

*Global Systems Support*  
*Roche Molecular Diagnostics, Branchburg*  
*Product Bulletin No. 2005/241*



Diagnostics

**Subject:** COBAS AmpliPrep/COBAS TaqMan HBV Test, CE-IVD      **GMMI/Part no.** 03587819190      **Lot no.** N/A

COBAS AmpliPrep/COBAS TaqMan HCV Test, CE-IVD      03568547190      N/A

COBAS AmpliPrep/COBAS TaqMan HIV-1 Test, CE-IVD      03543005190      N/A

**Issue:** Best Practices for Daily Maintenance and Performing a Run

**Date:** 6 October, 2005

Instrument/System	Component	Remark
<input type="checkbox"/> AMPLICOR (Manual)	<input type="checkbox"/> Reagent	<input checked="" type="checkbox"/> Customer Information
<input type="checkbox"/> Non-Roche Kit (Manual)	<input type="checkbox"/> Calibrator	<input type="checkbox"/> Company Information
<input type="checkbox"/> Non-Roche Instrument	<input type="checkbox"/> PC/NC	( do not disclose to customer)
<input type="checkbox"/> COBAS AMPLICOR	<input type="checkbox"/> IC/QS	<input type="checkbox"/> Feedback Requested
<input checked="" type="checkbox"/> COBAS AMPLIPREP	<input type="checkbox"/> Specimen	<input type="checkbox"/> Feedback Required
<input checked="" type="checkbox"/> COBAS TaqMan	<input type="checkbox"/> Panel	<input type="checkbox"/> Product Education
<input checked="" type="checkbox"/> COBAS TaqMan 48	<input checked="" type="checkbox"/> Other: Instrument	<input type="checkbox"/> Product Update
<input checked="" type="checkbox"/> AMPLILINK		<input checked="" type="checkbox"/> Control result affected
<input type="checkbox"/> TaqLink		<input checked="" type="checkbox"/> Sample result affected
<input type="checkbox"/> Other		<input type="checkbox"/> Result not affected
Distribution via <input checked="" type="checkbox"/> Email <input type="checkbox"/> Fax <input checked="" type="checkbox"/> Intranet <input type="checkbox"/> Mail		

Dear Colleagues,

The new COBAS AmpliPrep/COBAS TaqMan Tests offer improved sensitivity over the previous test generation while fully automating sample preparation, amplification, detection and calculation of results. While these improvements are welcomed by most customers, they do require customers to take care when running these high performance tests and maintaining the instrumentation.

To achieve optimal performance with the COBAS AmpliPrep/COBAS TaqMan Tests listed above, operators must:

- Adhere to general best practices for a laboratory that performs nucleic acid amplification tests
- Properly perform Daily Maintenance on the COBAS AmpliPrep Instrument and COBAS TaqMan Analyzer

- Clean the laboratory area and equipment used to prepare primary samples immediately before and after use
- Use care when starting a run and cleaning up after the run (*i.e.*, transferring primary samples to S-tubes, loading samples and reagents on the COBAS AmpliPrep Instrument and COBAS TaqMan Analyzer, disposing of used materials after the run).

This bulletin describes the best practices for performing each of these tasks. One possible consequence of not following these best practices is an elevated frequency of samples with invalid QS results, particularly when performing the COBAS AmpliPrep/COBAS TaqMan HCV Test.

These best practices provide additional detail on how to perform the test procedures. The information in this Product Bulletin should be used in conjunction with the instructions in the Package Inserts and Operator's Manuals and the maintenance procedures contained in the AMPLILINK Software.

### **General Laboratory Best Practices**

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- Primary samples should be handled in a dedicated area of the laboratory, preferably within a laminar flow hood. The COBAS AmpliPrep System and COBAS TaqMan or TaqMan 48 Analyzer can be located together, but should be in a different area than the area used to handle primary samples.
- Laboratory doors and windows should be kept shut.
- To reduce the amount of dust in the laboratory, a sticky mat may be placed inside each doorway and operators may step onto the mat with both feet when entering the room. Instead of using a sticky mat, operators may put paper booties over their shoes or change to a dedicated pair of laboratory shoes when entering the laboratory.
- Laboratory coats and gloves should be changed when moving from the sample handling area to the instrument area of the laboratory.
- Tubes used for storing serum and plasma should be made of polypropylene.
- Laboratory waste containers should have covers and should be lined with a bag. Waste should be removed from the lab at least once a day.

