04929616001V5.0

MULTI

cobas c pack MULTI

Order information

REF	CONTENT	System-ID	Analyzer(s) on which **cobas c** pack(s) can be used
04593138 190	**cobas c** pack MULTI	07 7777 3	Roche/Hitachi **cobas c** 311, **cobas c** 501
Open/close tool	on request		

English

System information

Development channel applications: ACN 316-320

Development channel diluents: ACN 958-960

Intended use

Empty reagent carrier for use on Roche/Hitachi **cobas c** systems.

Summary

Development channel applications are based on the open channel concept. Before using a development channel application, it must be installed on the analyzer via **cobas** link and all parameters entered manually.

For development channel applications, cassette kits from Roche Diagnostics are available (see the order information section). These kits consist of a **cobas c** pack MULTI with bottles in different sizes, which is prelabeled with a development channel barcode. Since the same development channel barcode label is used for all of the development channel applications, the **cobas c** pack MULTI has to be assigned to a development channel application before loading it onto the analyzer.

Tests not originating from Roche Diagnostics with a maximum of three reagents can be assigned to a given development channel. If a diluent for automatic sample predilution is required, this has to be provided in a separate **cobas c** pack MULTI.

Tests originating from Roche Diagnostics are described in the corresponding method sheets.

cobas c pack MULTI bottle information

Bottle positions:

Position A (large bottle): Maximum fill volume: 25.65 mL
Maximum variable dead volume: 1.8 mL
Minimum bottle dead volume: 3.85 mL
Maximum use volume: 20.0 mL

Position B (small bottle): Maximum fill volume: 18.3 mL
Maximum variable dead volume: 0.9 mL
Minimum bottle dead volume: 2.4 mL
Maximum use volume: 15.0 mL

Position C (small bottle): Maximum fill volume: 18.3 mL
Maximum variable dead volume: 0.9 mL
Minimum bottle dead volume: 2.4 mL
Maximum use volume: 15.0 mL

Note:

The variable dead volume is dependent on the total fill volume. It is necessary for correct **cobas c** pack MULTI handling on the instrument.

Reagent and diluent preparation

Use only accessories as listed in the order information section. Always use a new **cobas c** pack MULTI when preparing fresh reagent. Never reuse accessories designed for single use as this may cause reagent contamination and affect test results.

Filling the **cobas c** pack MULTI bottles incorrectly may result in a reduced number of tests or refusal of the **cobas c** pack MULTI by the instrument.

Please follow the described procedure step by step.

Reagent:

Prepare the reagent according to the manufacturer's instructions.

Calculation of use volume:

To calculate the use volume (V_{useRX}) for each reagent, first determine the following parameters for a given test:

- N = No. of tests per **cobas c** pack MULTI to be performed
- V_{pipRX} = Reagent pipetting volume per test in µL for each reagent R1, R2 and/or R3

Note:

The no. of tests per **cobas c** pack MULTI must not exceed 500.

The names R1, R2 and R3 refer to the reagent parameters in the application parameter screen. Please use these descriptors for all of the following steps, even if only one or two reagents are used in the test.

- V_{useR1} (mL) = N * V_{pipR1} (µL)/1000
- V_{useR2} (mL) = N * V_{pipR2} (µL)/1000
- V_{useR3} (mL) = N * V_{pipR3} (µL)/1000

Example: N = 150 tests per **cobas c** pack MULTI
V_{pipR1} = 100 µL per test V_{pipR2} = 40 µL per test V_{pipR3} = 20 µL per test
Calculation of use volume:
V_{useR1} = 150 * 100 / 1000 = 15.0 mL V_{useR2} = 150 * 40 / 1000 = 6.0 mL V_{useR3} = 150 * 20 / 1000 = 3.0 mL

Calculation of bottle fill volume:

To calculate the fill volume (V_{fillRx}) for each reagent, use the following equations. The first factor defines the variable dead volume.

