For use in quality control / manufacturing process only.

Phosphate Bio HT

Test kit for the Cedex Bio HT Analyzer

Version: 07

Content Version: June 2022

Applications PHO2L (084), PHO2B (742), PHO2D (773)

Cat. No. 06 990 088 001 250 tests

Store the reagent cassette at +2 to +8°C.

1. General Information

1.1. Contents

Vial	Content	Composition
PHO2B	Reagent cassette, 250 tests	Reagent 1 (R1): Sulfuric acid, 0.36 mol/L; non-reactive surfactant.
		Start Reagent (SR): Ammonium molybdate, 3.5 mmol/L; sulfuric acid, 0.36 mol/L; sodium chloride, 150 mmol/L.

1.2. Storage and Stability

Storage Conditions (Product)

Store at +2 to +8°C and at +2 to +15°C for onboard use.
The reagents are stable at +2 to +8°C until the expiry date printed on the label when stored unopened and kept free of contamination.
Onboard stability: After first use on the analyzer, the reagents are stable for up to 12 weeks.

1.3. Additional Equipment and Reagent required

Analyzer and accessories

- Cedex Bio HT Analyzer*, including accessories and disposables
- Standard laboratory equipment

Calibrators and Controls

- Calibrator A Bio*
- Control A Level 1 Bio*
- Control A Level 2 Bio*
- Control A Level 3 Bio*

1.4. Application

This product is intended for quantitative determination of inorganic phosphate ions (PO_4^{3-}) in aqueous solutions using the Cedex Bio HT Analyzer*.

2. How to Use this Product

2.1. Before you Begin

Safety Information

Precautions

- Handle all samples as if potentially infectious, using safe laboratory procedures. As the sensitivity and titer of potential pathogens in the sample material can vary, the operator must optimize pathogen inactivation and follow the appropriate measures according to local safety regulations.
- Do not eat, drink, or smoke in the laboratory work area.
- Do not pipette by mouth.
- Wear protective disposable gloves, laboratory coats, and eye protection, when handling samples and kit reagents.
- Wash hands thoroughly after handling samples and reagents.

Waste handling

- Discard unused reagents and waste in accordance with country, federal, state, and local regulations.
- Safety Data Sheets (SDS) are available online at documentation.roche.com, or upon request from the local Roche office.

2.2. Protocols

Test protocol

Phosphate concentrations can be determined in the ranges shown in the table below, depending on the selected test protocol.

Cedex Bio HT test definition

Test definition	PHO2L (084)	PHO2B (742)	PHO2D (773)
Measuring range	Low	Standard	High + dilution
mmol/L	0.01 – 0.837	0.1 – 8.37	1.1 – 92[1]
mg/L	0.95 – 79.5	9.5 – 795	105 – 8,745
Control level	Custom	A 1, 2, 3	A 2, 3
Sample predilution	No	No	1:11
Measuring mode	Absorbance	Absorbance	Absorbance
Abs. calc. mode	Endpoint	Endpoint	Endpoint
Reaction mode	R1-S-SR	R1-S-SR	R1-S-SR
Reaction direction	Increase	Increase	Increase
Wavelength A/B	340/659 nm	340/659 nm	340/659 nm
Calc. first/last	33/63	33/63	33/63
Unit	mmol/L, mg/L	mmol/L, mg/L	mmol/L, mg/L

[1] Up to 1 mol/L (96 g/L) with automatic predilution.

Pipetting parameters

Pipetting parameters	PHO2L (084)	PHO2B (742)	PHO2D (773)
Water Diluent (Sample Predilution)[1]	No	No	18 µL sample + 182 µL water
R1	90 µL	90 µL	90 µL
Sample (S)	25 µL + 5 µL water	2.5 µL + 27.5 µL water	2.5 µL + 27.5 µL water
SR	38 µL	38 µL	38 µL
Total Volume	**158 µL**	**158 µL**	**158 µL**

[1] Sample predilution is performed in a prior step, after which the reaction mix is prepared in the same way as the unmodified sample.