### **Best Practices for Daily Maintenance of the COBAS AmpliPrep Instrument**

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Daily Maintenance should be performed at the beginning of each workday by following the instructions in the Service Wizard and utilizing the best practices described below.

#### **Materials required:**

- 70% Ethanol (80% ethanol may be used if specified by local guidelines)
- Lint free tissues (*e.g.*, KimWipes, Cat # 7106)

- 0.5% sodium hypochlorite solution (freshly prepared each day in deionized or distilled water) or DNA-zap (Ambion, Cat # 9890) or Mikro Liquid (Schülke and Mayr, Cat # 109132)

NOTE: Commercial liquid household bleach typically contains sodium hypochlorite at a concentration of 5.25%. A 1:10 dilution of household bleach will produce a 0.5% sodium hypochlorite solution.

- Powder-free disposable Gloves

**Procedure:**

- Replace the Wash Reagent Cube Container only when instructed to by the AMPLILINK Software. Do not replace the Wash Reagent at other times; under certain circumstances, bubbles can form if a partially full container is removed.

NOTE: Do not transfer Wash Reagent from one container to another container. Any remaining Wash Reagent and the container should be discarded.

NOTE: The Lot Number of the Wash Reagent and the date should be recorded each time the Wash Reagent is changed.

- The COBAS AmpliPrep Instrument should stay on continuously. If the power is accidentally switched off for a few days, perform an EXTENDED PRIME after restarting the instrument. If accidentally switched off, the power should not be left off for more than a few days at a time.
- Powder-free disposable gloves must be worn for all steps of the daily maintenance procedure listed below.
- Each area within the COBAS AmpliPrep Instrument – reagent/sample area (*i.e.*, Transfer Head 1 area), SPU area, separation area (*i.e.*, Transfer Head 2 area) – should be cleaned separately as described in the step-by-step procedure below.
- Use a new lint-free tissue to clean each area as specified in the numbered instructions below.
- Use care when applying liquid to the lint-free tissue. The tissue should be damp, but not saturated, to avoid having drops of liquid fall onto the COBAS AmpliPrep Instrument. Do not spray liquids directly on any part of the COBAS AmpliPrep Instrument.

NOTE: AMPLILINK Software says that tissues should be moistened with deionized water. You may also use 70% ethanol where indicated in the cleaning steps listed below. The 70% ethanol solution more effectively cleans surfaces and evaporates rapidly, eliminating the need to dry the surface after wiping with the ethanol-moistened tissue. However, water should be used for cleaning the sensors and light barriers (see step 8).

- Perform the following steps in the order listed, which corresponds to the order specified in the Daily Maintenance procedure of the AMPLILINK Software.
  1. Empty the liquid in the Waste Container and rinse the Waste Container with water. Spray the outside of the Waste Container with Mikrozid or bleach (0.5% sodium hypochlorite solution); make sure to spray around the mouth of the Waste Container.
  2. Clean the initialization posts with a lint-free tissue moistened with 70% ethanol. Then use the same tissue to clean the platform surface in the reagent/sample area.
  3. Clean the platform surface of the SPU area with a new lint-free tissue moistened with 70% ethanol.
  4. Clean the platform surface of the separation area with a new lint-free tissue moistened with 70% ethanol.
  5. Clean the reagent needles with a new lint-free tissue moistened with 70% ethanol. Make sure that any crystals or droplets are removed.
  6. Inspect syringes and tubing for leakage and bubbles. If bubbles are visible, perform a normal prime to eliminate them.
  7. Clean the Sample Tube Handler and SPU Gripper with a new lint-free tissue moistened with 70% ethanol.
  8. Clean the sensors and light barriers on both Transfer Heads with a lint-free tissue moistened with **deionized water**. Use a separate tissue for each Transfer Head.
  9. Clean the inside of the Main Cover with a new lint-free tissue moistened with 70% ethanol.

NOTE: The Daily Maintenance procedure in the AMPLILINK Software does not specify cleaning the inside of the cover. This should be done just prior to closing the cover so that any matter on the cover surface will not fall onto the just cleaned instrument surfaces. **Slide the cover forward, support it with one hand, and use the other hand to wipe the underside of the cover.** Then, continue lowering the cover to the closed position.

NOTE: The procedure described in Steps 2 through 9 must also be performed after a system crash.

### Best Practices for Preparing Primary Samples

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- Primary samples should be handled in a dedicated area of the room, preferably in a laminar flow hood.
- The work area and pipettes should be cleaned immediately before transferring primary samples to S-tubes by wiping with bleach or DNA-zap and then with 70% ethanol. Change gloves before handling samples. This cleaning procedure should be repeated after all samples have been transferred to S-tubes.