- V_{fillR1} (mL) = 1.09 * N * V_{pipR1} (µL)/1000 + 3.85
- V_{fillR2} (mL) = 1.06 * N * V_{pipR2} (µL)/1000 + 2.4
- V_{fillR3} (mL) = 1.06 * N * V_{pipR3} (µL)/1000 + 2.4

Example: N = 150 tests per **cobas c** pack MULTI
V_{pipR1} = 100 µL per test V_{pipR2} = 40 µL per test V_{pipR3} = 20 µL per test
Calculation of fill volume:
V_{fillR1} = 1.09 * 150 * 100/1000 + 3.85 = 20.2 mL V_{fillR2} = 1.06 * 150 * 40/1000 + 2.4 = 8.8 mL V_{fillR3} = 1.06 * 150 * 20/1000 + 2.4 = 5.6 mL

Important:

The fill volume for bottle A (e.g. R1) must not exceed 25.65 mL. For bottle B and C (e.g. R2 and R3) the fill volume must not exceed 18.3 mL. If this is the case for one of the reagents the number of tests per **cobas c** pack MULTI must be reduced and the use and fill volumes for all reagents recalculated.

MULTI

cobas c pack MULTI

Filling the **cobas c** *pack MULTI:*

Bottle positions:

Filling rules:

- Usually fill position A with R1.
- Usually fill position B with R2.
- Usually fill position C with R3.

1. Turn the **cobas c** pack MULTI towards you as shown above.
2. Position A of the **cobas c** pack MULTI is now in the center, position B on the left side and position C on the right side of the **cobas c** pack MULTI.
3. Unscrew the screw cap of the bottle in position A in the center of the **cobas c** pack MULTI using the open/close tool.
4. Pour the appropriate volume of R1 as calculated above into the open bottle of the **cobas c** pack MULTI (position A).
5. Close the bottle tightly using the open/close tool.
6. Unscrew the screw cap of the bottle in position B on the left side of the **cobas c** pack MULTI using the open/close tool.
7. Pour the appropriate volume of R2 as calculated above into the open bottle of the **cobas c** pack MULTI (position B).
8. Close the bottle tightly using the open/close tool.
9. Unscrew the screw cap of the bottle in position C on the right side of the **cobas c** pack MULTI using the open/close tool.
10. Pour the appropriate volume of R3 as calculated above into the open bottle of the **cobas c** pack MULTI (position C).
11. Close the bottle tightly using the open/close tool.

Example (using the above calculations):
Pour 20.2 mL of R1 into the large bottle in the center of the **cobas c** pack MULTI (position A).
Pour 8.8 mL of R2 into the small bottle on the left side of the **cobas c** pack MULTI (position B).
Pour 5.6 mL of R3 into the small bottle on the right side of the **cobas c** pack MULTI (position C).

Note: Any combination of position and reagent type is possible. Above described consequences and limitations have to be considered.

Diluent:

Prepare the diluent according to the manufacturer's instructions. The defined diluent bottle (B, A and/or C) of the **cobas c** pack MULTI has to be filled with the maximum fill volume and closed tightly using the open/close tool. If more than one diluent bottle is used the instrument automatically switches to the next bottle until all bottles are empty. In the *Dilution and Cleaner Cassette Setting* screen (*Utility > System > Page 3/4 > button [Dil. + Cln.]*), select *Bottle Setting* to enter the use volume for the diluent bottles to be defined.

Position A (large bottle): Use volume: 19.0 mL

Position B (small bottle): Use volume: 12.0 mL

Position C (small bottle): Use volume: 12.0 mL

The **cobas c** pack MULTI is now ready for use.

Note:

Before loading the **cobas c** pack MULTI onto the instrument, it has to be reserved for a development channel application.

