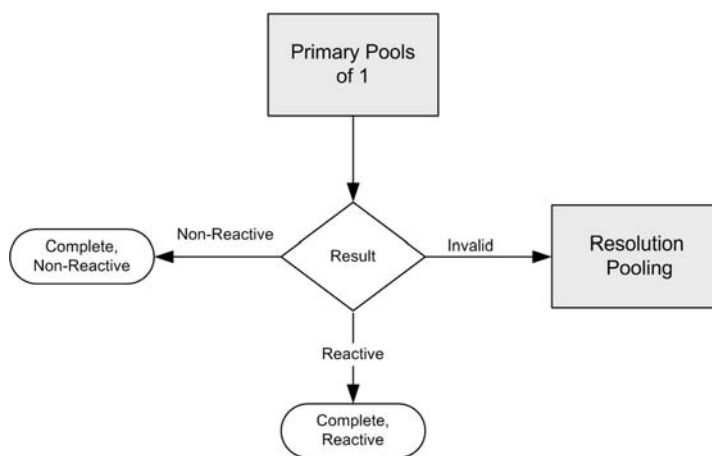


Figure 1.1
Primary Pools of 1

Primary Pools of 6

Primary Pools of 6 are tested for the presence of the screening analyte(s) (Figure 1.2).

- All donor samples in the pool are reported as non-reactive if the Primary Pool of 6 is non-reactive.
- All donor samples in the pool are scheduled for Resolution Pooling (Figure 1.4) if the Primary Pool of 6 is reactive.
- A Repeat Pool of 6 (Figure 1.3) is scheduled if test results are invalid.

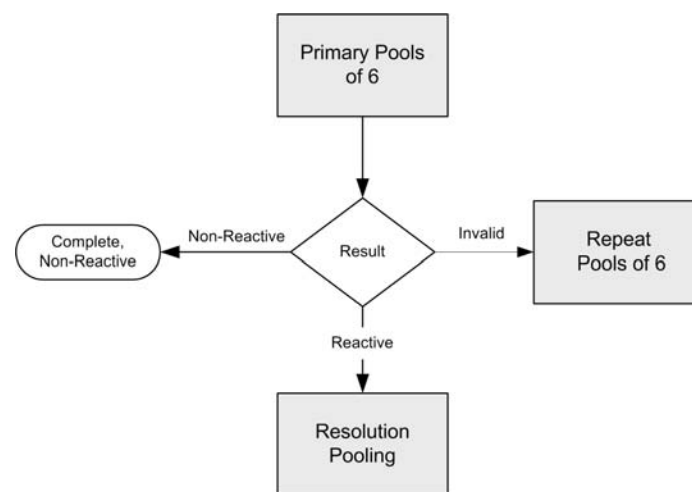


Figure 1.2
Primary Pools of 6



The laboratory administrator can also elect to use Resolution Pooling to resolve invalid Primary Pools of 6 (see *Changing the Pooling Request* in the *cobas s 201 system Hardware and Software Reference Manual*).

Simultaneous Pools of 6

Each donor sample is pipetted into two Primary Pools of 6 when **Simultaneous Pools of 6** is the selected pooling method. One of the pools is used for MPX testing and the other pool is used for WNV testing. Each test is performed independently according to the algorithm shown in Figure 1.2.

Repeat Pools of 6

Donor samples in a Primary Pool of 6 are eligible to be included in Repeat Pools of 6 if initial test results are invalid.

Repeat Pools of 6 are tested for the presence of the screening analyte(s) (Figure 1.3).

- All donor samples in the pool are reported as non-reactive if the Repeat Pool of 6 is non-reactive.
- All donor samples in the pool are scheduled for Resolution Pooling (Figure 1.4) if the Repeat Pool of 6 is reactive.
- Another Repeat Pool of 6 is scheduled if test results are invalid.

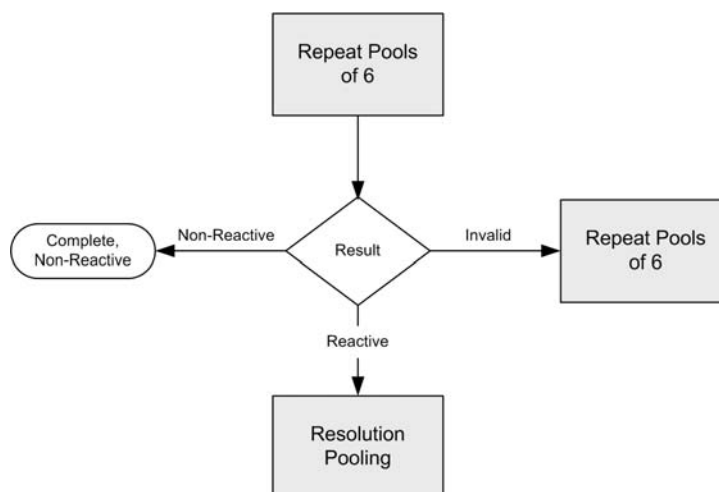


Figure 1.3
Repeat Pools of 6

i The laboratory administrator can also elect to use Resolution Pooling to resolve invalid Repeat Pools of 6 (see *Changing the Pooling Request* in the *cobas s 201 system Hardware and Software Reference Manual*).

Resolution Pooling

Donor samples are eligible for **Resolution Pooling** if a Primary Pool of 6 is reactive for the screening analyte or if a test result is invalid. Each Resolution Pool contains an aliquot of a single donor sample.

Resolution Pools are tested for the presence of the screening analyte(s) (Figure 1.4).

- The donor sample is reported as non-reactive if the Resolution Pool is non-reactive.
- The donor sample is reported as reactive if the Resolution Pool is reactive.
- The donor sample is scheduled for another Resolution Pool if the Resolution Pool is invalid.

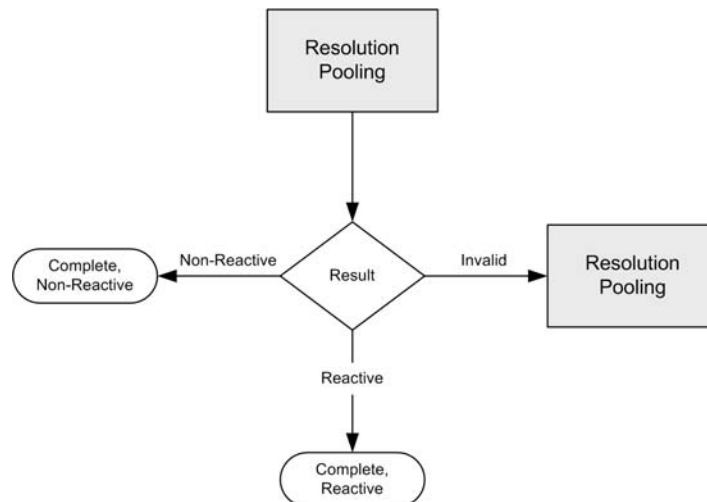


Figure 1.4
Resolution Pooling

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Pipetting

Batch Concept

The **cobas s 201** system is designed to process samples in **batches**. A batch is a collection of samples and controls that are pipetted, extracted, and amplified and detected together according to the rules for the associated test specification.

A batch consists of all samples and controls in one SK24 rack.

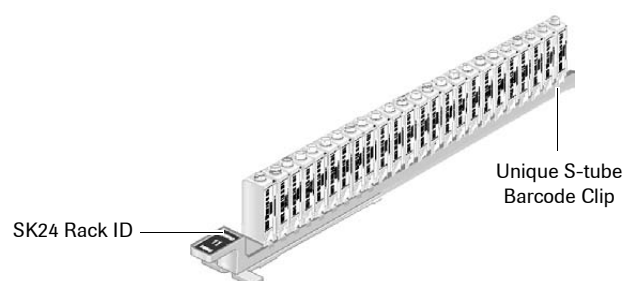


Figure 2.1
Batch

A batch is tracked from pooling through results review using the SK24 rack ID plus a unique batch ID assigned during pipetting.

Samples and controls in the batch are tracked by associating their scanned barcode IDs with the unique barcode clips that hold S-tubes (during pooling and sample preparation) and K-tubes (during amplification and detection).

Roche-Manufactured External Controls (RMECs)

Each batch requires Roche-manufactured external controls (RMECs). The number of RMECs required is test-specific.

MPX testing encompasses five analytes. Five positive RMECs plus one negative RMEC must be pipetted for each batch. During pipetting, an aliquot of the negative control is transferred to the S-tube in position 19 of each SK24 rack. Then, aliquots from each positive control are transferred to S-tubes in positions 20 through 24 of each SK24 rack (Figure 2.2).

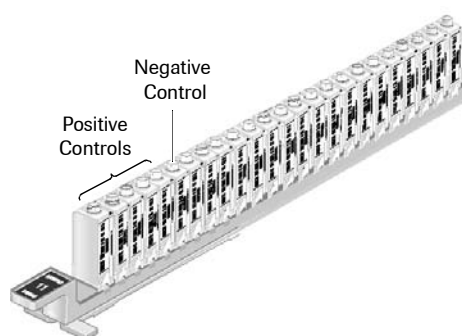


Figure 2.2
MPX RMECs in an SK24 Rack

WNV testing encompasses a single analyte. One negative RMEC and one positive RMEC must be pipetted for each batch. During pipetting, an aliquot of the negative control is transferred to the S-tube in position 23 of each SK24 rack. Then an aliquot of the positive control is mixed with a second aliquot of the negative control (obtained from a second tube of negative control to dilute the positive control) in the S-tube in position 24 of each SK24 rack (Figure 2.3).

