CDC01 - CDC10

Closed Development Channels 01 - 10

Order information

REF	CONTENT	System-ID	Analyzer(s) on which **cobas c** pack(s) can be used
06483810 190	**CDC01**	07 7505 3	Roche/Hitachi **cobas c** 501
06483836 190	**CDC02**	07 7506 1	Roche/Hitachi **cobas c** 501
06483844 190	**CDC03**	07 7508 8	Roche/Hitachi **cobas c** 501
06483879 190	**CDC04**	07 7509 6	Roche/Hitachi **cobas c** 501
06483887 190	**CDC05**	07 7511 8	Roche/Hitachi **cobas c** 501
06483895 190	**CDC06**	07 7512 6	Roche/Hitachi **cobas c** 501
06483909 190	**CDC07**	07 7513 4	Roche/Hitachi **cobas c** 501
06483925 190	**CDC08**	07 7514 2	Roche/Hitachi **cobas c** 501
06483933 190	**CDC09**	07 7515 0	Roche/Hitachi **cobas c** 501
06483941 190	**CDC10**	07 7516 9	Roche/Hitachi **cobas c** 501

English

Intended use

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

Summary

For development channel applications, cassette kits from Roche Diagnostics are available (see the order information section). These kits consist of a **cobas c** pack CDC*nn* (e.g. CDC01) with bottles in different sizes. The **cobas c** pack CDC*nn* is prelabeled with a development channel barcode.

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 CDC*nn* .

Precautions and warnings

Exercise the normal precautions required for handling all laboratory reagents.

Disposal of all waste material should be in accordance with local guidelines.

Procedure

The instruction is provided by the software **"cobas application file creator"**.

cobas c pack CDC bottle information

Position A (medium 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

Reagent and diluent preparation

Use only accessories as listed in the order information section. Always use a new **cobas c** pack CDC*nn* when preparing fresh reagent. The **cobas c** pack CDC*nn* cannot be reused.

Never reuse accessories designed for single use as this may cause reagent contamination and affect test results.

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

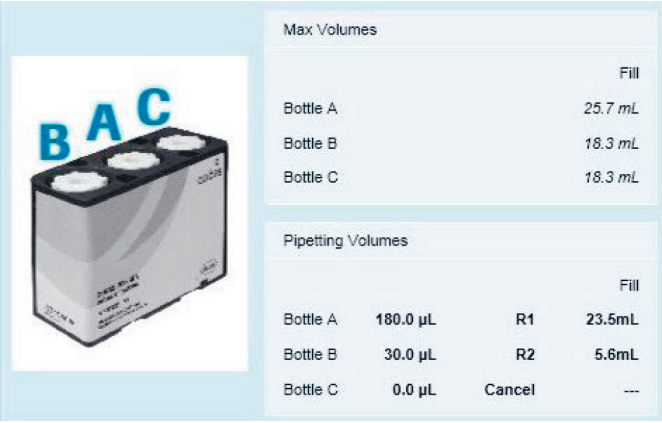
Please follow the described procedure step by step.

Reagent:

Prepare the reagent according to the manufacturer's instructions.

Calculation of use volume:

The **cobas** application file creator software will calculate and display the Use volume according to the specifications of the **cobas c** pack bottle and dead volumes.



Note:

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

The calculation is based on an average on board stability of 4 weeks.

The names R1, R2 and R3 refer to the reagent parameters in the application parameter screen. If a third reagent is pipetted a second **cobas c** pack has to be used to apply the assay. Please use these descriptors for all of the following steps, even if only one reagent is used in the test.

Important:

CDC01 - CDC10

Closed Development Channels 01 - 10

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 CDC*nn* must be reduced and the use and fill volumes for all reagents recalculated.

Filling the **cobas c** *pack CDCnn:*

Bottle positions:

Filling rules:

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

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

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

Diluent:

Note: The **cobas c** pack CDC*nn* cannot be used to introduce diluents into the system, therefore either diluents from Roche Diagnostics or user defined diluents in **cobas c** pack MULTI have to be used.

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 *Utility Reagent Settings* screen (*Utility* > *System* > *Utility Reagent Settings*), select *Dilution* to enter the use volume for the diluent bottles to be defined.

Position A (medium 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 CDC*nn* is now ready for use with a diluent.