Special Wash requirements have to be defined with wash cycles for the reagent probes and the reaction cell **after** each development channel (DC) determination. Following combinations have to be entered for each development channel (D1 = NaOHD in **cobas c** pack):

Reagent probe carry-over (depending on the reagent pipetting pattern defined in the DC application settings): Input in *Utility* > *Special Wash*

cobas c 501:

No.	From Test Reagent	From	To Test Reagent	To	Wash Type	Wash Vol. (µL)
1	**DC**	R1	**ALL**	R1	D1	180
2	**DC**	R2	**ALL**	R2	D1	180
3	**DC**	R3	**ALL**	R3	D1	180
4	**DC**	R2	**ALL**	R3	D1	180
5	**DC**	R3	**ALL**	R2	D1	180

cobas c 311:

No.	From Test Reagent	From	To Test Reagent	To	Wash Type	Wash Vol. (µL)
1	**DC**	R1	**ALL**	R1	D1	180
2	**DC**	R2	**ALL**	R1	D1	180
3	**DC**	R3	**ALL**	R1	D1	180
4	**DC**	R1	**ALL**	R2	D1	180
5	**DC**	R2	**ALL**	R2	D1	180
6	**DC**	R3	**ALL**	R2	D1	180
7	**DC**	R1	**ALL**	R3	D1	180
8	**DC**	R2	**ALL**	R3	D1	180
9	**DC**	R3	**ALL**	R3	D1	180

Reduce the carry-over combinations according to the used reagents in column 3.

Reaction cell carry-over: Input in *Utility* > *Special Wash*

cobas c 501 and cobas c 311:

Test	R1 Type	R1 Vol. (µL)	R2 Type	R2 Vol. (µL)
DC	D1	125	D1	125

Once a **cobas c** pack MULTI is removed from the instrument, it cannot be reloaded. When loaded onto the instrument, each **cobas c** pack MULTI is registered as full in the reagent inventory. Therefore, if a used and/or only partially filled **cobas c** pack MULTI is loaded onto the instrument, the number of tests may be reduced or it may be refused by the instrument.

Development Channel Application Parameters

Installing development channel applications

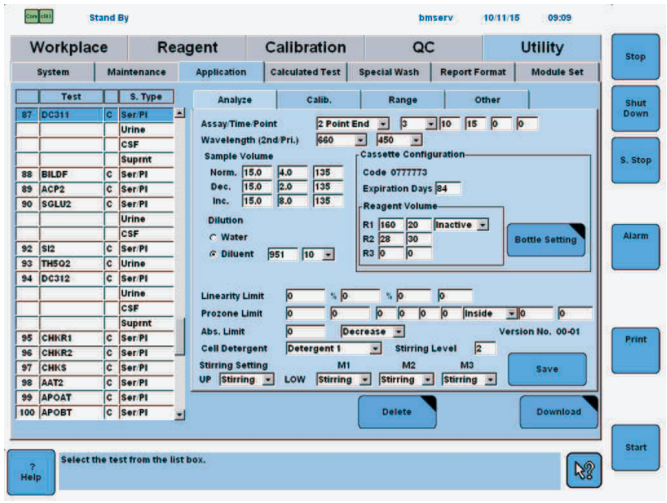
1. Select *Utility* > *Application* to display the application screen.
2. Select *Download* to open the download screen.
3. Select *Application Code* in the area *Search Using* and select an application code between 316 and 320 from the drop-down list.
4. Choose *Search* to start searching for the selected criteria. The search results will be displayed.
5. Mark the check box in the column *Selection* to download the corresponding application and choose *Download* .
6. The file transfer window will then open. Choose *OK* to transfer the file.

7. The *Confirmation* window will then open. The short test name assigned to the application will be automatically displayed in the *Test Name* text box (DC316-320). However, the user can enter a different short test name (up to five characters), if desired. The measurement unit and the registration number (channel) of the application can be selected here. Please be aware that these definitions cannot be changed later. Choose *OK* to download the application.
8. Select *Close* to close the download screen.
9. On the **cobas c** 501 analyzer: If multiple c modules are configured, assign the test application to the appropriate module (*Utility > Module Set >Test Assignment*).
10. Define a Print Order for the test application (*Utility > Report Format*) .
11. Define all parameters for the development channel as follows.

Please note: The following user interface screenshots are derived from the **cobas c** 501 analyzer. Despite minor differences for the **cobas c** 311 analyzer the provided description is also valid for the **cobas c** 311 analyzer.

