Roche Cell Collection Medium

For in vitro diagnostic use

Roche Cell Collection Medium Kit	250 x 20 mL	P/N: 07994745190
Roche Cell Collection Medium Replacement Cap Kit	250 Pieces	P/N: 08037230190

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Intended use

Roche Cell Collection Medium is designed for the preservation and transport of cells to be used in molecular testing.

Summary and explanation

Roche Cell Collection Medium is used to collect specimens to be tested by molecular PCR tests including the **cobas**® 4800 HPV Test. When used with the Roche PCR diagnostic products, it allows for detection of target nucleic acid.

The patient's specimen is collected by the clinician using a cervical sampling device and is immersed and rinsed in the Roche Cell Collection Medium vial.

The Roche Cell Collection Medium vial is then capped and sent to the laboratory for processing and testing.

Materials and reagents

Roche Cell Collection Medium

Store the unopened kit as recommended in Table 1 and Table 2.

Table 1 Roche Cell Collection Medium Kit

Roche Cell Collection Medium Kit
Store at 15-30°C
250 Vials (P/N 07994745190)

Component	Reagent ingredients	Quantity per kit	Safety symbols and warnings*
Roche Cell Collection Medium	Methanol-based, preservative solution	250 x 20 mL	 Danger H226: Flammable liquid and vapour. H301 + H311 + H331: Toxic if swallowed, in contact with skin or if inhaled. H370: Causes damage to organs. P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P260: Do not breathe dust/ fume/ gas/ mist/ vapours/ spray. P280: Wear protective gloves/ eye protection/ face protection. P301 + P310 + P330: IF SWALLOWED: Immediately call a POISON CENTER/doctor. Rinse mouth. P308 + P311: IF exposed or concerned: Call a POISON CENTER/doctor. P370 + P378: In case of fire: Use dry sand, dry chemical or alcohol-resistant foam to extinguish. P403 + P233: Store in a well-ventilated place. Keep container tightly closed.

*Product safety labeling primarily follows EU GHS guidance

Table 2 Roche Cell Collection Medium Replacement Caps

Roche Cell Collection Medium Replacement Caps
Store at 15-30°C
250 Caps (P/N 08037230190)

Component	Reagent ingredients	Quantity per kit	Safety symbols and warnings
Roche Cell Collection Medium Replacement Caps	N/A	250	N/A

Precautions and handling requirements

Warnings and precautions

- For *in vitro* diagnostic use only.
- The product is highly flammable, and explosive vapour/air mixtures may be formed even at normal room temperatures.
- Avoid contact of the Roche Cell Collection Medium with the skin or eyes. If contact does occur, immediately wash with large amounts of water.
- Not for external or internal use with humans or animals.
- Safety Data Sheets (SDS) are available on request from your local Roche representative.
- Specimens should be handled as if infectious using safe laboratory procedures such as those outlined in Biosafety in Microbiological and Biomedical Laboratories[1] and in the CLSI Document M29-A4.[2]

Good laboratory practice

- Always follow Good Laboratory Practices/Good Clinical Practices (GLP/GCP).
- Wear protective disposable gloves, coats, and eye protection when handling specimens and kit reagents. Wash hands thoroughly after handling specimens and kit reagents.

Reagent handling and storage

- Keep container tightly closed in cool, well-ventilated place.
- Do not use a kit after its expiration date.
- Use only with adequate ventilation.
- Follow rules for flammable liquids. Store away from incompatible material.
- Transport and store upright at 15°C to 30°C.

Disposal

- Dispose of unused reagents, waste and specimens in accordance with all applicable regulations.

Spillage and cleaning

- If Roche Cell Collection Medium is spilled, **FIRST** clean with a suitable laboratory detergent and water, and then with 0.5% sodium hypochlorite.

Specimen collection and preparation

Specimen collection

Collect specimens using a broom-type cervical collection device or endocervical brush/spatula combination collection device. Record required patient information in the space provided on the vial label.

To prevent leakage, tighten the closure until the line on cap and line on vial meet or slightly overlap and store upright.

Brush/spatula collection device

Collect specimens according to applicable Instructions for Use for the brush/spatula sampling device being used.

Broom-type collection device

Collect specimens according to applicable Instructions for Use for the broom-type sampling device being used.