Calibration

Calibration	
Calibrator	Calibrator A Bio (CAL A, 07-1100-4)
Calibration mode	Linear regression
Calibration interval	Each new lot, and if recalibration is required due to QC results.

Quality control

Protocol PHO2L

- Custom control: For quality control in the low range of test protocol PHO2L, prepare an appropriate control by diluting 'Control A Level 1 Bio' 1:5 using water as the diluent. Divide the phosphate concentration of the original control by 5 for entering the lot-specific phosphate value for this custom control. Also divide the corresponding "1s" value by 5.

Protocol PHO2B

- Control A Level 1 Bio (CONA1, 07-1101-2)
- Control A Level 2 Bio (CONA2, 07-1103-9)
- Control A Level 3 Bio (CONA3, 07-1104-7)

Protocol PHO2D

- Control A Level 2 Bio (CONA2, 07-1103-9)
- Control A Level 3 Bio (CONA3, 07-1104-7)

Use the recommended control material. Other suitable control material can also be used.
Control intervals and acceptance limits should be adapted to each laboratory's individual requirements. If values do not fall within the defined limits, corrective measures and recalibration are required.

Conversion factors

Conversion factors for phosphate concentration:
- 1 mmol/L = 94.97 mg/L
- 1 g/L = 10.53 mmol/L

Traceability

This method has been standardized against a primary reference material (NERL).

Precision

Representative performance data on Cedex Bio HT Analyzers are shown. Results obtained in individual laboratories may differ. Precision was determined in samples of two concentration levels. Coefficients of variation (CV) were calculated for in-run precision (n=21) and inter-run precision (on 21 days).

	Level 1	Level 2
Mean	1.17 mmol/L (111 mg/L)	2.01 mmol/L (191 mg/L)
CV in-run [%]	1.3	1.4
CV inter-run [%]	2.5	2.4

3. Additional Information on this Product

3.1. Test Principle

Inorganic phosphate and ammonium molybdate in the presence of sulfuric acid form a colored ammonium phosphomolybdate complex. The formation of this complex can be measured by increase of absorbance at 340 nm and is directly proportional to the phosphate concentration of the sample.

$$PO_4^{3-} + (NH_4)_6Mo_7O_{24} \xrightarrow{H_2SO_4} (NH_4)_3P(Mo_3O_{10})_4$$

4. Supplementary Information

4.1. Conventions

To make information consistent and easier to read, the following text conventions and symbols are used in this document to highlight important information:

Text convention and symbols	
Information Note: Additional information about the current topic or procedure.	
Important Note: Information critical to the success of the current procedure or use of the product.	
① ② ③ etc.	Stages in a process that usually occur in the order listed.
❶ ❷ ❸ etc.	Steps in a procedure that must be performed in the order listed.
* (Asterisk)	The Asterisk denotes a product available from Roche Diagnostics.

4.2. Changes to previous version

Layout changes.
Editorial changes.
Addition of the PHO2L protocol.

4.3. Ordering Information

Product	Pack Size	Cat. No.
Calibrator		
Calibrator A Bio	6 x 1 mL	06 682 189 001
Controls		
Control A Level 1 Bio	6 x 1 mL	06 682 197 001
Control A Level 2 Bio	6 x 1 mL	06 682 227 001
Control A Level 3 Bio	6 x 1 mL	06 682 545 001
Instruments		
Cedex Bio HT Analyzer	1 instrument	06 608 116 001

4.4. Trademarks

CEDEX is a trademark of Roche.
All other product names and trademarks are the property of their respective owners.

4.5. License Disclaimer

Consult product detail pages at **custombiotech.roche.com** for patent license limitations, if available.

4.6. Regulatory Disclaimer

For use in quality control / manufacturing process only.

4.7. Safety Data Sheet

Please follow the instructions in the Safety Data Sheet (SDS).

4.8. Contact and Support

For additional documentation such as certificates and safety data sheets, please visit **documentation.roche.com**.

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