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Analyzer Bulletin

Roche/Hitachi MODULAR *ANALYTICS*, cobas c 311, and cobas c 501 analyzers – Procedure for Manually Cleaning the Sample Probe

This Analyzer Bulletin has been revised to include additional information in the tables on page one and two and to update the Roche Diagnostics website address. Updates are indicated by black bars in the margins.

Background

When a sample probe becomes compromised by protein buildup inside the probe, clogged with a fibrin clot, or coated with gel from blood collection gel separation tubes, inaccurate sampling can occur resulting in imprecision and possibly erroneous results for calibrator, control, and patient samples.

If protein buildup or clogging from a fibrin clot is suspected, the sample probe should be cleaned and rinsed thoroughly. If the probe is coated with gel, it must be replaced. Roche Diagnostics has updated the procedure for removing, cleaning, and reinstalling the sample probes on your Roche/Hitachi **MODULAR** *ANALYTICS* (P, D, DAT, and ISE), **cobas c** 311, and **cobas c** 501 analyzers.

How to Determine if the Sample Probe is Obstructed or Damaged

Follow the steps below to supplement the instructions in the Maintenance Guide of your Roche/Hitachi **MODULAR** *ANALYTICS*, **cobas c** 311, or **cobas c** 501 analyzer Operator's Manual:

Step	Action
1	Visually inspect the sample probe for a fibrin clot protruding from the probe tip or for gel from blood collection tubes coating the tip. **Note:** If a clot is present, try to manually remove it using tweezers or a 0.2 mm gauge stylet. **Note:** If the outside of the sample probe is coated with gel, the probe must be replaced.
2	Visually inspect the tip of the sample probe for damage (i.e., burr, bend, pitting). **Note:** If the probe is damaged, replace the probe using the appropriate Operator's Manual, maintenance section.
3	Perform an Air Purge and watch the stream of water that comes from the probe's tip. The water should be delivered straight down into the probe's rinse station in a fine, steady stream. **Note: cobas c** 501 operators cannot observe the stream without the top cover opened. Only operators that have completed the Interlock Release Tool training will be able to do this. **Note:** The analyzers will dispense several streams of water during one air purge cycle. The **MODULAR** *ANALYTICS* P, D, DAT, and ISE sample probes also dispense a few water droplets between each stream, while the **cobas c** 311 and **cobas c** 501 sample probes dispense no droplets between streams.
4	If imprecision is suspected or confirmed after verifying steps 1-3 above, go to the Procedure "How to Clean/Flush the Sample Probe Thoroughly" in this Analyzer Bulletin.

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☑ MODULAR P ☑ **cobas c** 311
☑ MODULAR D ☑ **cobas c** 501
☑ MODULAR DAT

How to Clean/Flush the Sample Probe Thoroughly

Follow the steps below to supplement the instructions in the Maintenance section of your Roche/Hitachi **MODULAR** *ANALYTICS*, **cobas c** 311, or **cobas c** 501 analyzer Operator's Manual.

Step	Action
1	Remove the affected sample probe, following the appropriate analyzer's Maintenance Guide under "As needed maintenance." **Note:** For the **cobas c** 501 analyzer, refer to the "Interlock Function for **cobas c** 501 analyzer with ISE" manual.
2	Attach a short length of vinyl or rubber tubing to a 10 cc syringe.
3	Fill the syringe with 1N NaOH solution.
4	Insert the connector end of the probe (i.e., opposite end from the tip) into the tubing attached to the syringe. **Note:** Remove the white probe seal from the connector end of the probe before attaching the syringe tubing.
5	Push 5 cc of the cleaning solution through the probe. **Note:** If cleaning solution cannot be pushed freely through the probe tip in a fine, steady stream, replace the probe.
6	Repeat these steps for other sample probes, if necessary. **Note:** The **cobas c** 311 only has one sample probe.
7	Push a minimum of 10 cc of DI water from a clean syringe through the probe to rinse thoroughly.
8	Follow the instructions in the appropriate Operator's Manual daily maintenance section to clean the outside of the sample probe.
9	Follow all remaining procedures for replacing a sample probe in the appropriate Operator's Manual. **Note:** For the **cobas c** 501 analyzer, refer to the "Interlock Function for **cobas c** 501 analyzer with ISE" manual. **Note:** Reinstall the white probe seal (**MODULAR** *ANALYTICS* analyzer) or install a new white probe seal (**cobas c** 311 or 501 analyzer) in the connector end of the probe before reattaching the probe.
10	Run controls for all assays
11	Perform a precision study (e.g., n = 21) using a control material.
12	Compare the SD and %CV recoveries to the Roche/Hitachi or **cobas c** 311/**cobas c** 501 Within Run Precision Guidelines on the Roche Diagnostics USA website at usdiagnostics.roche.com.
13	If the problem is not completely resolved with this cleaning procedure, replace the probe.
14	If replacing the probe does not resolve the issue, please contact the Roche Support Network Customer Support Center at 1-800-428-2336 for assistance.

Actions Required

- Follow the revised cleaning procedure in this Analyzer Bulletin when manually cleaning a sample probe on your Roche/Hitachi **MODULAR** *ANALYTICS*, **cobas c** 311, or **cobas c** 501 analyzer.
- Discard Analyzer Bulletins 07-068R and 10-086.
- File this Analyzer Bulletin for future reference.

Questions

Please contact the Roche Support Network Customer Support Center at 1-800-428-2336 if you have questions about the information contained in this Analyzer Bulletin.