Specimen transport and storage

- Following specimen collection, transport and store the specimen collected in Roche Cell Collection Medium at 2°C to 30°C for up to 3 months.
- Transport and store upright.
- Consult the test-specific Instructions for Use for collected specimen stability claims.
- Transportation of collected specimens must comply with all applicable regulations for the transport of etiologic agents.[3]

Known interfering substances

The use of lubricants (e.g. K-Y® Jelly) should be minimized prior to specimen collection. Use of over-the-counter products Replens™, RepHresh™ Vaginal Gel and RepHresh™ Clean Balance™ Kit may lead to invalid or false-negative results with the **cobas®** 4800 HPV Test.

Processing instructions

Cellular specimens collected in Roche Cell Collection Medium are to be processed with Roche PCR products according to the Roche product Instructions for Use and the Roche Operator's Manuals.

Non-clinical performance evaluation

A total of 1462 subjects were enrolled to obtain pairs of cervical specimens collected into Roche Cell Collection Medium and PreservCyt® Solution. Each pair of cervical specimens was tested using the **cobas®** 4800 HPV Test to assess the result agreement. In Table 3, specimens with positive results in any of the three HPV detection channels were considered positive; specimens with negative results in all three of the HPV detection channels were considered negative. The positive agreement between results obtained with Roche Cell Collection Medium and PreservCyt® Solution specimens was 92.1%; the negative agreement was 96.8% and the overall agreement was 95.3%.

Table 3 Summary of cobas® 4800 HPV Test results for co-collected Roche Cell Collection Medium and PreservCyt® Solution specimens using the "HPV high risk panel" test result

Cervical Specimen Pairs N = 1462		PreservCyt® Solution		
		Positive	Negative	Total
Roche Cell Collection Medium	Positive	408	33	441
	Negative	35	986	1021
	Total	443	1019	1462

Positive Agreement = 408/443 = 92.1% (95% CI: 89.2%, 94.4%)
Negative Agreement = 986/1019 = 96.8% (95% CI: 95.5%, 97.8%)
Total Agreement = 1394/1462 = 95.3% (95% CI: 94.1%, 96.4%)

Study results from these 1462 subjects were also analyzed by combining the results from all three HPV detection channels. In this analysis (Table 4), the results from each of the HPV detection channels 1-3 were combined. The positive agreement between Roche Cell Collection Medium and PreservCyt® Solution specimens was 91.8%; the negative agreement was 99.1% and the overall agreement was 98.3%.

Table 4 Summary of cobas® 4800 HPV Test results for co-collected Roche Cell Collection Medium and PreservCyt® Solution specimens using the "HPV high risk panel plus genotyping" test result

Cervical Specimen Pairs N = 4386		PreservCyt® Solution		
		Positive	Negative	Total
Roche Cell Collection Medium	Positive	428	35	463
	Negative	38	3885	3923
	Total	466	3920	4386

Positive Agreement = 428/466 = 91.8% (95% CI: 89.0%, 94.2%)
Negative Agreement = 3885/3920 = 99.1% (95% CI: 98.6%, 99.5%)
Total Agreement = 4313/4386 = 98.3% (95% CI: 97.5%, 98.9%)

Additional information

Symbols

The following symbols are used in labeling for Roche PCR diagnostic products.

	Ancillary Software		*In Vitro* Diagnostic Medical Device
	Authorized Representative in the European community		Lower Limit of Assigned Range
	Barcode Data Sheet		Manufacturer
	Batch code		Store in the dark
	Biological Risks		Contains sufficient for <*n*> tests
	Catalogue number		Temperature Limit
	Consult instructions for use		Test Definition File
	Contents of kit		Upper Limit of Assigned Range
	Distributed by		Use-by date
	For IVD Performance Evaluation Only		Global Trade Item Number
	This product fulfills the requirements of the European Directive 98/79 EC for *in vitro* diagnostic medical devices.		

Manufacturer and distributors

Manufactured for:

Roche Molecular Systems, Inc.
1080 US Highway 202 South
Branchburg, NJ 08876 USA
www.roche.com

Roche Diagnostics
201, boulevard Armand-Frappier
H7V 4A2 Laval, Québec, Canada
(For Technical Assistance call:
Pour toute assistance technique,
appeler le: 1-877-273-3433)

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Trademarks and patents

See http://www.roche-diagnostics.us/patents

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EC REP

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References

1. Center for Disease Control and Prevention. Biosafety in Microbiological and Biomedical Laboratories, 5th ed. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institutes of Health HHS Publication No. (CDC) 21-1112, revised December 2009.
2. Clinical and Laboratory Standards Institute (CLSI). Protection of laboratory workers from occupationally acquired infections. Approved Guideline-Fourth Edition. CLSI Document M29-A4:Wayne, PA;CLSI, 2014.
3. International Air Transport Association. Dangerous Goods Regulations, 52nd Edition. 2011.

Document revision

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