Special Wash Requirements have to be defined with wash cycles for the reagent probes and the reaction cell **after** each development channel (CDC*nn*) determination. Following combinations have to be entered for each development channel (D1 = NaOH-D in **cobas c** pack):

Reagent probe carry-over (depending on the reagent pipetting pattern defined in the development channel application settings): Input in *Utility* > *Special Wash* > *Reagent Probe* > *Module Type 501* > *user rule*

Probe	From Test Reagent	From	To Test Reagent	To	Wash Type	Wash Vol. (µL)
1	**CDCnn**	R1	**ALL**	R1	D1	180
2	**CDCnn**	R2	**ALL**	R2	D1	180
2	**CDCnn**	R3	**ALL**	R3	D1	180
2	**CDCnn**	R2	**ALL**	R3	D1	180
2	**CDCnn**	R3	**ALL**	R2	D1	180

Reaction cell carry-over: Input in *Utility* > *Special Wash* > *Cell* > *Module Type 501* > *user rule*

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

Once a **cobas c** pack CDC*nn* is removed from the instrument, it cannot be reloaded. When loaded onto the instrument, each **cobas c** pack CDC*nn* is registered as full in the reagent inventory. Therefore, if a used and/or only partially filled **cobas c** pack CDC*nn* 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

Refer to the **cobas** application file creator software users guide on how to create an installation CD for applications supporting **cobas c** pack CDC*nn*.

Then on the instrument:

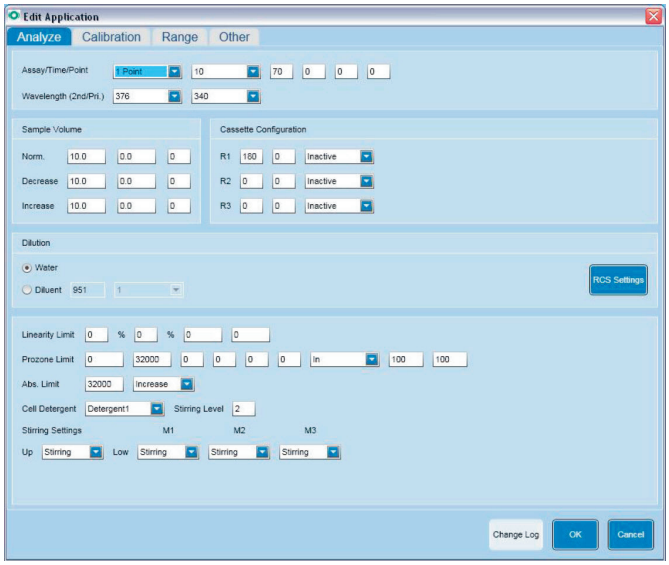
1. Select *Utility* > *Application* to display the application screen.
2. Select *Download* to open the download screen.
3. Select *Application Code* in the area *Search Using* and select an application code between 237 and 249 from the drop-down list.
4. Choose *Search* to start searching for the selected 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 *Confirmation* window will then open. The short test name assigned to the application will be automatically displayed in the *Application Name* text box. 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 and close the window.
7. Define all parameters for the development channel as follows.

Defining application parameters - Analyze tab

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

CDC01 - CDC10

Closed Development Channels 01 - 10



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 primary 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.
- 4th entry field: The stirring level of the test application can be defined in this field. Range: [1-14]. Use the default (4) for this field unless otherwise advised.

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* or
- *Cassette:* 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 *Utility Reagent Settings* (*Utility > System > Utility Reagent Settings*).

R. Pack Configuration (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* .
- 4th entry field: The stirring level of the test application can be defined in this field. Range: [1-14]. Use the default (4) for this field unless otherwise advised.
- The remaining entry fields are not used.

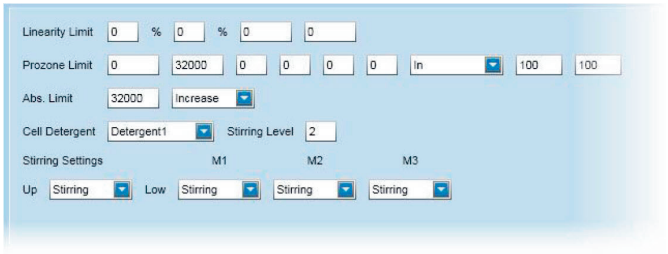
R. Packs Setting applying a one/two/three reagent assay:

Reagent Container Settings Dialog: *Edit > Analyze > RCS Settings*

- 1st entry field: CPack: CDC*nn-nnnnnn (System-ID)* (fixed entries for development channels) for R1 and/or R2 and/or R3, respectively.
- 2nd entry field: Enter the reagent on board stability in days.
- 3rd entry field: Enter the number of tests the **cobas c** pack should carry. Take care do not exceed the filling volume.
- 4th entry field: Enter the reagent position from the drop-down menu, A denotes the bottle position in the **cobas c** pack CDC*nn*. For A usually select R1.
- 5th entry field: Enter the reagent position from the drop-down menu, B and C denote the bottle position in the **cobas c** pack CDC*nn*. For B usually select R2 and for C usually select R3.