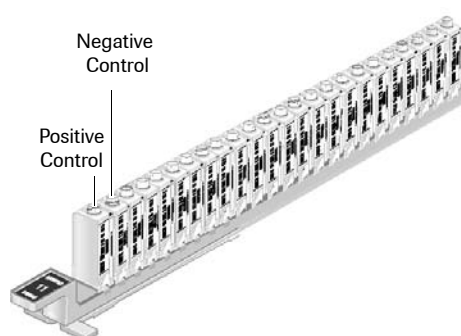


Figure 2.3
WNV RMECs in an SK24 Rack

- ➔ Pipetting of RMECs always occurs before sample pipetting. This allows the operator to correct any control pipetting errors before sample pipetting begins.
- ➔ RMECs are always placed in the last positions in each SK24 rack so that the entire testing process, from sample preparation through amplification and detection, is monitored by control samples.

User-Defined External Controls (UDECs)

The cobas s 201 system allows up to five user-defined external controls (UDECs) to be assigned to each test. UDEC requirements, including the control name, barcode pattern, lot number, expiration date, and position of the UDEC in the SK24 rack, are specified by the laboratory administrator.

- ➔ See *Selecting UDECs* in the *cobas s 201 system Hardware and Software Reference Manual* for details.

Once UDECs are assigned for a particular test, the operator can determine whether to include them in a Primary Pooling run.

- ➔ If included, UDECs are always pipetted in the first SK24 rack of a Primary Pooling run.

UDECs are identified in the Roche PDM Pooling Manager and Roche PDM Data Manager screens and reports.

Library Plate

A **Library Plate** (Figure 2.4) can be prepared during Primary Pooling to save an aliquot from each donor tube in case Secondary Pooling is required.

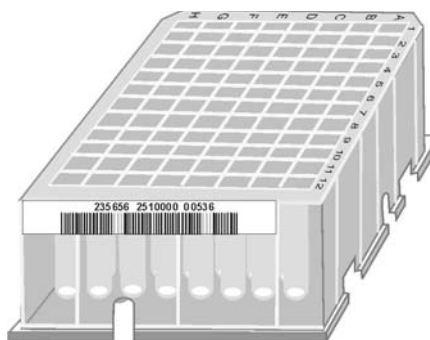


Figure 2.4
Library Plate

- ➔ Secondary Pooling can be performed directly from the donor tubes if a Library Plate is not prepared or if a particular well in the Library Plate is unusable.
- ➔ The well position that a sample occupies in the Library Plate is dependent on the number of samples in the run and the type of pooling being performed.

Primary Pools of 1

A **Primary Pool of 1** is a single-specimen pool created for initial sample testing. A Primary Pool of 1 is prepared by pipetting an aliquot from one donor tube into its own S-tube.

The maximum number of donor sample tubes that can be pipetted in a Primary Pool of 1 run depends upon the assay, the pipettor used, and the dimension of the donor tubes.

Assay	Hamilton Microlab STAR IVD Pipettor		Hamilton Microlab STARlet IVD Pipettor	
	7mL tubes	10mL tubes	7mL tubes	10mL tubes
MPX	216	216	90	90
WNV	264	264	88	88

During a Primary Pool of 1 run, 1 mL of each donor sample is aspirated from each of the first group of donor sample tubes and dispensed into its own S-tube (Figure 2.5).

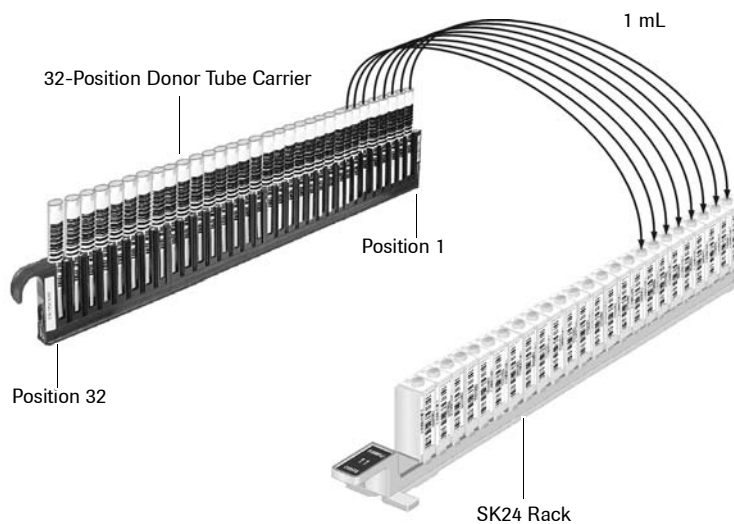


Figure 2.5
Pipetting Primary Pools of 1

If a Library Plate is being prepared, 1 mL of each donor sample is then aspirated from each donor sample tube and dispensed into its own well in the Library Plate. An additional 135 μ L is then aspirated from the same donor sample tubes and dispensed into the same Library Plate wells, resulting in a total volume of 1.135 mL in each well (Figure 2.6).

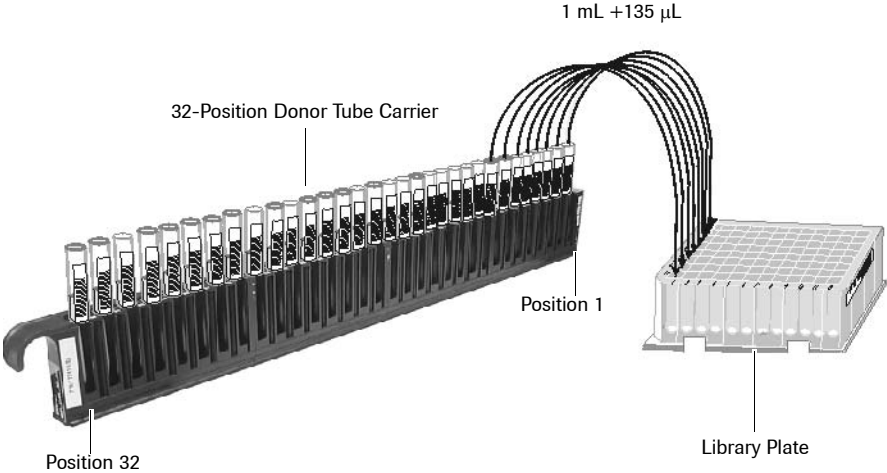


Figure 2.6
Pipetting a Library Plate for Primary Pools of 1

Primary Pools of 6

A **Primary Pool of 6** is a six-specimen pool created for initial sample testing. A Primary Pool of 6 is prepared by combining equal aliquots from six donor sample tubes into one S-tube.

The maximum number of donor sample tubes that can be pipetted in a Primary Pool of 6 run depends upon the assay, the pipettor used, and the dimension of the donor tubes.

Assay	Hamilton Microlab STAR IVD Pipettor		Hamilton Microlab STARlet IVD Pipettor	
	7mL tubes	10mL tubes	7mL tubes	10mL tubes
MPX	432	432	216	216
WNV	480	480	264	264

➔ The number of donor samples loaded must be a multiple of 6.

During a Primary Pool of 6 run, 1 mL of each donor sample is aspirated from each of the first group of donor sample tubes and dispensed into its own well in a Library Plate. An additional 700 μL is then aspirated from the same donor sample tubes and dispensed into the same Library Plate wells, resulting in the transfer of 1.7 mL of donor sample into a corresponding well of a Library Plate. Finally, 167 μL is aspirated from each Library Plate well and dispensed into S-tubes, starting in position 1 of the first SK24 rack (Figure 2.7).

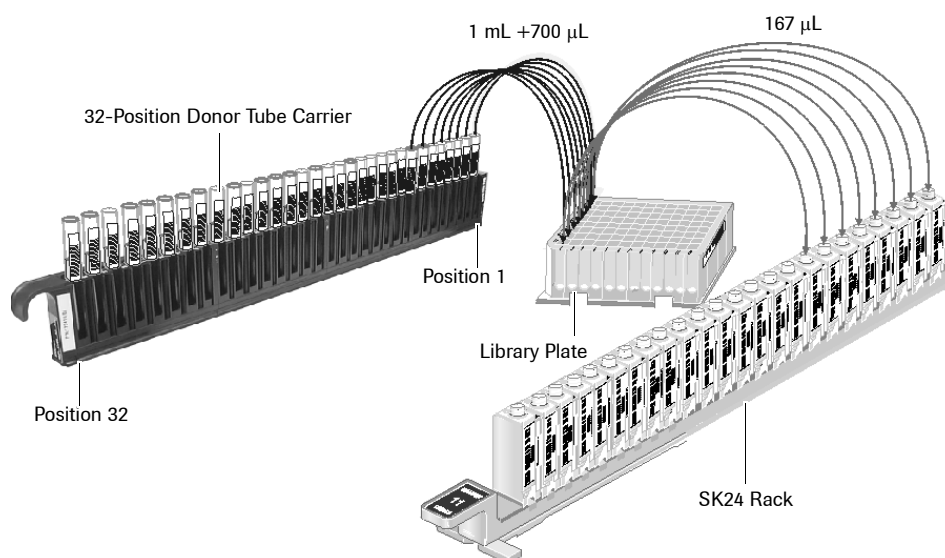


Figure 2.7
Pipetting the First Group of Donor Sample Tubes for Primary Pools of 6

After the first group of donor samples has been pipetted, aliquots from the next group of donor samples are pipetted into the next available Library Plate wells and an aliquot from each of those wells is also pipetted, starting in position 1 of the first SK24 rack (Figure 2.8).