Defining application parameters - Analyze tab

To display the analyze screen select *Utility > Application > Analyze* .



Select the development channel from the *Test* list on the left side of the screen.

Assay/Time/Point:

Choose the settings for the parameters assay type, assay time and measuring points.

- 1st entry field: Select the assay type from the drop-down menu.
- 2nd entry field: Select the assay time from the drop-down menu.
- 3rd - 6th entry fields: Enter the appropriate measuring points in the given fields.

Wavelength:

Choose the wavelength to be used with the application.

- 1st entry field: 2nd or sub wavelength.
- 2nd entry field: 1st or main wavelength.

If the application is intended for monochromatic measurements, choose *Cancel* in the first entry field.

Sample Volume:

On **cobas c** systems it is possible to perform automatic predilution for patient samples and controls.

- 1st entry field: Sample volume (µL) of the undiluted sample for the normal, decreased and increased volume settings.
- 2nd entry field: Sample volume (µL) of the prediluted sample for the normal, decreased and increased volume settings.
- 3rd entry field: Diluent volume (µL) for the normal, decreased and increased volume settings.

Usually the first run is performed with the normal sample volume settings. A rerun is performed with decreased or increased volume settings, if necessary. In case the decreased sample volume setting is used, the diluted sample volume is used for the rerun.

Note:

When programming dilutions for development channel applications, the total (undiluted) sample volume and diluent volume must be at least 100 µL (due to mixing).

Dilution:

In the *Dilution* area, the diluent for the development channel application can be defined.

- *Water*
- *Diluent* : Enter the appropriate diluent ACN: 951 (NaCl 9 %), 958, 959 or 960. In addition, enter the dilution factor for a concentrated diluent. For more information refer to the *Dilution and Cleaner Cassette Setting* (*Utility > System > Page 3/4 > button [Dil. + Cln.]*).

Cassette Configuration:

- *Code* : 0777773 (fixed for development channels)
- *Expiration Days:* Enter the on board stability of the reagent in days.

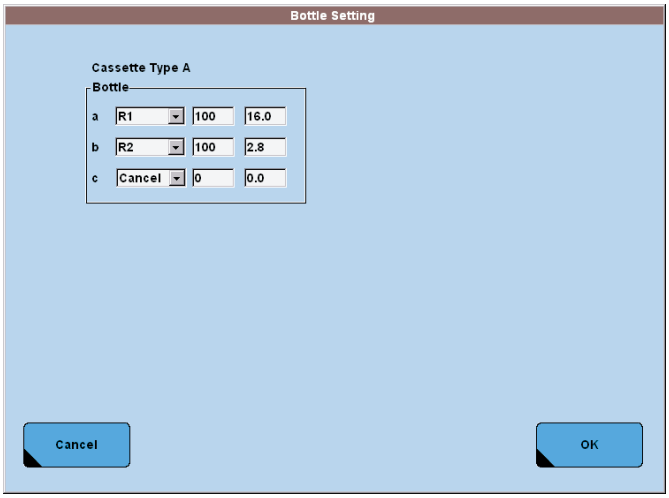
Reagent Volume:

Up to three different reagents (R1, R2, R3) for one test can be used, but usually only two reagents are used (R1 and R2 or R3). R1 is added directly after the sample is pipetted.

- 1st entry field: Reagent pipetting volume (µL) for R1, R2 and R3 in µL, respectively.
- 2nd entry field: Water volume (µL) that should be added by the system after pipetting R1, R2 and R3, respectively.
- 3rd entry field: Always select *Inactive* .

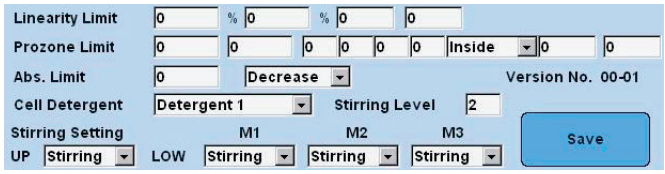
Bottle Setting:

The bottle settings can be entered after opening the *Bottle Setting* screen in the *Cassette Configuration* area.