Click *OK* to continue or *Cancel* to abort the entry.

Checks and other settings (for more information, refer to COBI (Compendium for Background Information) 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 4-8 points	[1-100] (0: No Check)
2nd entry field	Linearity limit for rate assays with ≥ 9 points	[1-100] (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 3 (6) points and the last 3 (6) 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	[1-38] (0: Cancel)
4th entry field	MP2: Measuring point of 1st slope	[1-38] (0: Cancel)
5th entry field	MP3: Measuring point of 2nd slope	[1-38] (0: Cancel)
6th entry field	MP4: Measuring point of 2nd slope	[1-38] (0: Cancel)
List box	Defines the range where the flag occurs	[In, Out]
7th entry field	Minimal signal difference of 1st slope to perform the check	[0-32000]
8th entry field	Minimal signal difference of 2nd slope to perform the check	[0-32000]

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 3 or less measure points remain within the set absorbance limit. The alarm is not issued if there are 4 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.

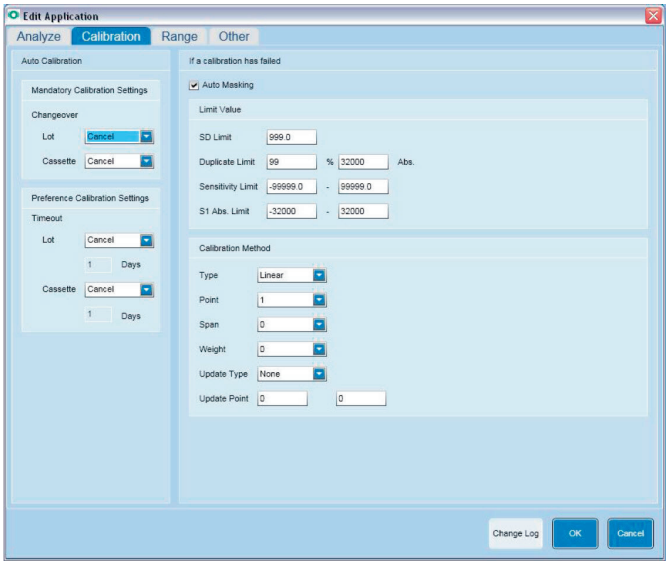
Cell Detergent:

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

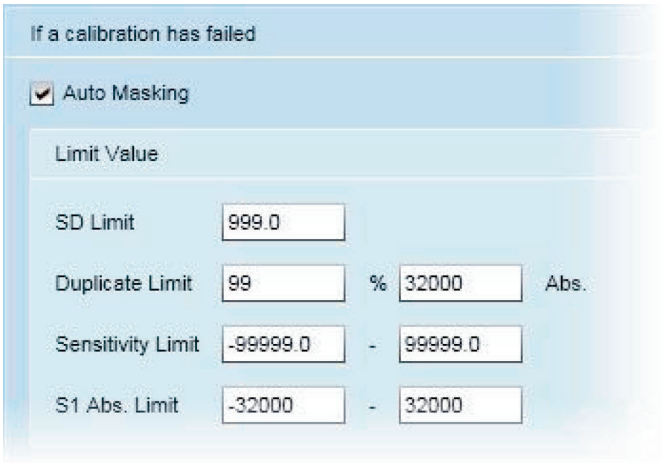
- Detergent 1: Cell Wash Solution I / NaOH-D
- Detergent 2: Cell Wash Solution II / Acid Wash
- Detergent 1 + 2

Defining application parameters - Calib. tab

To display the calibration screen select *Application Edit > Calibration.*



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



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. and QC Settings* on the analyzer.

SD Limit:

Definable 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* (Standard Deviation Error) alarm is issued. The SD limit value is defined in the SD Limit box (in Abs x 10^4). An SD limit value of 999 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 (S_N). 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.

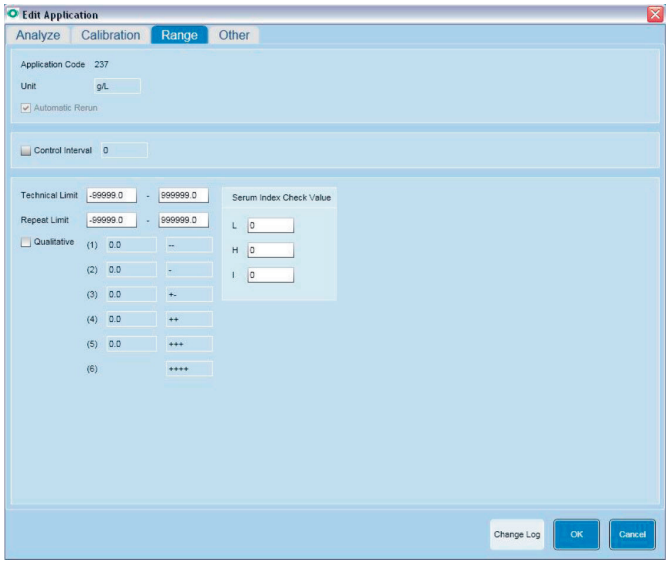
- 1st entry field: Enter the lower absorbance limit.
- 2nd entry field: Enter the upper absorbance limit.