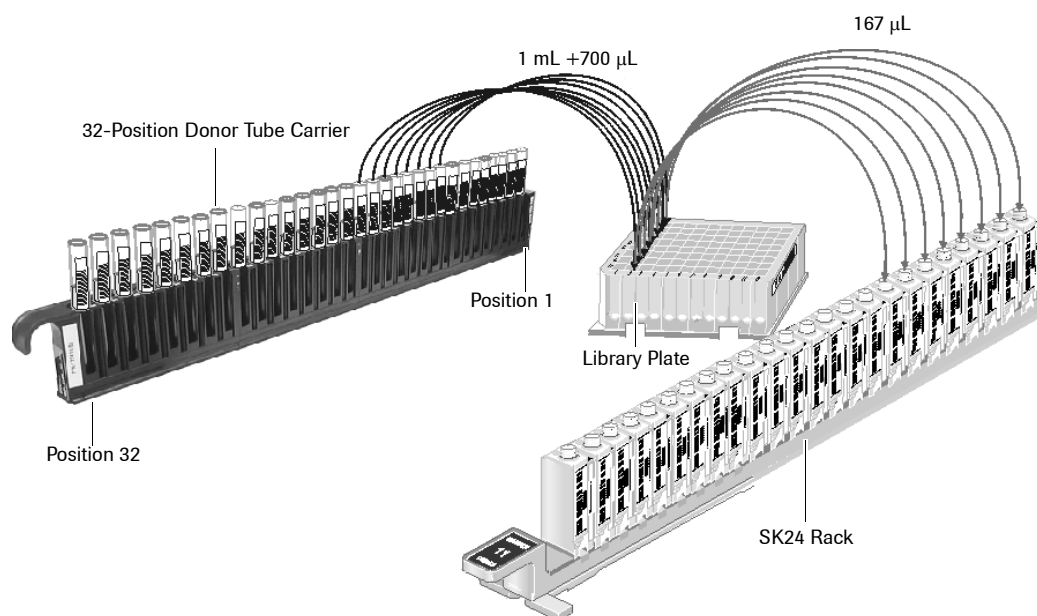


Figure 2.8
Pipetting the Next Group of Donor Sample Tubes for Primary Pools of 6

This process continues until the S-tubes each contain pooled 167 µL aliquots of six donor samples and the Library Plate contains a 1.533 mL aliquot from each of the donor sample tubes.

- ➔ If a Library Plate is not prepared, 167 µL aliquots are pipetted directly into the S-tubes from the donor sample tubes.

Simultaneous Pools of 6

Simultaneous Pools of 6 are two six-specimen pools created for initial sample testing. Simultaneous Pools of 6 are prepared by combining equal aliquots from six donor sample tubes into each of two S-tubes.

The maximum number of donor sample tubes that can be pipetted in a Simultaneous Pool of 6 run depends upon the assay and the dimension of the donor tubes.

Assay	Hamilton Microlab STAR IVD Pipettor		Hamilton Microlab STARlet IVD Pipettor	
	7mL tubes	10mL tubes	7mL tubes	10mL tubes
MPX and WNV	396	396	N/A	N/A

- ➔ The number of donor samples loaded must be a multiple of 6.
- ➔ Simultaneous Pools of 6 is not available on the Hamilton Microlab STARlet IVD Pipettor.

During a Simultaneous Pool of 6 run, 1 mL of each donor sample is aspirated from each of the first group of donor sample tubes and dispensed into its own well in a Library Plate. An additional 700 μL is then aspirated from the same donor sample tubes and dispensed into the same Library Plate wells, resulting in the transfer of 1.7 mL of donor sample into a corresponding well of a Library Plate. Finally, 334 μL is aspirated from each Library Plate well and 167 μL is dispensed into each of two S-tubes, starting in position 1 of the two SK24 racks (Figure 2.9).

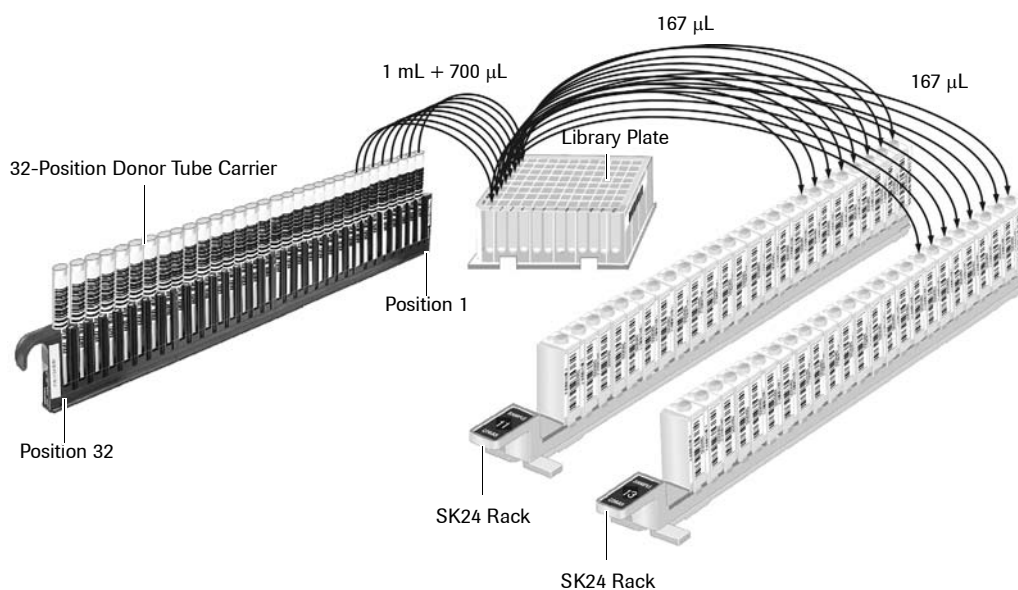


Figure 2.9
Pipetting the First Group of Donor Sample Tubes for Simultaneous Pools of 6

After the first group of donor samples has been pipetted, aliquots from the next group of donor samples are pipetted into the next available Library Plate wells, and an aliquot from each of those wells is also pipetted, starting in position 1 of the two SK24 racks.

This process continues until the S-tubes each contain pooled 167 μL aliquots of six donor samples and the Library Plate contains a 1.366 mL aliquot from each of the donor sample tubes.



If a Library Plate is not prepared, 334 μL is aspirated from the donor sample tubes, and 167 μL is dispensed into each of two S-tubes.

Repeat Pools of 6

A Repeat Pool of 6 is a six-specimen pool created to retest donor samples from a Primary Pool of 6 with an invalid test result.

Library Plate

A Repeat Pool of 6 is prepared by combining 167 μ L from each of six Library Plate wells into one S-tube (Figure 2.10).

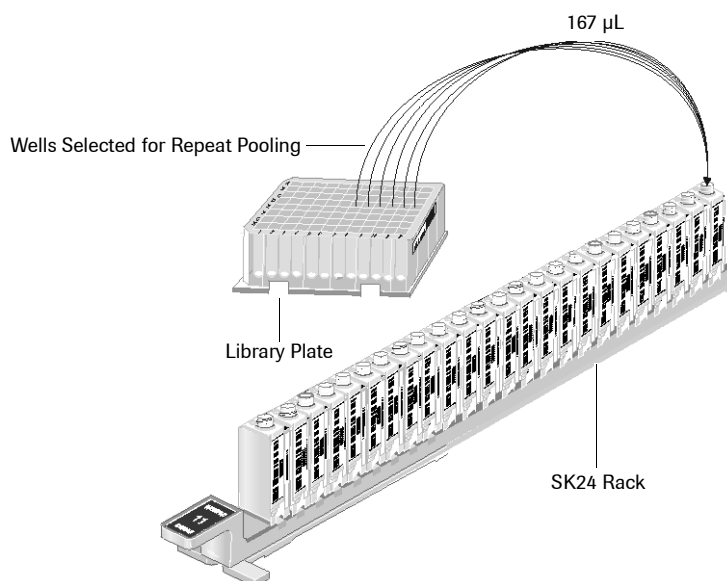


Figure 2.10
Pipetting a Repeat Pools of 6 from the Library Plate

- ➔ Only one Library Plate can be loaded for a Repeat Pool of 6 run. Each Repeat Pool of 6 contains the same donor samples originally pooled in the Primary Pool of 6.

Donor Tubes

A sample can be aspirated from the donor tube if a Library Plate was not prepared or if the Library Plate well for that donor sample is unusable.

The maximum number of donor tubes that can loaded for a Repeat Pool of 6 run depends upon the assay and pipettor that is used.

Assay	Hamilton Microlab STAR IVD Pipettor		Hamilton Microlab STARlet IVD Pipettor	
	7 mL tubes	10 mL tubes	7 mL tubes	10 mL tubes
MPX	216	216	216	216
WNV	264	264	264	264

- ➔ A Repeat Pool of 6 prepared from donor tubes may contain samples from different starting Primary Pools of 6.

Resolution Pooling

A **Resolution Pool** is a single-specimen pool created to identify the reactive sample(s) in a reactive Primary Pool of 6. The laboratory administrator can also elect to perform Resolution Pooling, rather than a Repeat Pool of 6, to retest samples from an invalid Primary Pool of 6.

Library Plate

A Resolution Pool is prepared by pipetting 1 mL from a Library plate well into a single S-tube.