- *a, b* and *c* denote the bottle position in the **cobas c** pack MULTI.
- 1st entry field: Select the reagent type from the drop-down menu. For *a* usually select R1, for *b* usually select R2 and for *c* usually select R3.
- 2nd entry field: Enter the number of tests per bottle, which is identical to the number of tests per **cobas c** pack MULTI for all three reagents.
- 3rd entry field: Enter the calculated use volume (mL).

Checks and other settings (for more information, refer to the COBI CD):



Linearity Limit:

When performing rate assays, the relationship between the absorbance change and time must be linear. If the linearity is beyond the limit value, an alarm flag *>Lin.* is displayed with the result.

1st entry field	Linearity limit for rate assays with 4-16 points	[0-100] (0: No Check)
2nd entry field	Linearity limit for rate assays with ≥ 17 points	[0-100] (0: No Check)
3rd entry field	Minimal total rate in the measuring window to perform the check	[0-32000]
4th entry field	Minimal rate difference between the first 5 (11) points and the last 5 (11) points in the measuring window to perform the check	[0-32000]

Prozone Limit:

The prozone check is used to detect the effect of excess antigen on turbidimetric immunoassays, which can lead to deagglutination and detection of concentrations on the right side of the signal dose response curve (Heidelberger Curve). Due to this, abnormally high samples may give incorrect or even false normal results.

The prozone limit check can also be used to detect unexpected reaction kinetics when measuring gammopathic samples.

1st entry field	Prozone Limit (lower limit value)	[-32000-32000]
2nd entry field	Prozone Limit (upper limit value)	[-32000-32000]
3rd entry field	MP1: Measuring point of 1st slope	[1-70] (0: Cancel)
4th entry field	MP2: Measuring point of 1st slope	[1-70] (0: Cancel)
5th entry field	MP3: Measuring point of 2nd slope	[1-70] (0: Cancel)
6th entry field	MP4: Measuring point of 2nd slope	[1-70] (0: Cancel)
List box	Defines the range where the flag occurs	[Inside, Outside]
7th entry field	Minimal signal difference of 1st slope to perform the check	[-32000-32000]
8th entry field	Minimal signal difference of 2nd slope to perform the check	[-32000-32000]

Abs. Limit (for rate assays only):

In rate assays, correct data cannot be obtained if the concentration or activity value is beyond the quantitative range. For this reason, a check is performed with reference to a set upper or lower absorbance limit. For rate assays with ascending absorbances, the limit is an upper limit; for assays with descending absorbances, the limit is a lower limit.

A data alarm (> *React*) is issued if only 2 or less measure points remain within the set absorbance limit. The alarm is not issued if there are 3 or more measure points within the absorbance limit.

- 1st entry field: Enter absorbance limit [0-32000 (Abs x 10^4)].
- 2nd entry field: Choose the appropriate assay direction from the drop-down menu [Decrease, Increase].

Cell Detergent:

In general, detergents are used for washing the reaction cell after measurements are taken.

- Detergent 1: Cell Wash Solution I / (CellCln 1) NaOH-D
- Detergent 2: Cell Wash Solution II / (CellCln 2) AcidWash
- Detergent 1 + 2

Stirring Level:

The stirring level of the test application can be defined in this field.

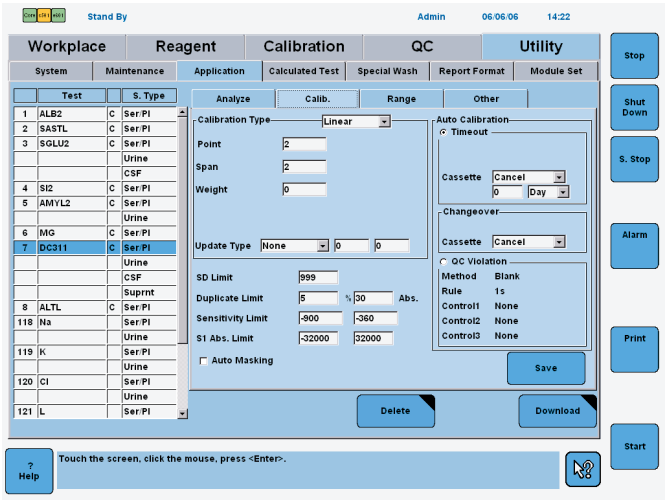
Range: [1-15]

