In Prague, 26th May 2026

Subject: Selected group C eSens PCR kits no longer to be supplied as IVDs

Dear business partners,

We have thoroughly assessed the situation arising from the requirements set out in the legislation for continuing to place so-called legacy IVDDs (i.e., products that meet the requirements of Article 110 of the IVDR) on the market and have made the following decisions:

Unfortunately, we will no longer supply **selected** IVD products from our portfolio that are legacy IVDD devices and classified in group C according to IVDR criteria (listed below).

Please note that most of these products are currently in stock. These batches have already been manufactured and placed on the market; therefore, in accordance with the provision of the art. 110 par. 4, may continue to be supplied (to be made available on the market or put into service) with the CE-IVD status until their expiry date. Any newly manufactured batches will be supplied as RUO products only. Information on the availability of IVD batches is reflected in the CE-IVD/RUO indication displayed for each item on our websites, www.ecolidx.com.

ES3049A	eSens N.gonorrhoeae/M.genitalium QL PCR kit	IVD batch in stock
ES3083A	eSens HPV HR 14 genotype QT PCR kit, variant 4C	IVD batch in stock
ES3200A	eSens HSV QL PCR kit	IVD batch in stock
ES4100B	eSens F2/F5 SNP PCR kit	Not in stock
ES4200B	eSens BRCA1 SNP PCR kit	IVD batch in stock
ES4201B	eSens BCR-ABL QT PCR kit	IVD batch in stock
ES3310B	eSens NA RespiViral Multiplex	Not in stock
ES3311A	eSens NA SARS-CoV-2/Influenza A/B Multiplex	IVD batch in stock

With regard to the other legacy IVDDs in our portfolio, namely those that will fall under Class B and the remaining 60 eSens kits that will fall under Class C according to the IVDR criteria, we have decided to take the necessary steps to meet the applicable requirements for their continued marketing within the maximum time limits allowed by the IVDR.

Sincerely,

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