

Product Change Notification Letter

Date: February 8, 2024

Product Change Notification #: PCN-2024-02-08

Re: Minor Changes to Product Label and Instructions for Use (IFU)

Dear Valued Distributor/Customer:

We would like to inform you of a minor update affecting a select few of our CE-IVD products. As of March 1, 2024, production for selected products will incorporate updated labels. Remaining stock and circulating lots with the old labels will be available until all previous lots are sold.

Description of Change: The modification involves a minor update to the product's label and Instructions for Use (IFU). We will add Zymo's Swiss Representative (CH Rep), Casus Consulting, and contact information to the product's outer package label and IFU alongside the existing CE Representative information. This update will not have an impact on the products or their functionality. Please refer to the table below for a full list of products affected by this label and IFU update.

Product Name	Part No.	
DNA/RNA Shield Collection Tube w/ Swab - DX (1 ml fill) (50 pack)	R1107-E	
DNA/RNA Shield Collection Tube w/ Swab - DX (2 ml fill) (50 pack)	R1109-E	
DNA/RNA Shield SafeCollect Saliva Collection Kit	R1211-E	
DNA/RNA Shield SafeCollect Swab Collection Kit (1 ml)	R1160-E	
DNA/RNA Shield SafeCollect Swab Collection Kit (2 ml)	R1161-E	
DNA/RNA Shield Fecal Collection Tube (10 pack)	R1101-E	
DNA/RNA Shield Fecal Collection Tube (1 each)	R1101-1-E	
DNA/RNA Shield (Bulk)	R1100-50-E, R1100-250-E, R1200-25-E, R1200-125-E	
ZymoBIOMICS 96 MagBead DNA Kit	D4302-E, D4306-E, D4308-E	
EZ-96 DNA Methylation-Lightning MagPrep	D5046-E, D5047-E	

We request that you share this notification with the relevant personnel in your organization.

Thank you for your continued partnership.

Julie Ogi

QA and Regulatory Officer



The Beauty of Science is to Make Things Simple

Approved By: [For Zymo Internal Use Only]			
Title	Name (Print)	Signature	Date