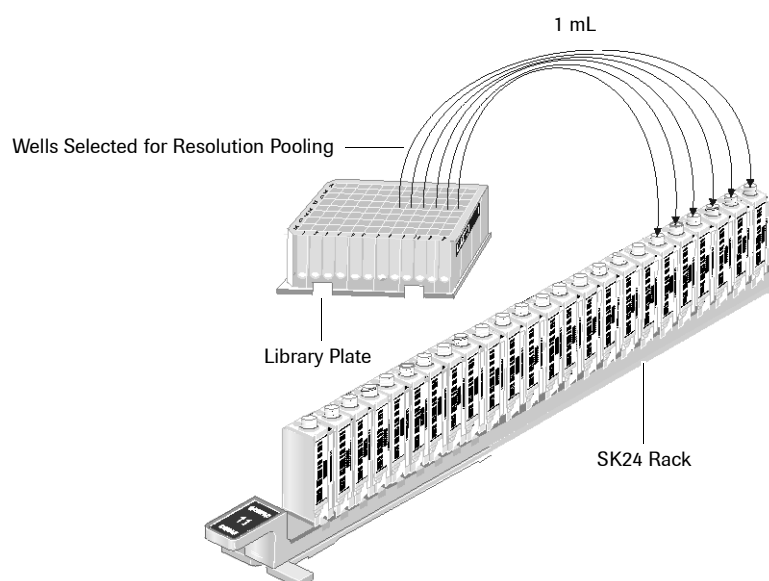


Figure 2.11
Resolution Pooling from the Library Plate



Only one Library Plate can be loaded for Resolution Pooling. Any wells on the plate, up to a maximum of 36, can be included in the Resolution Pooling run.

Donor Tubes

A sample can be aspirated from the donor tube if a Library Plate was not prepared or if the Library Plate well for that donor sample is unusable.

The maximum number of donor tubes that can be loaded for a Resolution Pooling run depends upon the assay and pipettor that is used.

Assay	Hamilton Microlab STAR IVD Pipettor		Hamilton Microlab STARlet IVD Pipettor	
	7mL tubes	10mL tubes	7mL tubes	10mL tubes
MPX	36	36	36	36
WNV	44	44	44	44

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Workflow

The workflow for processing small pools on the cobas s 201 system is shown in Figure 3.1.

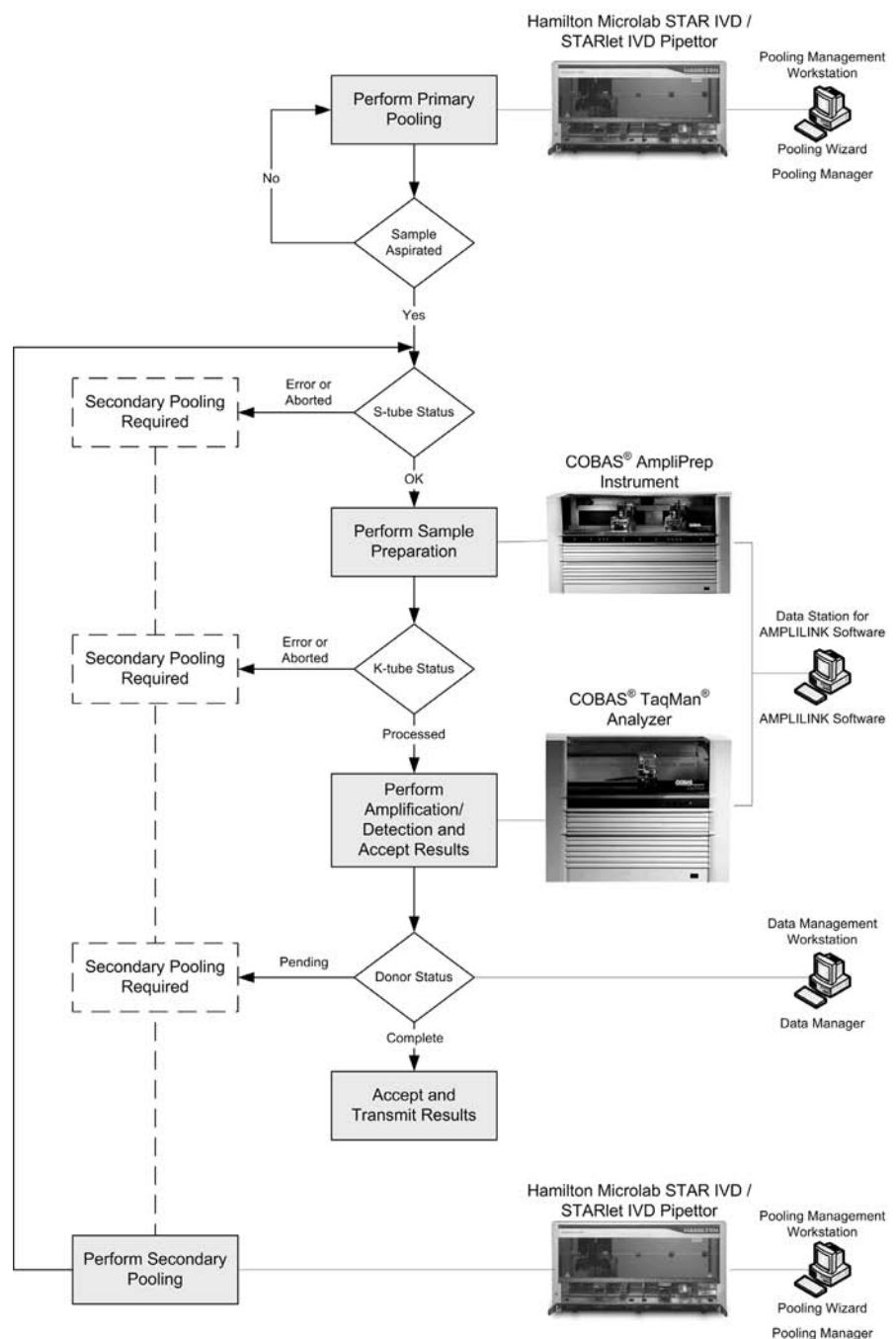






Figure 3.1
Workflow

Perform Primary Pooling





-  Do not eat, drink, or smoke in laboratory work areas.
-  Wear protective disposable gloves and laboratory coats whenever handling samples, preparing consumables, or cleaning.
-  Wear eye protection when handling samples. Wash hands thoroughly afterwards.

Remove Samples from Storage




Warm specimens to room temperature before using.

-  See the assay-specific package insert for recommended instructions on collection, storage, and handling.

Initialize Hardware and Software

- 1 Turn on the Pooling Management workstation if it is powered off. The *Welcome to Roche PDM* dialog box is displayed.
 -  The Pooling Management workstation is normally left on, except for a daily restart. The *Welcome to Roche PDM* dialog box is displayed if the previous user has logged off.
 -  Press the **Ctrl**, **Alt**, and **Del** keys simultaneously if the *Welcome to Roche PDM* dialog box is not displayed.
- 2 Enter the appropriate login ID and password into the *Welcome to Roche PDM* dialog box and then click **OK**. The Roche PDM Pooling Manager application starts automatically.
- 3 Turn on the Hamilton Microlab STAR IVD / STARlet IVD Pipettor if it is powered off.
 -  The Hamilton Microlab STAR IVD / STARlet IVD Pipettor is normally left in *Standby* mode.
- 4 Click the **Wizard** button  (in the global command button panel on the right side of the Pooling Manager screen) to access the Pooling Wizard.
- 5 Perform maintenance procedures if required (see *Hamilton Microlab STAR IVD / STARlet IVD Pipettor* in the *cobas s 201 system Hardware and Software Reference Manual* for details).

Select the Primary Pooling Type

- 1 Select the pooling type in the Pooling Wizard *Primary Pooling* panel.
 -  A description of the pooling option is provided next to each button.
 -  Once a sample has been successfully aspirated by the system, then that sample is no longer eligible to be included in a Primary Pool. A Primary Pool can only include **new** donors and donors listed in the *Required Pooling Worklist* with a request of **Primary run required**.
- 2 Click **Start**.
 -  A map of the pooling deck displays. The pooling run ID is automatically assigned and displayed in the title bar (see *Deck Layout* in the *cobas s 201 system Hardware and Software Reference Manual*).
- 3 The system displays the *UDEC Selection* dialog box if the laboratory administrator assigned UDECs to the selected test. Mark the UDECs, if any, to be pipetted in the first batch of the pooling run (see *Selecting UDECs* in the *cobas s 201 system Hardware and Software Reference Manual*).

Load Donor Tubes

- 1 Place uncapped individual donor tubes in a donor tube carrier (see *Donor Tubes* in the *cobas s 201 system Hardware and Software Reference Manual* for additional information).

➡ Load donor tubes starting in position 1 of the carrier. Do not leave gaps between the tubes. The donor tube barcode labels must face right, visible through the gap, when the carrier is placed on the loading deck.



CAUTION

To prevent a carrier with individual donor tubes from tipping over and contaminating the area, handle donor tube carriers carefully during filling and before inserting on the loading deck.

- 2 Insert the donor tube carrier into the designated track on the loading deck.

➡ The *Workflow Guide* (see *Deck Layout* in the *cobas s 201 system Hardware and Software Reference Manual*) contains a prompt to indicate the correct track.

- 3 Slide the carrier forward slowly and carefully (to avoid splashing) until it engages the stop hook at the end of the loading deck.

- 4 Repeat steps 1 through 3 until all donor tube carriers have been loaded.

➡ Load full carriers first. The application assumes donor tube loading is complete when all tracks are loaded or if a partially full rack is loaded. Otherwise, select **Done** to indicate donor tube loading is complete.


➡ Refer to *Error Handling* in the *cobas s 201 system Hardware and Software Reference Manual* if a loading error occurs.

