



April 01, 2025

Information Regarding Select Lots of EZ1&2 DNA Investigator Kits

Dear Valued Customer,

In 2024, QIAGEN received feedback from a small number of customers regarding unexpectedly low DNA yields when using certain lots of Cat. No. 952034 EZ1&2 DNA Investigator Kit (the "Kit"). As part of our certified Quality Management System, we conducted a thorough investigation in line with our standard quality assurance procedures.

All Kit lots associated with this feedback had previously passed QIAGEN's quality control release testing, including assessments of DNA yield. These QC tests, performed on cartridges from the start, middle, and end of each production run, did not identify any issues.

Our investigation did not replicate low yields when the Kits were used according to the large volume protocol described in the handbook for EZ1 Instruments. In additional exploratory testing—where the protocol was intentionally varied—lower yields were occasionally observed. Based on this, we hypothesized that, under certain non-standard conditions, a drift in the pH of Buffer MTL might have contributed to reduced yields in isolated cartridges. While this potential drift was not confirmed as a root cause, and we could not establish a definitive link to the reported performance, we implemented an update to the buffer filling process in October 2024 as a precaution. This improvement was applied to all Kits beginning with Lot #178038861.

In parallel, we performed a stock recovery of remaining Kits from the small number of lots associated with customer feedback. These lots were originally released between February 28 and October 23, 2024, and remaining inventory was blocked from distribution on October 24, 2024. The specific lot numbers of EZ1&2 DNA Investigator reagent cartridges associated with customer feedback were: #178024040, 178016379, 178011822, 178024570, 178010359, 178021865, and 178018149.

Consistent with our complaint-handling procedures, we responded to the customers and concluded the investigation. Based on the data available, there

is no indication of a broader or systemic issue. It's also important to note that a wide range of factors—many unrelated to the Kit—can contribute to variability in DNA yields. The total number of complaints related to this topic was low, representing approximately 0.1% of Kits shipped during the timeframe in question.

Recently, we've become aware of additional questions raised within the forensics community about whether other Kits manufactured before October 2024 could potentially show similar behavior under certain conditions. We want to emphasize that we have **no evidence** suggesting that Kits beyond those already reviewed are affected, or that test results generated using these Kits are unreliable.

At QIAGEN, we are committed to transparency and collaboration. We are sharing this update with the broader forensics community to foster dialogue, answer questions, and encourage customers to report any unexpected performance observations through techservice-na@qiagen.com, so that we may investigate further if needed.

Thank you for your attention and for your continued trust in QIAGEN. We value our ongoing partnership and remain dedicated to supporting your important work.

Sincerely,

Your QIAGEN team