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FOR *IN VITRO* USE ONLY.

Cedex Control Beads

Control Beads for the Cedex Analyzer

Cat. No. 05 650 542 001	100 ml (5×10^5/ml)
Cat. No. 05 650 534 001	100 ml (1×10^6/ml)
Cat. No. 05 650 526 001	100 ml (5×10^6/ml)

Version 3.0
June 2010

Cedex HiRes Control Beads

Control Beads for the Cedex HiRes Analyzer

Cat. No. 05 650 780 001	30 ml (5×10^5/ml)
Cat. No. 05 650 771 001	30 ml (1×10^6/ml)
Cat. No. 05 650 763 001	30 ml (5×10^6/ml)

1. What this Product Does

Contents

Cedex Control Beads: 100 ml (5×10^5/ml ±10%, 1×10^6/ml ±10%, or 5×10^6/ml ±10%) in 20% ethanol (vol).

Cedex HiRes Control Beads: 30 ml (5×10^5/ml ±10%, 1×10^6/ml ±10%, or 5×10^6/ml ±10%) in 20% ethanol (vol).

Application

Cedex and Cedex HiRes Control Beads are used to monitor trends in the accuracy of the cell concentration results. They are available in three different concentrations to allow for linearity checks. Regular use of Control Beads allows for monitoring trends in measurement results and permanent documentation of the system integrity. Routine monitoring of the Cedex and Cedex HiRes Analyzers allows for early initiation of prompt counter-measures, such as thorough cleaning of the system, as soon as minor deviations occur.

Storage and Stability

- Store at +2°C to +8°C. Stable through the control date printed on the label.
- Do not freeze!
- Keep bottle closed when not in use.

2. How to Use this Product

2.1 Introduction

The SST (system suitability test) is designed to ensure that the Cedex and Cedex HiRes Analyzers are in good condition, which is essential for guaranteeing proper operation and valid analysis results.

The SST comprises three procedures:

1. Use of Density Reference Standard Beads* as an absolute check of the measurement accuracy of Cedex and Cedex HiRes Analyzers.
2. Use of Control Beads to check performance of the Analyzer at regular intervals in order to detect trends or changes in the measurement process.
3. Use of the Chamber Monitor (Cedex Analyzer) or Scan function (Cedex HiRes Analyzer) for visual inspection of the flow chamber (the inlet in particular) in order to detect impurities in the flow chamber.

⚠ Control Beads cannot be used as a replacement for Density Reference Standard Beads as an absolute check of the accuracy of the system. Before determining the device-specific target value for a new bottle of Control Beads, an absolute check of the system must first be carried out with Density Reference Standard Beads.

Type of Control Beads

Two types of Control Beads are available: 1) Cedex Control Beads and 2) Cedex HiRes Control Beads. The Cedex Control Beads are intended for Cedex Analyzers, whereas the Cedex HiRes Control Beads must be used for Cedex HiRes Analyzers. Each type of Control Beads is composed of 3 bottles filled with beads with a nominal density value of 5×10^5, 1×10^6 and 5×10^6.

Preparation for Carrying Out an SST with Control Beads

Due to slightly variations in hardware from system to system, measurement results using a single bottle of Control Beads can differ slightly when the measurements are carried out with different Analyzers. Therefore, Control Beads bottles that have not been used before must be checked with regard to the certified nominal value. A so-called device-specific target value must be determined for each individual bottle of Control Beads and each Analyzer.

The device-specific target value is calculated by taking the mean of 10 measurements that have been carried out on the Analyzer for which the Control Beads are intended to be used.

The device-specific target value is used as the benchmark (100%) for the evaluation of future results from measurements carried out with that specific bottle of Control Beads.

Before carrying out measurements with Control Beads it is recommended to run a standard clean and a blank check with distilled or deionized, PCR grade water.

The Control Beads must be at +23 to+27°C before a sample can be drawn from the bottle. Control Beads must always be stored in, and directly taken from, the original bottle. They cannot be put into any other container. Before drawing a sample, the Control Bead solution must be thoroughly mixed. Turn the bottle upside down and shake for two minutes. The bottle should subsequently be rolled on a table for half a minute. A record of every sample drawn from the bottle should be kept by marking the container with the amount drawn. A bottle can be used until 5 ml of the solution remains in the bottle.

2.2 Procedure for Determining the Device-specific Target Value

Carry out the following steps to determine the device-specific target value for a bottle of Control Beads and an Analyzer:

1. Start the Cedex or Cedex HiRes software.
2. Carry out a **Prime**.
3. Carry out a **Standard Clean.**
4. Run a blank check with distilled or deionized, PCR grade water. See Table 1 for a list of the Process Parameter settings that should be used for the blank check. This procedure serves as a check of the reagents (in particular Trypan Blue) and the flow chamber. Acceptance criterion: not more than 20 Total Cell counts should be recorded by the Analyzer. If this value is exceeded, the reagents need to be replaced and, if necessary, cleaning routines should be performed. Once the reagents have been replaced, repeat the measurement.
5. Carry out a check of the accuracy of the Analyzer with Density Reference Standard Beads*.
6. Pipette 10 samples of 1 ml (Cedex Analyzer) or 0.3 ml (Cedex HiRes Analyzer) Control Beads each into Cedex Sample cups. Mix Control Beads well as described above and mix again after pipetting two samples; verify that the beads are correctly prepared and are at a temperature of +23 to +27°C.
7. Run all 10 samples using the Process Parameters specified for Control Beads measurements in Table 1.
8. Calculate the mean value of the Total Cell Density (TCD) of the 10 samples used.
9. Calculate the relative standard deviation of the TCD values of the 10 samples used and verify that the relative standard deviation is within less than or equal to 6%. Otherwise check the Analyzer, beads or handling and repeat the measurements.
10. If the relative standard deviation of the TCD for the 10 measurements is within less than or equal to 6%, the mean value calculated for the 10 measurements can be used as the device-specific target value for that bottle of beads and the Analyzer that was used to determine the target value. Use the target value as the benchmark (100%) for the evaluation of future results from measurements carried out with that specific bottle of Control Beads.

