Resp-4-Plex Collection Device Change

Issued August 4, 2026 | Begin transitioning immediately

ACTION REQUIRED: Begin collecting Resp-4-Plex specimens using a nasopharyngeal swab placed in Copan Universal Transport Medium (UTM) immediately.

What is changing?

Garcia Clinical Laboratory is transitioning from the Abbott Alinity m Resp-4-Plex Emergency Use Authorization (EUA) assay to the FDA-cleared version of the assay. For specimens submitted to Garcia Laboratory, the new collection requirement is a nasopharyngeal swab transported in Copan Universal Transport Medium (UTM).

The universal collection device currently used by many facilities is not included in the FDA-cleared specimen requirements for the new assay and will be discontinued for Resp-4-Plex collection after the transition period.

Why is Abbott making this change?

The original Resp-4-Plex assay was distributed under an FDA Emergency Use Authorization during the COVID-19 public health emergency. Abbott subsequently obtained FDA clearance for its permanent, commercially marketed version. Transitioning to the FDA-cleared assay allows routine use under the cleared labeling rather than continued reliance on the EUA configuration.

What facilities need to do

1	Start now: Begin using Copan UTM collection kits for Resp-4-Plex specimens immediately.
2	Collect the correct specimen: Obtain a nasopharyngeal swab and place it into the Copan UTM tube according to the collection-device instructions.
3	Use remaining devices only during the transition: Current universal collection devices will be accepted temporarily while Garcia Laboratory uses its remaining EUA assay-control inventory, estimated at approximately 2-3 weeks.
4	Prepare for final conversion: Once the EUA inventory is exhausted, specimens submitted in the current universal collection device will no longer be acceptable for Resp-4-Plex testing and recollection may be required.

REQUIRED COLLECTION DEVICE

Copan Universal Transport Medium (UTM)
Collect a nasopharyngeal swab and place it into the Copan UTM tube. The tube has a red cap and is labeled UTM-RT, as shown.

Garcia Clinical Laboratory will communicate the final discontinuation date as the remaining EUA inventory is depleted. Please begin replacing current Resp-4-Plex collection supplies now to avoid testing delays or recollection.

Questions or supply assistance? Contact Garcia Clinical Laboratory at 517-787-9200.

Technical basis: Abbott Alinity m Resp-4-Plex FDA 510(k) clearance K241573. This notice applies specifically to Garcia Clinical Laboratory Resp-4-Plex testing.