Load Library Plates


- ➔ Library Plates are optional. If your system is configured to use Library Plates, load them now.
- 1 Place the required number of Library Plates (up to five) on a plate carrier. (see *Plate Carrier* in the *cobas s 201 system Hardware and Software Reference Manual*).
- ➔ Inspect each Library Plate for defects when placing it on the carrier.
- ➔ Library Plates cannot be reused.
- ➔ The *Consumables Calculator* shows the required number of Library Plates.
- ➔ The Library Plates will not seat properly on the carrier unless the Library Plate barcode labels face right when the carrier is placed on the loading deck.
- 2 Insert the plate carrier into the designated tracks on the loading deck.
- ➔ The *Workflow Guide* contains a prompt to indicate the correct track. The plate carrier occupies six tracks.
- 3 Slide the carrier forward until it engages the stop hook at the end of the loading deck.
- ➔ Refer to *Error Handling* in the *cobas s 201 system Hardware and Software Reference Manual* if a loading error occurs.

Load SK24 Racks


- 1 Place the required number of uncapped S-tubes with attached S-tube barcode clips on an SK24 rack.

 The *Consumables Calculator* shows the number of S-tubes that are necessary for sample pools and UDECs. In addition, S-tubes must always be placed in the positions reserved for RMECs.


Assay	Available for samples and UDECs	Reserved for RMECs
MPX	1 through 18	19 through 24
WNV	1 through 22	23 through 24

 Do not load more than the required number of S-tubes.

- 2 Insert the SK24 rack into an S-tube carrier.

 S-tubes for the MPX assay are loaded first when the pooling type is Simultaneous Pools of 6.

- 3 Insert the S-tube carrier into the designated tracks on the loading deck.

 The *Workflow Guide* contains a prompt to indicate the correct track. The S-tube carrier occupies two tracks.


- 4 Slide the carrier forward until it engages the stop hook at the end of the loading deck.

- 5 Depending on the number of pools being created, the *Consumables Calculator* may indicate additional SK24 racks are required. Repeat steps 1 through 4 if additional S-tube carriers are needed.









CAUTION

Never pipette a sample directly into an S-tube. All donor specimens and controls must be processed by the Hamilton Microlab STAR IVD / STARlet IVD Pipettor.

 Refer to *Error Handling* in the *cobas s 201 system Hardware and Software Reference Manual* if a loading error occurs.

Load Pipette Tips

- 1 Place the required number of tip racks (up to five) on a tip carrier (see *Tip Carrier* in the *cobas s 201 system Hardware and Software Reference Manual*).
 -  Always load more than the required number of pipette tips. The *Consumables Calculator* shows the number of pipette tips that are required.
 -  The tip rack barcode labels must face right when the carrier is placed on the loading deck.
 -  The tip rack in the first position in the tip carrier must contain at least one tip in order to pass load check.
- 2 Insert the tip carrier into the designated tracks on the loading deck.
 -  The *Workflow Guide* contains a prompt to indicate the correct track. The tip carrier occupies six tracks.
- 3 Slide the carrier forward until it engages the stop hook at the end of the loading deck.
 -  Refer to *Error Handling* in the *cobas s 201 system Hardware and Software Reference Manual* if a loading error occurs.
 -  A second tip carrier containing up to five additional tip racks can be loaded if required.

Load Negative RMECs

- 1 Obtain a 24-position donor tube carrier.



CAUTION

Handle the control tubes carefully when uncapping, loading, and unloading them on the donor tube carrier. Do not vortex RMECs.

- 2 Uncap a negative control tube. Carefully place the control tube in position 1 on the 24-position donor tube carrier.



The Hamilton Microlab STAR IVD / STARlet IVD Pipettor pipettes liquid directly from the control vial. Do not transfer the control liquid to a test tube.



WARNING

Universal safety precautions should be taken when handling and processing controls.



The barcode label must face right, visible through the gap, when the carrier is placed on the loading deck.

- 3 Uncap and place the required number of additional negative control tubes in adjacent positions on the 24-position donor tube carrier.



The *Consumables Calculator* shows the required number of negative control tubes.



One negative control tube is required for each MPX batch.



Two negative control tubes are required for each WNV batch. The second negative control is used for diluting the positive control.



The MPX negative controls must be placed on one carrier and the WNV negative controls must be placed on another carrier when the pooling type is Simultaneous Pools of 6.



Load control tubes starting in position 1 of the 24-position donor tube carrier. Do not leave any gaps between control tubes.

- 4 Place the donor tube carrier with the negative control(s) on the loading deck.



The *Workflow Guide* contains a prompt to indicate the correct track.



Refer to *Error Handling* in the *cobas s 201 system Hardware and Software Reference Manual* if a loading error occurs.

Load Positive RMECs

- 1 Obtain a 24-position donor tube carrier.
- 2 Uncap a positive control tube. Carefully place the control tube in position 1 on the 24-position donor tube carrier.

**CAUTION**

Handle the control tubes carefully when uncapping, loading, and unloading them on the donor tube carrier. Do not vortex RMECs.



The Hamilton Microlab STAR IVD / STARlet IVD Pipettor pipettes liquid directly from the control tube. Do not transfer the control liquid to a test tube.

**WARNING**

Universal safety precautions should be taken when handling and processing controls.

**CAUTION**

Handle positive controls carefully, to prevent contamination of negative controls and donor specimens.



The barcode label must face right, visible through the gap, when the carrier is placed on the loading deck.

- 3 Uncap and place the required number of additional positive control tubes in adjacent positions on the 24-position donor tube carrier(s).



The *Consumables Calculator* shows the required number of positive control tubes.



Five positive control tubes, one for each tested analyte, are required for each MPX batch.



One positive control tube is required for each WNV batch.



The MPX positive controls must be placed on one carrier and the WNV positive controls must be placed on another carrier when the pooling type is Simultaneous Pools of 6.



Load the positive controls in any order starting in position 1 of the 24-position donor tube carrier. Do not leave gaps between the controls. If a second carrier is required, fill the first carrier before using the second carrier. The second carrier must also be loaded starting in position 1 without any gaps between the controls.

- 4 Place the first carrier with the positive control(s) on the loading deck.
 - ➔ The *Workflow Guide* contains a prompt to indicate the correct track.
- 5 If required, load the second carrier in the indicated track.
 - ➔ Refer to *Error Handling* in the *cobas s 201 system Hardware and Software Reference Manual* if a loading error occurs.

Load UDECs

Load the UDECs now if you elected to include them in the pipetting run.

- 1 Load the UDECs in uncapped 7 mL tubes starting in position 1 in a 32-position donor tube carrier.
 - ➔ The barcode labels must face right, visible through the gap, when the carrier is placed on the loading deck. UDECs can be loaded in any order. Do not leave gaps between the tubes.
 - ➔ Barcodes on the tubes must match the barcodes defined by the laboratory administrator (see *UDEC Tab* in the *cobas s 201 system Hardware and Software Reference Manual*).



CAUTION

Handle the control tubes carefully when uncapping, loading, and unloading them on the donor tube carrier.

- 2 Insert the donor tube carrier into the designated track on the loading deck.
 - ➔ The *Workflow Guide* contains a prompt to indicate the correct track.
- 3 Slide the carrier forward slowly and carefully (to avoid splashing) until it engages the stop hook at the end of the loading deck.
 - ➔ Refer to *Error Handling* in the *cobas s 201 system Hardware and Software Reference Manual* if a loading error occurs.

Complete the Run

Once controls are loaded, the pooling run starts and proceeds automatically. RMECs are pipetted first, and the run is paused if a pipetting error occurs during pipetting of RMECs. The RMEC samples can then be replaced and the run continued (see *Error Handling During Pipetting of RMECs* in the *cobas s 201 system Hardware and Software Reference Manual*).



The operator should monitor pipetting of the RMECs. The system does not allow donor pipetting to begin until all RMECs have been successfully pipetted.

The *Workflow Guide* displays *Unloading carriers* when pooling is complete. All carriers are unloaded from the main deck to the loading deck.





Review Alarms for the Run

- 1 Click **Exit** in the Pooling Wizard to return to the Roche PDM Pooling Manager.
- 2 Use the *Query* tab (see *Query Tab* in the *cobas s 201 system Hardware and Software Reference Manual*) to retrieve pooling information.
- 3 Display the *Alarms View* tab. Review any alarm messages that may have been generated during the pooling run.



The *Pooling Alarms Report* can be printed by selecting **Print Alarms** in the *Alarms View* tab.

Print the Pooling Reports

- 1 Display the *Pools View* tab.
 -  Successfully pipetted S-tubes have an S-tube status of **OK**. The pool information is displayed in bold red type and the S-tube status is **Error** or **Aborted** if an error occurred.
- 2 Select a batch in the *Batches* panel. Examine the status of the pools in the batch, then click **Print**. The *Pooling Manager Reports* dialog box is displayed.
- 3 Click **Print** to print the *Pooling Batch Report* and the *Required Pooling Report* (if one was created) for the selected batch.
 -  The *Pooling Batch Report* includes a barcoded batch ID that is scanned during AMPLILINK software order creation (see *Create Orders* in the *cobas s 201 system Hardware and Software Reference Manual*).
 -  The *Required Pooling Report* is created only if one or more donor tubes in the current batch must be included in another pooling run.
- 4 Repeat steps 2 and 3 for each batch (including an error batch, if one exists).
 -  Error batches are described in *Displaying Information for an Error Batch* in the *cobas s 201 system Hardware and Software Reference Manual*.

Cap S-tubes and Transfer for Sample Preparation



CAUTION

Do not remove carriers from the Hamilton Microlab STAR IVD / STARlet IVD Pipettor until they have been transferred back to the loading deck.

- 1 Carefully replace the caps on each of the S-tubes.



Do not over-tighten the S-tube caps.