Stirring Setting:

Defines complex ultrasonic mixing patterns. Please do not change predefined settings.

Defining application parameters - Calib. tab

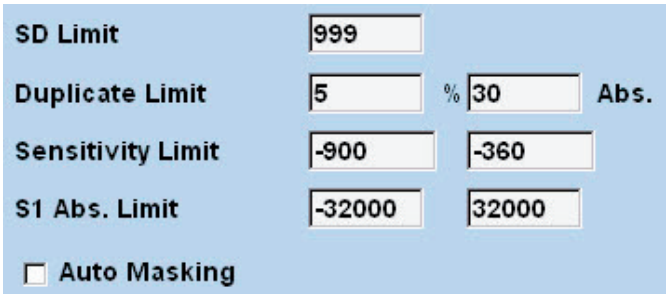
To display the calibration screen select *Utility > Application > Calib* .



Calibration Type area:

- *Calibration Type:* Choose the appropriate calibration type from the drop-down menu.
- *Point* : Up to 6 calibrators (points) can be defined to calibrate a test.
- *Span* : The calibrator that corresponds to the span point is measured and the previously measured calibration curve is adjusted to this setpoint for each applicable calibration type.
- *Weight* : A weighting function can be applied, which favors those calibration points with a lower absorbance (or rate of change in absorbance) during the curve fitting process. This may result in a more accurate curve fit in that particular concentration range [0,1,2] (The input of the value 0 means weighting function is not used).

Checks and other settings (for further information refer to the COBI CD):



SD Limit:

Defineable for nonlinear or multipoint linear tests. For each calibrator, an absorbance value is calculated from the given concentration and the current calibration curve. This calculated absorbance is compared to the measured

absorbance. If the difference between the two exceeds the SD limit value, an *SD.E* alarm is issued. The SD limit value is defined in the SD Limit box (in Abs × 10^4). An SD limit value of 999.9 denotes omission of the check.

Duplicate Limit:

All photometric calibrators are run in duplicate. The duplicate check calculates the % error and the absolute absorbance error (difference) between these duplicate measurements. The obtained check values are compared to the % error limit and the absorbance error limit. Duplicate Limit entries of 99 and 32000 denote omission of the check.

- 1st entry field: Enter the % error limit.
- 2nd entry field: Enter the absorbance error limit.

Sensitivity Limit:

Sensitivity refers to the ratio of an absorbance difference to a concentration difference. It is calculated from the measured absorbances and given concentration values of the blank calibrator (S1) and the span calibrator (SN). The sensitivity obtained in a calibration must lie within certain limits. If the obtained sensitivity is not within these limits, a *Sens.E* alarm is issued, indicating calibration failure. The calibration curve of the affected test will not be updated. A Sensitivity Limit range of -99999 to 999999 denotes omission of the check.

- 1st entry field: Enter the lower sensitivity limit.
- 2nd entry field: Enter the upper sensitivity limit.

S1 Abs. Limit:

This check sets an upper and lower absorbance limit for the blank calibrator, Std (1). If the absorbance for Std (1) falls outside these limits, the system issues a *S1A.E* alarm indicating erroneous calibration. The calibration curve of the affected test will not be updated. An S1 Abs. Limit minimum of -32000 and maximum of 32000 denotes omission of the check.

