



## Test Change Beginning March 30, 2010 \*HIV-1 RNA Quantitation by PCR\*

Alverno Clinical Laboratories is making a change in HIV viral load testing, effective Tuesday, March 30, 2010. We will be changing our methodology from Branched Chain DNA technology (bDNA) to Polymerase Chain Reaction technology (PCR).

This change will **improve turn around times, increase sensitivity**, and overall service to our physicians and patients while maintaining an FDA-approved test available.

**\*\*Please be advised that our validation studies, as well as available literature, indicate a potential increase in patient values of 0.3 - 0.4 log higher when utilizing the new PCR assay. This fact will be added as a comment on all patient results reported. \*\***

Successful treatment is indicated by a  $\geq 0.5$  log decrease in viral load. Re-establishment of patient baseline is available upon physician request.

### Specimen Collection

**Specimen:** Plasma ONLY.

**Volume:** 3 mL.

**Minimum Volume:** 1.1 mL. Submitting the minimum specimen volume makes it impossible to repeat the test. A minimum specimen volume may result in a QNS (quantity not sufficient) result, requiring a second specimen to be collected.

**Container:** Ship in a polypropylene frozen transport tube.

**Collection:** Collect specimen in lavender-top (EDTA) tube or PPT™. Do not use green-top (heparin) tubes. Centrifuge specimen within six hours of collection and transfer plasma to a screw-cap polypropylene transport tube, and freeze. Ship frozen (preferred). Do not ship frozen in PPT™. If PPT™ is used to collect plasma, specimen must be transferred to a screw-cap tube prior to freezing to avoid false elevation of low viral load samples.

**Storage Instructions:** Freeze. Room Temperature: 24 hours; Refrigerated: 5 days; Frozen: -70°C for 90 days.

**Use:** Detect and quantitate HIV-1 in plasma.

**Limitations:** Assay range: 48-10,000,000 copies/mL.

**Methodology:** COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 PCR test.

**Production schedule:** Batched 2 times a week.

**The Soft order code:** HIVQT.

*For further test information, please contact our client services department. (800) 937-5521*