CAUTION



Do not separate an S-tube from its attached barcode clip. To avoid inadvertently separating an S-tube and/or its barcode clip, do not remove the S-tubes from the SK24 racks or change the position of the S-tubes in the SK24 racks.



Make sure that the S-tubes and barcode clips are correctly seated in the SK24 racks.

- 2 Remove the SK24 racks from the S-tube carriers.
- 3 Visually inspect each S-tube for consistent volume and red cell contamination.
 - Reject a pool if an inconsistent volume or red cell contamination is observed (see *Rejecting a Pool* in the *cobas s 201 system Hardware and Software Reference Manual*).
 - Do not remove any S-tubes from the SK24 racks (including S-tubes from rejected pools and S-tubes with a status of Error or Aborted).
- 4 Transfer the SK24 racks and *Pooling Batch Reports* to the sample preparation area.

Store Library Plates, Donor Tubes, and UDECs

- 1 If Library Plates were pipetted, remove them from the plate carrier.
- 2 Visually inspect each Library Plate well for consistent volume and red cell contamination.
 -  Reject a well if an inconsistent volume or red cell contamination is observed (see *Rejecting a Well* in the *cobas s 201 system Hardware and Software Reference Manual*).
- 3 Place a sealing mat on each Library Plate (see *Sealing Mats* in the *cobas s 201 system Hardware and Software Reference Manual*).
 -  Place the sealing mat carefully to avoid cross-contamination.
- 4 Store the Library Plates and donor tubes according to instructions in the assay-specific package insert.
- 5 UDEC IDs can be reused. Store UDECs according to standard laboratory practices.



WARNING

Universal safety precautions should be taken when handling and processing controls.

Discard RMECs

Remove the RMEC tubes from their carriers and discard. RMECs are for single use only.









WARNING


Universal safety precautions should be taken when handling and processing controls.


Perform Sample Preparation, Amplification, Detection


Initialize the COBAS® AmpliPrep Instrument


-  The Data Station for AMPLILINK software is normally left on, except for a daily restart. Refer to *Start up and Log on* in the *cobas s 201 system Hardware and Software Reference Manual* if the Data Station is powered off.
-  The COBAS® AmpliPrep Instrument is normally left in *Standby* mode. Refer to *Starting the Instrument* in the *cobas s 201 system Hardware and Software Reference Manual* if the instrument is powered off.
- 1 Check the status of the wash reagent reservoir. Replace if necessary.
 -  A reservoir icon on the *Systems* window *System* tab is red if the corresponding reservoir is empty (see *System Tab* in the *cobas s 201 system Hardware and Software Reference Manual*).
- 2 Empty the waste container if it requires emptying.
 -  The waste icon on the *Systems* window *System* tab is red if the waste level is too high.
- 3 Perform any maintenance listed in the *Systems* window *Service Due* tab.
 -  The background on the *Systems* icon turns yellow and an oil can appears on the icon when service is due. Perform the required service before starting the next run.
 -  The system is automatically primed after each service is performed.

Initialize the COBAS® TaqMan® Analyzer


 The processed samples containing the Master Mix solution have a limited stability, so the COBAS® TaqMan® Analyzer should be ready to accept samples as soon as the COBAS® AmpliPrep Instrument run is complete. Refer to the assay-specific package insert for time limits.


 If the COBAS® TaqMan® Analyzer is not ready to accept samples, wait and transfer the samples once it is ready. The system automatically invalidates any sample that was not transferred from the COBAS® AmpliPrep Instrument to the COBAS® TaqMan® Analyzer within the allowed transfer time, and will require the sample be repeated.

 AMPLILINK software displays a warning message and flags the affected results if Master Mix stability time is exceeded.


 The COBAS® TaqMan® Analyzer is normally left in *Standby* mode. Refer to *Starting up the analyzer* in the *cobas s 201 system Hardware and Software Reference Manual* if the analyzer is powered off.

1 Place 24 empty and capped K-tubes into a K-carrier, then place the K-carrier in park position 2 on the left side of the COBAS® TaqMan® Analyzer.

 The analyzer must be powered off to perform this step.

 The COBAS® TaqMan® Analyzer uses these empty K-tubes to fill K-carrier positions 12, 13, 8, 17, 7, and 18 if a batch contains fewer than six K-tubes. These positions must be occupied to balance the K-carrier in the thermal cycler.

2 Perform any maintenance that is listed in the *Systems* window *Service Due* tab before starting the next run.

 The background on the *Systems* icon turns yellow and an oil can appears on the icon when service is due. Perform the required service before starting the next run.

Load Reagents

The reagents required depend upon the cassette status check and the daily workload.

i Reagents should be removed from the refrigerator prior to use. Reagents should be loaded onto the COBAS® AmpliPrep Instrument immediately after they are removed from storage to avoid condensation on the barcode labels. Allow the reagents to equilibrate on the instrument for at least thirty minutes before the first sample is to be processed.

i If the cassette barcode label is not readable by the instrument, carefully dry the condensation from the label and reload the affected cassette onto the instrument.

i Cassettes with barcodes that are unreadable by the instrument should be discarded.

i Do not pool reagents from different lots or from different bottles of the same lot.

i Do not mix reagents (including cassettes) from different kits.

i Do not use more than one lot number of reagents for a processing run on the COBAS® AmpliPrep Instrument. A single lot of reagents must be used for processing all specimens and controls in a batch.

i Do not open COBAS® AmpliPrep Instrument cassettes and exchange, mix, remove, or add bottles.

i Do not use a kit after its expiration date.

i Do not use a kit on more than one COBAS® AmpliPrep Instrument unless the instruments are connected to the same Data Station for AMPLILINK software.

i Do not freeze reagents.

i Never attempt to remove a rack when the LED for that rack is red.

1 Obtain the required magnetic glass particle (MGP) cassettes.

i Reloading of MGP cassettes is not possible during a run due to the shaking of the rack. The rack containing the MGP cassette is unlocked after no more tests remain for that cassette, and a new MGP cassette can be loaded at that time.

2 Place the MGP cassettes on a single reagent rack.

3 Obtain the required other cassettes.

4 Place these cassettes on other (up to four) reagent racks.

- ➔ Other reagent cassettes required to complete the orders in the worklist can be loaded on up to four additional reagent racks. These reagent racks are loaded in reagent rack positions B through E, which are not shaken.
- ➔ More than one cassette may be needed for a particular reagent to complete a run. The system automatically switches to the next cassette when the first cassette is depleted.

5 Open the load panel.



WARNING

Transfer Head 1 contains a class 1 laser diode. Do not stare into the laser transmitter.

- 6 Slide the reagent rack containing the magnetic glass particle cassettes onto rack position A. Slide the rack up to the first pin.
- 7 Wait for the reagent rack LED to begin flashing green. Then continue sliding the rack to the back of the instrument. The LED turns orange.
- 8 Load the other reagent racks on rack positions B through E. All of the reagent rack LEDs turn solid green when a complete kit of reagent cassettes has been loaded.

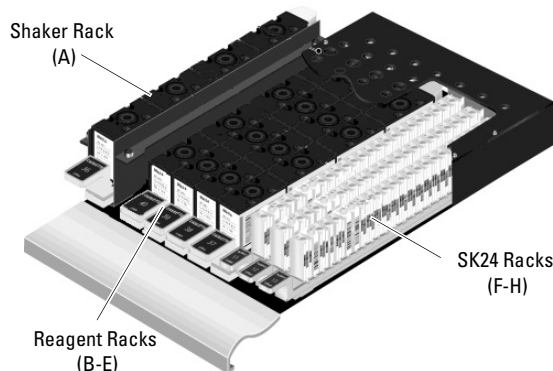


Figure 3.2
Rack Platform

The COBAS® AmpliPrep Instrument scans the reagent rack barcode label and the reagent cassette barcode labels as each rack is loaded onto the instrument.

The AMPLILINK software updates the *Systems* window *Cassettes/Samples* tab with the scanned information (see *Cassettes/Samples Tab* in the *cobas s 201 system Hardware and Software Reference Manual*).

- ➔ Reagents are supplied in a kit package that includes two sets of four cassettes. The reagent cassettes that are loaded must all be from the same kit package. If any cassette is missing, the remaining cassettes for that assay are *Blocked* (see *Displaying Cassette Error Details* in the *cobas s 201 system Hardware and Software Reference Manual*).

9 Close the load panel.

Load SPUs

Determine the load requirements. One SPU, one K-tube, and one K-tip are needed for each S-tube order.

- 1 Obtain the required number of SPUs (up to three full SPU racks can be loaded).
- 2 Remove the SPUs from their packaging. Inspect each SPU for defects.
- 3 Place the SPUs in the SPU racks, using the arrow on the SPU rack for proper alignment.

- ➔ Always make sure that the tips are properly seated. Press down on the SPU splash guard (not the sample tips) to properly seat the SPU in the rack. Ensure the sample tips are even.

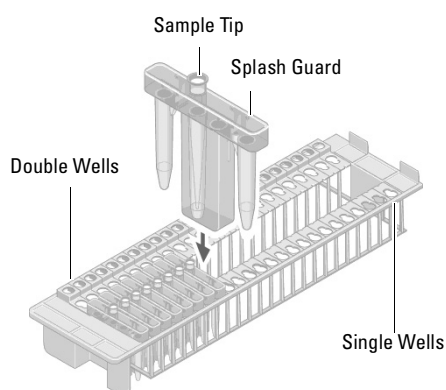


Figure 3.3
Filling an SPU Rack

- 4 Open the load panel.



WARNING

Transfer Head 1 contains a class 1 laser diode. Do not stare into the laser transmitter.