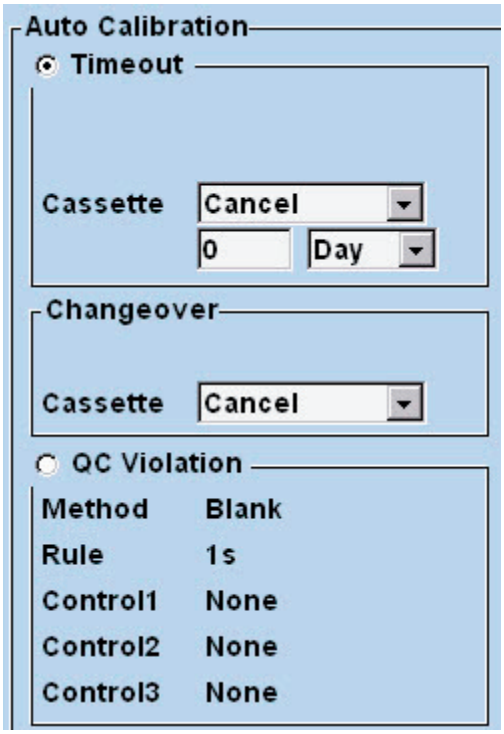
- 1st entry field: Enter the lower absorbance limit.
- 2nd entry field: Enter the upper absorbance limit.

Auto Masking:

If *Auto Masking* is selected, the particular test requiring calibration due to calibration failure will be automatically masked.

To activate the auto masking function for the system, check the *Auto Masking* check box on *Utility > System > Calib. Mask Setting* .

Auto Calibration:



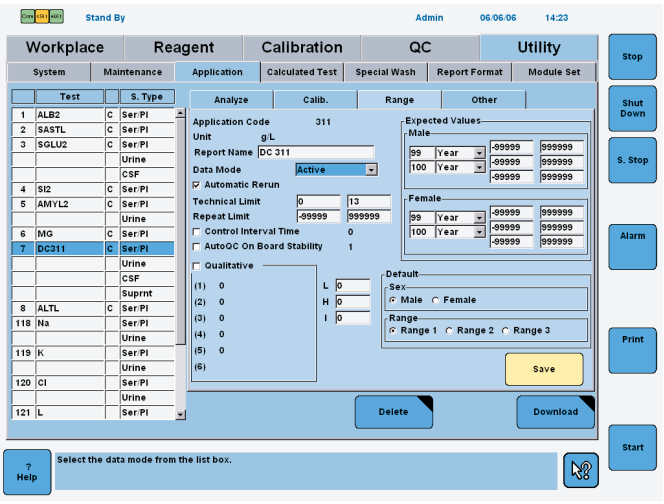
In the Auto Calibration area the trigger for automatic calibration is defined for each application.

Calibration can be requested automatically in the following cases:

- *Timeout* : If the calibration time period for a **cobas c** pack has expired.
- *Changeover* : If a new **cobas c** pack is loaded onto the analyzer.
- *QC Violation* : If a QC measurement has violated a defined rule. For QC-triggered calibration, you must configure the QC violation parameters and activate QC-triggered calibration.

Defining application parameters - Range tab

To display this screen select *Utility > Application > Range* .



Report Name:

User definable test name to be printed on result reports.

Data Mode:

Temporary inactivation of an installed method without deinstallation.

Automatic Rerun:

Select this check box to activate the automatic rerun function for the selected test. If the check box is selected, the test is automatically requested for rerun each time a result is flagged with a data alarm. If

Automatic Rerun is selected, the sample remains on the rack rotor until the results of the test are available.

To activate the automatic rerun function for the system, select *Start (global button)* and in the *Automatic Rerun* area, select *Change*. In the following screen, check the *Routine* and/or *Stat* check boxes.

Technical Limit:

The technical limit reflects the analyte concentration range within which the relation between measured signal (absorbance or rate of change in absorbance) and concentration is well defined.

Any result below the lower technical limit (<*Test* data alarm) is repeated with increased volume. Any result over the upper technical limit (>*Test* data alarm) is repeated with decreased volume.

- 1st entry field: Enter the lower technical limit.
- 2nd entry field: Enter the upper technical limit.