Calibration Method 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.

Defining application parameters - Range tab

To display this screen select *Application > Range*.



Decimal Places:

Entry field: defines decimal places of the result on the printout [0-3].

Automatic Rerun:

Note: The Automatic Rerun entry is only available once the application is installed on the analyzer and not in the **cobas** application file creator software.

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.

Control Interval:

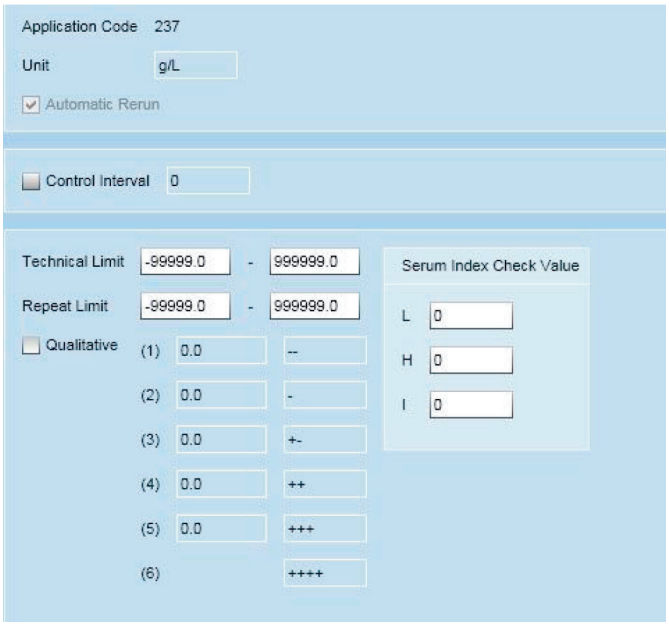
A timer-based control interval can be activated and defined. After the time (hours) is specified, a QC measurement is automatically requested (Cause: Timeout) or an auto QC measurement is triggered.

If check box is activated, enter the interval time [1-1000 hours].

Auto QC On Board Stability Time:

Select this check box to define an on board stability time of Auto QC samples.

If check box is activated, enter the on board time [1-99 hours].



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.

Qualitative area:

If *Qualitative area* is selected:

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):

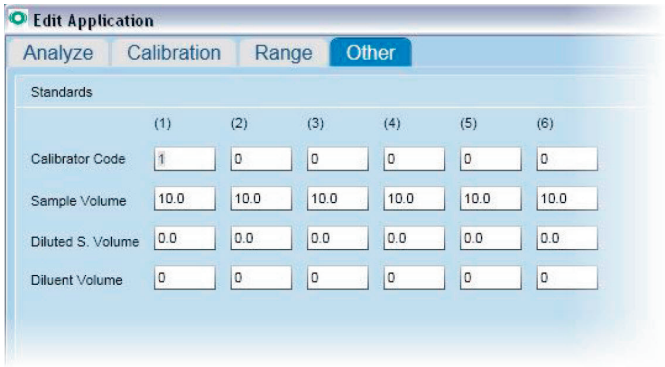
Defines the check values for sample serum index results. If the measured results exceed the entered values, a flag is issued. If 0 is entered, the corresponding check is not performed.

Changing application parameters - Other tab

To display this screen select *Application Edit > Other*.

CDC01 - CDC10

Closed Development Channels 01 - 10



Calibrator Code:

Enter the appropriate calibrator code numbers (911-930) in the entry fields for calibrators (1) to (6). Do not use calibrator codes other than 901 (system water) from Roche Diagnostics products.

Note: Calibrator set point values have to be entered manually on the instrument (in the *Calibration > Install* screen), also rack assignment for the calibrator positions must be done by the analyzer.

Sample Volume:

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

Diluted S. Volume:

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

Diluent Volume:

The amount of diluent dispensed for predilution is displayed.

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
GTIN	Global Trade Item Number

FOR US CUSTOMERS ONLY: LIMITED WARRANTY

Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

CE

Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim
www.roche.com

Distribution in USA by:
Roche Diagnostics, Indianapolis, IN
US Customer Technical Support 1-800-428-2336