Tip #1

When performing comparability studies, if the analytes have different reportable ranges due to the method and sample type, a method comparison is still required. There is nothing in the guidance that the instruments/methods must produce the same results. The laboratory needs to define the relationship between the different results (acceptance criteria) and perform the comparison twice yearly. CMS requirement 493.1281
Tip #2

Laboratories are not required to perform comparability for waived instruments unless their own policies state that they are to be done.
Tip #3

Laboratories should have records of action or corrective action when the instrument comparability criteria are not met.
COM. 04250

Comparability of Instruments and Methods - Nonwaived Testing Phase II

If the laboratory uses more than one nonwaived instrument/method to test for a given analyte, the instruments and methods are checked against each other at least twice a year for comparability of results.
Summary

This requirement applies:

• To tests performed on the same or different instrument makes/models or by different methods.
• Only for nonwaived instruments/methods accredited under a single CAP number.
• NOT for calculated parameters or waived testing.
Additional reminders

• Quality control data may be used, but use of human samples is preferred.

• If using quality control material:
  – it must be the same instrument platform
  – quality control and reagents must be of the same manufacturer and lot number.

• The use of pooled patient samples is acceptable.
For Microbiology testing, this requirement:

• Applies when two instruments (same or different manufacturers) are used to detect the same analyte.

• Does not apply to multiple analytical methods (eg, antigen typing versus culture or detection of DNA versus a biochemical characteristic) designed to detect the same organism but not the same analyte.
Single data collection systems

• Two or more detectors or incubation cells connected to a single data collection, analysis and reporting computer need not be considered separate systems

• For example:
  – multiple incubation and monitoring cells in a continuous monitoring blood culture instrument,
  – two identical blood culture instruments connected to a single computer system, or
  – multiple thermocycler cells in a real time polymerase chain reaction instrument.