



COPAN Diagnostics Inc.

HQ: 26055 Jefferson Ave, Murrieta, California, 92562

Plant: 2728 Loker Avenue West, Carlsbad, California, 92010

## NOTICE OF CHANGE 01/2025

### UTM® New 510(k) Molecular Claim and Product Line Optimization

To the Attention of:

### PURCHASING & QUALITY DEPARTMENTS

Dear Valued Customer:

Copan is pleased to inform you of our new molecular claim for its UTM® Universal Transport Medium™ without beads. Per Copan's 510(k) K232357, the following codes are adopting this new claim.

Item	Description
3C047N	UTM 3ML NO BEADS IN BULK 16X100 TUBE
3C057N	UTM 3ML NO BEADS+FLEXIBLE FLOQSWAB BP100
3C064N	UTM 3ML NO BEADS+REGULAR BP80 FLOQSWABS
3C071N	UTM MINI 3ML ROUND NO BEADS+PROGR. FLOQSWAB BP80
3C075N	UTM MINI 3ML ROUND NO BEADS IN BULK
3C085N01	UTM 3ML NO BEADS+PROGR. MINITIP FLOQSWABS BP80
3C088N01	UTM MINI 3ML ROUND NO BEADS+REG.FLOQSWAB BP80

**The 510(k) K232357 intended use is:**

*UTM-RT is intended for the stabilization and transportation of an unprocessed upper respiratory clinical specimen suspected of containing respiratory viral nucleic acids. UTM-RT is intended for use with compatible molecular assays.*

The Instructions for Use can be accessed by clicking here: [UTM IFU](#)

Additionally, Copan is optimizing our product portfolio to better serve customer needs by consolidating lower-demand SKUs. This helps us to continually improve our efficiency and quality in our offerings



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while continuing to support your sample collection and transport product needs. Copan will accept orders for the deactivated SKUs (see table below) through April 7, 2025, and stop deliveries by April 30, 2025.

Item	Description	Alternative SKU's
3C048N	UTM 3ML NO BEADS+PLASTIC APPL.POLYESTER TIP BP100	NA
3C058N	UTM 3ML NO BEADS+FOAM MINITIP SWAB BP80	3C047N + 502CS01
3C059N	UTM 3ML NO BEADS+PLASTIC APPL.POLYESTER TIP BP100	3C047N + 519CS01
3C060N	6ml UTM in 16x100 Tube w/o Beads	NA
3C061N	UTM 3ML NO BEADS+REG. BP80+FLEX. BP100 FLOQ	3C057N OR 3C064N
3C062N	UTM 6ML NO BEADS+5 REGULAR BP30 FLOQSWABS	3C047N + 520CS01
3C072N	UTM 3ML NO BEADS+REG. BP100+FLEX. BP100 FLOQSWABS	3C047N + 519CS01 OR 503CS01
3C073N	UTM 3ML NO BEADS+MID TURBINATE FLOQSWAB BP80	3C047N + 5638CS01
3C080N01	UTM 3ML NO BEADS+CONTOURED FLOQSWAB W/STOPPER BP50	3C047N + 56750CS01
3C083N01	UTM 3ML NO BEADS W/BARCODE+FLEXIBLE FLOQSWAB BP100	3C057N
3C084N01	UTM 3ML NO BEADS+ULTRA THIN MINITIP FLOQSWAB BP80	3C047N + 525CS01
3C086N01	UTM 3ML NO BEADS+REG.+PROGR.MINITIP BP80 FLOQSWABS	3C064N OR 3C047N + 5U088S01

If you have any questions, please contact [customerserviceUS@copangroup.com](mailto:customerserviceUS@copangroup.com). We appreciate your continued trust in Copan and remain committed to providing innovative solutions for your laboratory.

Regards,

Customer Service Department

Copan Diagnostics, Inc.