- 5 Position the end of an SPU rack at the front of the SPU load positions. Then slide the SPU rack towards the rear of the instrument. The SPU LED is green when the rack is loaded properly.

- i** When positioning the SPU rack, be sure that the single wells of the SPU rack are to the right, that the left side of the SPU rack is under the lip, and that all SPUs are seated properly.

- ➔ The COBAS® AmpliPrep Instrument counts the SPUs and the *Systems* window *System* tab updates supply status as each SPU rack is loaded onto the system.

- 6 Close the load panel.

K-tubes

- 1 Open the load panel.



WARNING

Transfer Head 1 contains a class 1 laser diode. Do not stare into the laser transmitter.

- 2 Load a full rack of K-tubes onto the COBAS® AmpliPrep Instrument output platform in an available load position M, N, O, or P.

- ➔ Up to four racks containing K-tubes or K-tips can be loaded.
- i** Be sure the rack is full when it is loaded. The system does not check each position in the rack, and assumes the rack is full when loaded. Do not move partially filled racks to another position.
- ➔ The *Systems* window *System* and *Samples* tabs update status as each rack is loaded onto the instrument.

- 3 Close the load panel.

K-tips

- 1 Open the load panel.



WARNING






Transfer Head 1 contains a class 1 laser diode. Do not stare into the laser transmitter.

- 2 Load full racks of K-tips onto the COBAS® AmpliPrep Instrument output platform in an available load position M, N, O, or P.

- ➔ Up to four racks containing K-tubes or K-tips can be loaded.
- i** Be sure the rack is full when it is loaded. The system does not check each position in the rack, and assumes the rack is full when loaded. Do not move partially filled racks to another position.
- ➔ The *Systems* window *System* and *Samples* tabs update status as each rack is loaded onto the instrument.

- 3 Close the load panel.

Create Orders

- 1 Display the AMPLILINK software *Orders* window *Sample-Rack* tab.
- 2 Click **New**.
- 3 Position the cursor in the Sample Rack ID field, then scan the barcode ID on one of the pooled SK24 racks.
 -  The SK24 rack barcode can also be entered manually (by typing it). In either case, visually verify that the barcode entry is correct.
- 4 Position the cursor in the Batch ID field, then scan the batch ID barcode printed on the *Pooling Batch Report* for the selected SK24 rack.
 -  The batch ID can also be entered manually (by typing it). In either case, visually verify that the barcode entry is correct.
- 5 Select **Tools > Auto Order** from the menu bar. Twenty-four orders are created starting with the next available order number.
 -  An order can also be created using a saved **order profile**.
- 6 Delete the unused orders if less than 24 S-tubes are being processed.
 -  Be sure to verify that orders are created only for S-tube positions that are occupied on the SK24 rack.
- 7 Click the desired test button.
- 8 Click **Save**.
- 9 Load the SK24 rack onto the COBAS® AmpliPrep Instrument (see page 3.22). The barcode clip IDs are read and displayed.
- 10 Repeat steps 2 through 9 to create orders for additional SK24 racks.
 -  Refer to *Creating Orders* in the *cobas s 201 system Hardware and Software Reference Manual* for additional options to create orders.

Load SK24 Racks

- 1 Open the load panel.
 - ➔ Orders should be created prior to loading the SK24 rack onto the COBAS® AmpliPrep Instrument.



WARNING

Transfer head 1 contains a class 1 laser diode. Do not stare into the laser transmitter.

- 2 Slide an SK24 rack containing pooled samples onto one of the three sample rack positions, position F, G, or H. Slide the rack up to the pin.



WARNING

If a tube or barcode clip becomes separated from the SK24 rack, do not attempt to re-insert the tube or barcode clip back into the SK24 rack. Sample(s) corresponding to that tube must be repeated.

- ➔ Up to three SK24 racks can be loaded onto the COBAS® AmpliPrep Instrument at one time.
- 3 Wait for the sample LED to begin flashing green.
- 4 Continue sliding the rack to the back of the instrument (Figure 3.4).

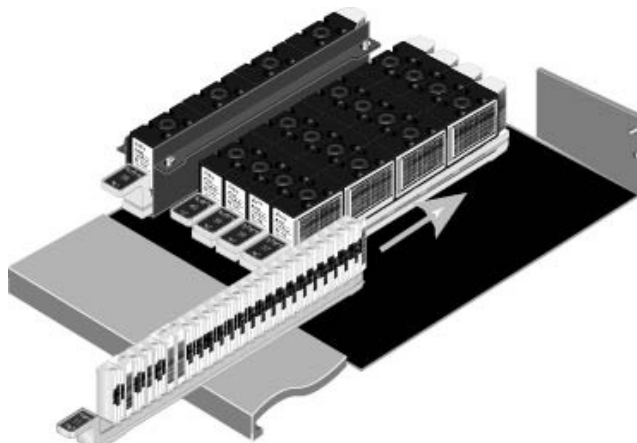


Figure 3.4
Loading an SK24 Rack

- ➔ The sample LED turns solid green and the rack image appears in the *Systems* window *Cassettes/Samples* and *Samples* tabs if the rack is properly positioned.
 - ➔ The rack containing the fewest samples should be loaded last if more than one rack is loaded.
- 5 Close the load panel.

Start the Sample Preparation Run

- 1 Examine the COBAS® AmpliPrep Instrument indicator bar. Verify that each LED indicates the run is ready to proceed.
 - ➔ An LED is solid green if a rack is properly loaded and ready for use.
- 2 Click the **Systems** button to display the *Systems* window.
- 3 If it is not already selected, choose the COBAS® AmpliPrep Instrument using the *Instrument Selection Box*.
- 4 Select the *System* tab.
- 5 Examine the instrument status.
 - ➔ The *Temperature* and *Supplies* panels should indicate that the status is OK, and the *Missing & Blocked* panel should be empty.
- 6 Select the *Cassettes/Samples* tab.
- 7 Examine the status of the samples (see *Sample Icon Representation* in the *cobas s 201 system Hardware and Software Reference Manual*).
 - ➔ All of the sample icons should be shown in white on the *Cassettes/Samples* tab. If not, remove the rack and reinsert.
- 8 Select the *System* tab.
- 9 Click **Start** to begin sample processing.

A load check is performed. Sample processing begins if the load check passes.



WARNING

Never attempt to operate the COBAS® AmpliPrep Instrument with the main cover open. Keep hands away from all moving parts while the instrument is in use.

Correcting Load Problems

Errors are listed in the *Missing & Blocked* panel in the COBAS® AmpliPrep Instrument *System* tab (see *Displaying Sample Error Details* in the *cobas s 201 system Hardware and Software Reference Manual*) if the load check fails.

- 1 Correct the load problems.
- 2 Click **Start** to begin sample processing.

Processing Samples

The COBAS® AmpliPrep Instrument processes the samples according to the test sample preparation protocol.



Do not turn off the instrument during a run.


Review Run Status

- 1 Click the **Messages** button when processing is complete.
- 2 Examine the *New Messages* tab for any error messages.
- 3 Click the **Systems** button.
- 4 Examine the *Samples* tab.



Icons for successfully processed samples are green.

Transfer Processed Samples

-  SK24 racks are locked and cannot be removed if the indicator light is red.

Once processing is complete, the indicator light turns orange and samples can be transferred for analysis.

- 1 Open the COBAS® AmpliPrep Instrument load panel.



WARNING


Transfer head 1 contains a class 1 laser diode. Do not stare into the laser transmitter.


- 2 Remove the SK24 rack containing the processed samples.





CAUTION


Do not remove the K-tubes and barcode clips from the SK24 rack or rearrange the K-tubes and barcode clips in the SK24 rack. Never separate the K-tubes from the barcode clips.

-  Processed samples containing Master Mix solution have a limited stability. They must be immediately loaded into the COBAS® TaqMan® Analyzer for analysis. Refer to the assay-specific package insert for time limits.

-  If the COBAS® TaqMan® Analyzer is not ready to accept samples, wait and transfer the samples once it is ready. The system automatically invalidates any sample that was not transferred from the COBAS® AmpliPrep Instrument to the COBAS® TaqMan® Analyzer within the allowed transfer time, and will require the sample be repeated.

-  AMPLILINK software displays a warning message and flags the affected results if Master Mix stability time is exceeded.

-  Processed samples containing Master Mix are photosensitive and should be protected from direct sunlight and intense artificial light.

-  Do not freeze or store processed samples at 2° C to 8° C.

- 3 Close the COBAS® AmpliPrep Instrument load panel.
- 4 Open the COBAS® TaqMan® Analyzer load panel and slide the rack containing processed samples onto one of the four sample rack positions.
- 5 Slide the rack up to the pin.
- 6 Wait for the sample rack LED to turn solid green, indicating that the rack was properly loaded.

- 7 Continue sliding the SK24 rack to the back of the analyzer.
- 8 Close the load panel.
- 9 Examine the *Samples* tab of the AMPLILINK software *Systems* window and verify that all of the sample tube icons for each sample rack are white. If not, remove and reinsert the rack.

When the rack is properly loaded and matching work orders are found, K-tubes are moved to a K-carrier and the K-carrier is loaded into an available thermal cyclers segment.

- ➡ The LED will turn from green to red when the K-tubes are being loaded onto the K-carrier.

The run starts automatically if samples are properly loaded and matching work orders are found.



WARNING

Never attempt to operate the COBAS® TaqMan® Analyzer with the cover open. Keep hands away from moving parts while the analyzer is in use.

Correcting Load Problems

Errors are listed in the *Missing & Blocked* panel in the *Systems* window *System* tab if the load check fails.

- 1 Correct the load problems.
- 2 Click **Start** to begin amplification and detection.

