

IMPORTANT PRODUCT REMOVAL NOTICE

Date: 05 Aug 2009

Attention: Laboratory Director
PCR Laboratory

Subject: Defective (closed) K-Tips (M/N: 03287343001), Lots 09001108, 09002108, 09003108, 09004108, 09005108, 09006108, 09007108, 09008108 and 09009108 for use with the COBAS® AmpliPrep Instrument

Issue

Roche Molecular Diagnostics has confirmed a problem with K-Tips (M/N: 03287343001), Lots 09001108, 09002108, 09003108, 09004108, 09005108, 09006108, 09007108, 09008108 and 09009108. The affected lots contain K-Tips that are completely closed (near the pipetting end of the K-Tip), which prevents the COBAS® AmpliPrep Instrument from pipetting eluate from the SPU into the K-Tube.

Impact on Results

Pipetting with these defective K-tips is not possible. Use of these defective K-Tips will result in an invalid run and no reportable results.

Corrective Actions

1. Discontinue use of K-Tips (M/N: 03287343001) Lots 09001108, 09002108, 09003108, 09004108, 09005108, 09006108, 09007108, 09008108 and 09009108.
2. Request replacement material through your local Roche Diagnostics affiliate.