- Lab coats and gloves should be changed after the samples have transferred from primary tubes to S-tubes and the sample handling area has been cleaned. Put on a clean lab coat and new gloves before loading samples on the COBAS AmpliPrep Instrument.

#### Best Practices for Performing a Run and Cleaning Up at the End of the Day \_\_\_\_\_

- Clean gloves must be worn when loading reagents and samples on the COBAS AmpliPrep Instrument.
  - Load the COBAS AmpliPrep Instrument with the quantity of disposables needed for the run. Do not load extra disposables.
  - Rotate between slots when loading racks of K-tubes and K-tips. For example, if racks are loaded into slots 1 and 2 on Day 1, then load them into slots 3 and 4 on Day 2 and again in slots 1 and 2 on Day 3.
  - Remove all used disposables from the COBAS AmpliPrep Instrument at the end of each day.
    - Immediately discard all used SPUs and S-tubes according to local requirements. Place them in plastic bags and close the bag by knotting. Care should be taken to prevent splashing when S-tubes are discarded into waste bags.
    - Unused SPUs should be covered with a white SPU cover (the cover that is on them when they are delivered) and stored in a clean area that has been wiped with bleach and 70% ethanol. These SPUs may be used in future runs.
  - Racks containing unused k-tips and k-tubes may be left on the COBAS AmpliPrep Instrument at the end of the day, but should be covered while performing the Daily Maintenance. They may be covered with left over white SPU covers or with Parafilm.
  - At the end of each day, clean SPU Racks, Reagent Racks and Sample Racks by wiping with bleach and then with 70% ethanol. If any foreign matter is visible on the racks, remove the foreign matter by washing with water before wiping the rack with bleach and ethanol.
  - Cleaned SPU Racks, Reagent Racks and Sample Racks should be stored in a dedicated, covered space that has been wiped with bleach and 70% ethanol or sealed in plastic bags.
  - The UV light in the COBAS AmpliPrep Instrument should be turned on at the end of each work day for at least 30 minutes. If the Instrument is not used every day, the UV light should be turned on at least twice a week.
- NOTE: All reagent racks and sample racks should be removed from the Instrument before turning on the UV light.
- Discard used k-tubes at the end of each day.
    - For the COBAS TaqMan Analyzer, always place a waste bag in the K-tube Waste Box. Knot the bag, remove it from the Analyzer, and discard it in a covered waste container. Then wipe the inside and outside of the K-tube

Waste Box with bleach or DNA-zap.

- For the COBAS TaqMan 48 Analyzer, remove the k-carrier from the Analyzer and discard the k-tubes in a plastic bag. Knot the bag and place it in a covered waste container.

### **Background**

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Several customers have reported a higher than expected frequency of invalid QS results when performing the COBAS AmpliPrep/COBAS TaqMan HCV Test. In customer laboratories, the high frequency of invalid QS results has been reduced by thoroughly cleaning the laboratory and then implementing the best practices described in this Product Bulletin.

Laboratories that experience an increased frequency of invalid QS results for the COBAS AmpliPrep/COBAS TaqMan HCV Test may also observe invalid QS results for the COBAS AmpliPrep/COBAS TaqMan HIV Test, but the frequency will be much lower than that observed for the COBAS AmpliPrep/COBAS TaqMan HCV Test.

### **Corrective Action(s)**

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This Product Bulletin is being distributed to describe the current best practices to use when performing the COBAS AmpliPrep/COBAS TaqMan HBV, HCV and HIV-1 Tests. Affiliates should use the information in this Product Bulletin to train their customers.

### **Required Actions**

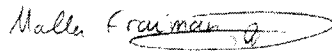
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- Please inform customers who perform the COBAS AmpliPrep/COBAS TaqMan HBV, HCV and HIV-1 Tests that careful adherence to laboratory technique and performing daily maintenance is required to achieve optimal performance.
- Please train customers on the best practices described in this Bulletin.
- Please explain that failure to adhere to these best practices may result in a high frequency of samples with invalid QS results, particularly when performing the COBAS AmpliPrep/COBAS TaqMan HCV Test.

If you have any questions or need additional information, please contact Roche Diagnostics' International Technical Service in the US at +1 925 730 8338 or in Switzerland at +41 41 799 2977.

Best regards

Date: 6 October, 2005

Handwritten signature of Malka Fraiman in cursive, with the name circled.

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