Processing Samples

The temperature of the thermal cycler segment is cycled according to the PCR profile contained in the test definition file. The fluorometer reads the K-tubes during each amplification cycle.



Do not turn off instrument power during a run.



Once all thermal cyclers are in use, do not load additional samples on the COBAS® TaqMan® Analyzer unless a thermal cycler will be free to perform amplification and detection of the additional samples within the allowable time limit. Refer to the assay-specific package insert for time limits.

Review Run Status

- 1 Click the **Messages** button.
- 2 Examine the *New Messages* tab for any error messages (see *New Messages Tab* in the *cobas s 201 system Hardware and Software Reference Manual*).
- 3 Click the **Systems** button.
- 4 Examine the *Samples* tab.



Icons for successfully processed samples are green.

Accept Results in AMPLILINK Software

Test results appear in the *Results* window as soon as the COBAS® TaqMan® Analyzer finishes a test.

1 Click the AMPLILINK software **Results** button.

2 Select the **Review** tab to display results.



The SK24 rack must be removed from the COBAS® TaqMan® Analyzer before results for the samples in that batch are accepted.

3 Highlight the results to be accepted, then click **Accept** (see *Accepting Results* in the *cobas s 201 system Hardware and Software Reference Manual*).



Information displayed in the AMPLILINK *Results* window is intermediate information from the COBAS® TaqMan® Analyzer. Roche PDM software imports this information and determines the final disposition of donor results. No decision can be made concerning the status of a donor from information displayed in the AMPLILINK *Results* window.

Since Roche PDM software determines the final disposition of donor results, all results displayed in the AMPLILINK *Results* window should be accepted for automatic transmission to the PDM server without operator review.

Review and Release Donor Samples

Access the Roche PDM Data Manager

- 1 Turn on the Data Management workstation if it is powered off. The *Welcome to Roche PDM* dialog box is displayed.
 - ➔ The Data Management workstation is normally left on, except for a daily restart. The *Welcome to Roche PDM* dialog box is displayed if the previous user has logged off.

Press the Ctrl, Alt, and Del keys simultaneously if the *Welcome to Roche PDM* dialog box is not displayed.
- 2 Enter the appropriate login ID and password into the *Welcome to Roche PDM* dialog box and then click OK. The Roche PDM Data Manager application starts automatically.

Retrieve Unevaluated Batches

Display the *Review Batches* tab to list all unevaluated batches (see *Review Batches Tab* in the *cobas s 201 system Hardware and Software Reference Manual*).

- ➔ Once results are accepted in AMPLILINK software, they are automatically exported within three minutes. Exported results are processed by the thin client within seven minutes and are then available for review on the Data Management workstation.
- ➔ Results can also be retrieved using the *Query* tab.

Review Alarms

Highlight a batch and click Next. The *Alarms Review* tab for the selected batch displays.

Review any alarm messages generated while processing the AMPLILINK software export file.

Review RMEC and UDEC Results

Display the *Controls Review* tab for the selected batch.

- ➔ Refer to the assay-specific package insert for control validity criteria.

Review Pool Results

Display the *Pools Review* tab for the selected batch.

- ➔ Non-Reactive pools can be invalidated manually by the user if required (see *Rejecting a Pool* in the *cobas s 201 system Hardware and Software Reference Manual*). Donor samples in an invalidated pool must be retested.

Review and Release Donors with a Donor Status of Complete

Display the *Donor Review* tab for the selected batch (see *Donor Review Tab* in the *cobas s 201 system Hardware and Software Reference Manual*).

Donors that are ready for release have a *Donor Status* of **Complete**.

Donor Status	Meaning
Complete, Non-Reactive	The donor is non-reactive for the tested analyte(s).
Complete, Reactive	The donor is reactive for the tested analyte(s).
Complete, Unresolved	The viability time limit expired before the donor was assigned a complete status.

Donors requiring additional testing (i.e., donor tubes included in a reactive pool and donor tubes whose pool status is invalid) have a *Donor Status* of **Pending**.

- ➔ Donors that require additional testing are not displayed in the *Donor Review* tab if one or more database filters are selected.

Release Complete Donors

- 1 Click to place a check mark in the *Mark* column.
- 2 Click **Accept**, then click **OK** to confirm the request.

The *Testing Status* changes from *Completed* to *Accepted*.
- 3 Click to place a check mark in the *Mark* column.
- 4 Click **Send to LIS**, then click **OK** to confirm the request.

The *Transmission Status* changes from *Not Transmitted* to *Transmitted(1)*.

- ➔ The system may have been configured to auto accept and/or auto transmit results.

Perform Secondary Pooling

Follow-up (secondary) pooling is required if a pipetting error occurred, if initial (primary) testing on multiple-sample pools is reactive, or if a test result is invalid.

Change the Pooling Request (optional)


Certain default testing paths are defined. For example, if test results on a Primary Pool of 6 are invalid, the pooling algorithm indicates a Repeat Pool of 6 should be performed. However, any sample can instead be tested individually in Resolution Pooling.

- 1 Display the Roche PDM Data Manager *Worklist* tab.
- 2 If desired, use the *Pooling Requests* tab to change the type of Secondary Pooling on samples that require additional testing (see *Changing the Pooling Request* in the *cobas s 201 system Hardware and Software Reference Manual*).







Print the Required Pooling Report

- 1 Display the *Details > Required Pooling* tab.
 - ➔ The *Details > Required Pooling* tab displays samples in the selected batch that require additional testing. The *Worklist > Required Pooling* tab displays samples in all batches that require additional testing.
 - ➔ A sample has a status of *Primary run required* if a sample was not pipetted during a Primary Pooling run. This sample must be included in another Primary Pooling run (see exception below).
 - ➔ For a Primary Pools of 6 run, if Library Plate usage is turned off and a sample is not successfully pipetted because of a clot, that sample, along with the five other donors in the invalid pool, is assigned a status of *Repeat required*.
- 2 Click **Print** to display the *Data Manager Reports* dialog box.
- 3 Click to deselect all except the *Required Pooling Report*, then click **Print** again.
 - ➔ Use information in the *Required Pooling Report* to locate samples that require follow-up testing and to determine whether testing will be performed from the Library Plate or donor tube.
 - ➔ If the Plate ID is listed in the *Required Pooling Report*, Secondary Pooling for that sample must be performed from the Library Plate. If the Library Plate or Library Plate well are not usable, the well must be rejected (see *Rejecting a Well* in the *cobas s 201 system Hardware and Software Reference Manual*) before the donor tube can be used in its place.

Select the Secondary Pooling Type

- 1 Start the Roche PDM Pooling Wizard.
- 2 Use information in the *Required Pooling Report* to select the type of Secondary Pooling to be performed.
- 3 Click **Start**.
 -  A map of the pooling deck is displayed. The pooling run ID is automatically assigned and displayed in the title bar.

Load Library Plates

- 1 If no Library Plates will be loaded, continue with instructions to *Load Donor Tubes* on page 3.33.
 -  Use information in the *Required Pooling Report* to determine loading requirements.
- 2 Load the Library Plate that will be used. The *Pending required pooling requests* dialog box is displayed (see *Pending Required Pooling Requests Dialog Box* in the *cobas s 201 system Hardware and Software Reference Manual*). Samples available for the selected pooling run are listed and automatically selected.
 -  The plate must be at room temperature before using.
 -  Remove the sealing mat carefully to avoid cross-contamination.
- 3 Click to remove the check from the *Mark* column for any samples that should not be included in the pooling run.
 -  All samples from the starting Primary Pool must be selected when a Repeat Pool of 6 is performed.
 -  Leave all the desired samples checked, including those with unusable wells. Donor sample tubes can be substituted for samples that have unusable wells.
- 4 Click **OK** to proceed.
 -  Refer to *Error Handling* in the *cobas s 201 system Hardware and Software Reference Manual* if a loading error occurs.

Load Donor Tubes

The *Workflow Guide* prompts for a donor tube carrier to be loaded if a Library Plate was not created or if some of the selected samples have unusable wells.

➔ The *Required Pooling Report* lists the donor tube IDs for samples with unusable wells.

➔ If the *Workflow Guide* prompts to load the plate carrier, click **Done**.


Load the donor tubes to be included in the run. A donor tube carrier is transferred back to the loading deck and an error message is displayed if a donor tube that is not available for the selected pooling run is loaded.

➔ If an error message displays, remove the unavailable donor tube(s) from the carrier and reload the carrier.

Complete Secondary Pooling

- 1 Continue loading any consumables and controls required for the pooling run (see page 3.6).

Once RMECs are loaded, the pooling run starts and proceeds automatically. RMECs are pipetted first.

 The operator should monitor pipetting of the RMECs. The system does not allow donor pipetting to begin until all RMECs have been successfully pipetted. Refer to procedures on *Error Handling During Pipetting of RMECs* in the *cobas s 201 system Hardware and Software Reference Manual* if a pipetting error occurs.

- 2 Review the pooling results and print the *Pooling Batch Report* using the Roche PDM Pooling Manager software.
- 3 Perform sample preparation, amplification, detection, and accept results in AMPLILINK software.
- 4 Review and release donor sample results using the Roche PDM Data Manager Software.
- 5 Perform additional follow-up testing if required.

Perform End of Day Processing

Refer to the *Hamilton Microlab STAR IVD / STARlet IVD Pipettor* (Section 3), *COBAS® AmpliPrep Instrument* (Section 4), and *COBAS® TaqMan® Analyzer* (Section 5) of the *cobas s 201 system Hardware and Software Reference Manual* for procedures to remove used consumables from the instrument when the run is complete.



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