2.3 Procedure for Carrying Out an SST with Control Beads

After the device-specific target value has been determined, carry out the following check with Control Beads on a regular basis:

1. Start the Cedex or Cedex HiRes Software.
2. Run a **Prime**.
3. Run a **Standard Clean.**
4. Run a blank with distilled or deionized, PCR grade water. See Table 1 for a list of Process Parameter settings that should be used for the blank check.
   Acceptance criterion: not more than 20 Total Cell counts should be recorded by the system.
5. Perform measurements with Control Beads as follows:
   a) Carry out three measurement with Control Beads with the nominal density of 5×10^5 beads/ml.
   b) Carry out one measurement with Control Beads with the nominal density of 1×10^6 beads/ml.
   c) Carry out one measurement with Control Beads with the nominal density of 5×10^6 beads/ml.
   (See Table 1 for Process Parameter settings that should be used for measurements with Control Beads). These measurements should take place before work with the analyzer starts. Frequency of the measurements will depend on the requirements of the individual lab with regard to quality assurance needs. Control Beads measurements may, for example. be carried out on a daily, bi-weekly or weekly basis, depending on lab requirements. The device-specific target value determined as described in chapter 2.2 should be declared in the comment field for every measurement.
6. Compare the results to the device-specific target value. The acceptance range is ± 7.5% of the target value established for the specific bottle of Control Beads and Analyzer.

Tab. 1: Standard Process Parameter settings for the SST measurements

	Blank Measurement		Control Beads Measurement	
	Cedex Analyzer	Cedex HiRes Analyzer	Cedex Analyzer	Cedex HiRes Analyzer
Cell Type	Std. Cells	Min. Size	Std. Cells	Std. Size
Dilution	none	none	none	none
Precision (images)	Superior (or 30 images)	Maximum (or 300 images)	Normal (or 20 images)	Maximum (or 250 images)

Data Evaluation in a Control Chart

The data can be evaluated via the SST function found in the Cedex Software version 2.x (see Operator's Guide for more details). Alternatively, export the results of the measurements into, *e.g.,* Microsoft Excel format and create a Control Chart to get an overview of the deviations or fluctuations in measurement results (see Operator's Guide for more information about exporting measurement results). Using a graphing program, define the device-specific target value as the benchmark of 100%, and plot the deviations from that value in terms of %. The acceptance range limits are defined as ± 7. 5% of device-specific target value of the Control Beads. Control Beads with a different device-specific target value can be evaluated in one Control Chart, providing an overview for an extended period of time.

The Control Chart can show whether measures, such as cleaning or maintenance, may need to be taken. If measurement results are outside the acceptance range, or if the results from 6 consecutive rounds of measurements are constantly increasing or decreasing, the following steps should be taken:

1. Execute Intensive Cleaning routines (see Operator‘s Guide).
2. Back-flush flow chamber in the case of the Cedex Analyzer (use the Cleaning Kit Measuring Cell* to flush the flow chamber).

If deviations continue to occur, the Analyzer may not be suitable for proper operation and further maintenance may need to be carried out by a Roche service technician.

3. Additional Information on this Product

3.1 How this Product Works

Product Description

Cedex Control Beads are used for carrying out System Suitability Tests for Cedex and Cedex HiRes Analyzers. Three concentrations are available. The exact concentrations are not certified, but are determined for each bottle and Analyzer before use.

Product Advantage

- Control Beads complement DRSB* for the inspection of the suitability of a system.
- Control Beads are less expensive than DRSB* and enable more frequent checks of measuring trends in Cedex and Cedex HiRes Analyzers.
- The entire linearity range can be checked with Control Beads using three measurement points to confirm that an Analyzer is measuring consistently.

3.2 Glossary

Nominal Value: 5×10^5, 1×10^6, 5×10^6 beads per ml note on bottle and certificate.

Device-specific target value: Average Value determined by 10 measurements on a specific Cedex or Cedex HiRes Analyzer.

3.3 Changes to Previous Version

- Editorial changes

4. Supplementary Information

Text Conventions

To make information consistent and memorable, the following text conventions are used in this Instruction Manual:

Text Convention	Usage
Numbered instructions labeled ❶, ❷ etc.	Steps in a procedure that must be performed in the order listed.
Asterisk *	Denotes a product available from Roche Applied Science.

Symbols

In this Instruction Manual, the following symbols are used to highlight important information:

Symbol	Description
	Information Note: Additional information about the current topic or procedure.
⚠	Information critical to the success of the procedure or use of the product.

Ordering Information

Product	Pack Size	Cat. No.
Density References Standard Beads (for Cedex and Cedex HiRes Analyzers)		
Density Reference Standard Beads	1 × 10 ml	05 650 488 001
Density Reference Standard Beads	2 × 10 ml	05 963 583 001
Cedex Cleaning Kit Measuring Cell (Cedex Analyzer only)	1	05 661 897 001

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