Repeat Limit:

For each test a clinically relevant range can be entered. If the test result lies outside this limit but inside the concentration range defined as the technical limit of the application, the test is repeated using the same sample volume and dilution as in the first run.

The concentration range entered in *Repeat Limit* must lie within that entered in *Technical Limit* .

- 1st entry field: Enter the lower repeat limit.
- 2nd entry field: Enter the upper repeat limit.

Control Interval Time:

A timer-based control interval can be activated and defined. After the time (hours) is specified, a QC measurement is automatically requested (Cause: Timeout) or an auto QC measurement is triggered.

Auto QC On Board Stability:

Activates and defines the on board stability of the analyte in control material in hours to execute the Auto QC concept.

Qualitative area:

In the fields of the first column (1-5) the upper limit concentration can be entered. Any result less than or equal to the value defined here will be printed with the text entered in the second field. If a result is higher than range (5), the entry from field (6) is used.

L, H, I (serum index)

Defines the check values for sample serum index results. If the measured results exceed the entered values, a flag is issued. If 0 is entered, the corresponding check is not performed.

Expected Values area

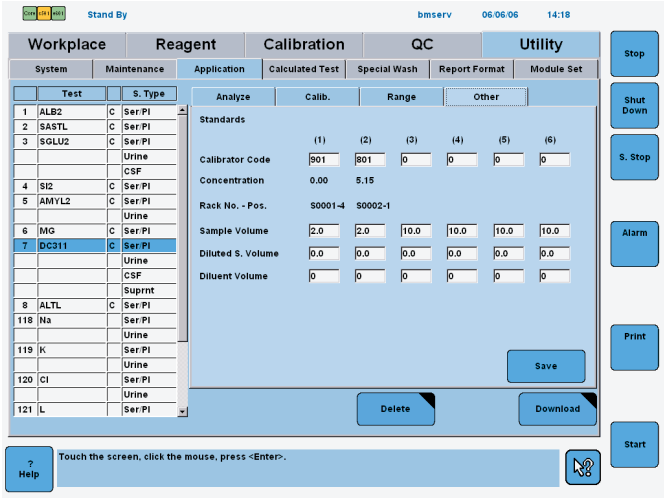
The *Expected values* area is used to define the normal range for men and women in three different age groups. If the results from a test fall outside the ranges entered here, the system issues an alarm (*H, L*). The last row of each category (male, female) does not allow an age limit to be entered. These expected values correspond to those for patients older than the upper limit of the second age group.

Default area:

- *Sex* : Select either male or female values to be used as the default expected values if sex is not defined for a sample.
- *Range* : Select the range of values to use as the default expected values if age is not defined for a sample.

Changing application parameters - Others tab

To display this screen select *Utility > Application > Others* .



Calibrator Code:

Enter the appropriate calibrator code numbers (911-930) in the entry fields for calibrators (1) to (6). Do not use calibrator codes from Roche Diagnostics products.

Concentration:

After entering the calibrator setpoint values (in the *Calibration > Install* screen), the concentrations are displayed here.

Rack No.-Pos.:

After rack assignment, the corresponding rack number and position is displayed.

Sample Volume:

The calibrator sample volume which is used for calibration is displayed. In case a predilution is required this sample volume is taken to prepare the predilution.

Diluted sample volume:

In case the calibrator material is diluted [with diluent (water)] the amount of diluted calibrator material which is taken for calibration is displayed in this field.

Diluent volume:

The amount of diluent dispersed for predilution is displayed.

Assigning reagents and diluents to development channel applications

1. For **cobas c** 501: Select *Open Channel* on the *Reagent > Setting* screen. For **cobas c** 311: Select *Development Channel* on the *Reagent > Setting* screen.
2. Select the appropriate test.
3. Select *Reserve* and *OK* to close the window.
4. Load a filled **cobas c** pack MULTI onto the instrument to assign it to the selected test.
5. Assign a **cobas c** pack MULTI containing a special diluent analogously.

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard.

CONTENT	Contents of kit
→	Volume after reconstitution or mixing

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