Cannabis Control Commission
COMMONWEALTH OF MASSACHUSETTS

Bulletin – Recalled Microbial Test Kits

To: Marijuana Establishments and Medical Marijuana Treatment Centers licensed pursuant to *935 CMR 500.000* and *501.000*, Certifying Healthcare Providers, Registered Qualifying Patients and Personal Caregivers, and Consumers
From: Shawn Collins, Executive Director
Date: April 11, 2023
Subject: MGC Microbial Test Kit Recall

On March 9, 2023, a Marijuana Establishment notified the Cannabis Control Commission (Commission) of a product recall issued by Medicinal Genomics Corporation (MGC) regarding a test kit that can be used to measure microbial contaminants in cannabis products under proper laboratory conditions. According to MGC's Quality Alert Bulletin dated January 18, 2023 (Tab B), this recall was prompted by a potential defect that may have occurred within one specific kit, identified in the alert bulletin by its Stock Keeping Unit no. 420201.

At this time, the Commission has confirmed that only two Independent Testing Laboratories (ITLs) had previously purchased the kit subject to this recall. The agency's Investigation and Enforcement department is actively identifying cannabis products tested for microbial contaminants that may not be compliant with Commission regulations. The purpose of this bulletin is to inform the public of its active and ongoing investigations into this matter.

The Commission is committed to promoting public health, safety, and welfare. It is possible that some products which passed testing based on the recalled test kits may have moved into the market and remain at Marijuana Establishments or Medical Marijuana Treatment Centers or have been sold. The Commission is investigating this matter and will keep the public updated if it makes findings that implicate an immediate or serious risk to public health, safety, and welfare.

Questions regarding this notice may be directed to the Commission by calling the agency at (774) 415-0200 or emailing **Inspections@CCCMass.com**.

Quality Alert Bulletin

Date: January 18th, 2023

From: Medicinal Genomics Corporation

Subject: Product Replacement/Recall Notice for qPCR Master Kit V3 Lot 10169542 with qPCR Master Mix V3 Lot 10170939 (SKU 420201)

Summary

We have discovered a defect in qPCR Master Kit v3 lot 10169542, specifically with the master mix component Lot 10170939. This issue was not present during our normal QC and functional testing, but was observed weeks later in R&D use under different conditions than those in which functional testing is performed. The defect appears to affect the robustness of amplification and therefore sensitivity could be compromised. This has been confirmed in our internal testing as sufficiently different from all previous lots of master mix. Out of an abundance of caution we are recalling this lot and providing replacements.

Products Impacted

qPCR Master Kit v3 Lot 10169542 SKU 420201 (Specifically Master Mix Lot 10170939)

Corrective Action

Out of an abundance of caution we are recalling this lot and replacing it with a new lot. Any customers that have already received this lot of 420201 Master Kit v3 will be shipped replacements.

1. US customers' replacements will be shipped on Thursday, January 19th for delivery on Friday, January 20th.
2. Canadian customers' replacements will be shipped Monday, January 23rd.
3. All previous lot retains have been tested internally under new procedures and this is the only lot affected.
4. Customers that have not yet used this lot but have it in inventory are asked to discard or send back their kits. We will provide shipping labels upon request.
5. Customers that have used this lot in compliance or R&D testing should review their data and look for any abnormalities. The problem we observed internally was intermittent, but enough of a difference was observed that we determined a recall was necessary. Any tests performed using this lot of master mix may be compromised.

Investigation

While our reagents undergo extensive final quality control testing before being released, this particular problem was identified after release when the master kit lot in question was being used in a serial dilution experiment. Assay robustness appeared to be compromised and was different from our other lots at the low end of serial dilutions. The problem was isolated to one specific lot.

Preventative Action

We have implemented additional functional testing to ensure our reagents are free from this type of defect. Serial dilutions will be performed to further test robustness of each new lot of master kits. We are working with our manufacturing partner to identify the root cause in the supply chain.

Questions

Please contact us immediately for additional information or help with replacing your lots of inventory or managing this recall.

We extend our sincerest apologies for any inconvenience this defective qPCR Master Kit v3 may cause your operation. We will take any steps necessary to maintain accountability for this issue and put forth every effort to regain your confidence and that of your own clients.

We are so grateful for your partnership and we are eager to work through this issue together.

Timothy Olcott
Vice President, Operations

Tim Olcott
Timothy Olcott (Jan 18, 2023 13:29 EST)