



Clinigo wipes contamination VEP001, VEP003 and VEP004 – Follow-Up Report

1st June 2026

1. Background

Following the voluntary product withdrawal notification issued on **25th March 2026** for Clinigo products VEP001, VEP003, and VEP004 due to confirmed sporadic mould contamination, this report provides an update on the investigation, corrective actions taken and the current status of the recall.

The original withdrawal letter is attached for reference.

2. Root Cause Analysis

Through a thorough investigation, conducted with guidance from an external specialist consultant, the root cause of the contamination has been identified as follows:

- A review of production records identified a specific time period during which environmental conditions within the manufacturing area were temporarily compromised, leading to the introduction of airborne mould spores.
- The wipes provided an ideal environment for mould to thrive due to their damp, acidic conditions, allowing any introduced spores to proliferate within a small number of affected packs.
- The presence of Penicillium mould species was confirmed via an external laboratory.
- The issue was sporadic and not widespread across entire batches, which is consistent with a temporary, localised environmental factor.

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Company Registered in England and Wales - Co. Reg. No. 05446285

3. Actions Taken Post-Recall

The following actions have been completed since the voluntary withdrawal notification was issued:

Action	Status
Quarantine of all affected stock (VEP001, VEP003, VEP004) held at NHS depots	Complete
Collection and disposal of all quarantined stock from depots	Complete
Credit notes issued via NHS Supply Chain for all disposed stock	Complete
Engagement of external specialist consultant to review cleaning protocols, identify gaps and implement enhanced training for all staff	Complete
Enhanced cleaning and fogging of the entire production area using disinfectants effective against mould	Complete
Weekly progress calls with NHS Supply Chain to provide updates	Ongoing

4. Post-Recall Manufacturing & Testing

In early April, we manufactured an additional 10,000 packs of VEP001 and VEP003 for testing purposes (VEP004 has been discontinued).

- Samples from this production run were sent to an external laboratory for microbial contamination testing.
- Accelerated testing was also performed to stimulate real life conditions which were also monitored for mould growth.
- All test results were clear, with no contamination detected.

5. Warehouse Storage & Ongoing Monitoring

The finished packs from the post-recall production run were stored in our warehouse under ambient conditions for a period of 6–7 weeks.

During this time, boxes were randomly opened and packs inspected. We are pleased to advise that **no further mould growth** has been observed in any of the inspected packs.

6. Conclusion

Based on the following evidence, we are confident that the issue has been resolved:

- Negative laboratory test results from post-recall production
- Successful storage trial with no recurrence of mould growth over 6–7 weeks
- Enhanced cleaning, fogging and training measures implemented with external expert guidance

We therefore consider the corrective actions to be effective and the risk of recurrence to be significantly reduced.

7. Moving Forward – Planned Corrective Actions

To prevent recurrence of this issue, the following ongoing measures will be maintained:

- Enhanced cleaning protocols will continue, including regular fogging of the production area
- Ongoing staff training on contamination prevention and hygiene standards
- Any future changes to the production environment or equipment will be subject to an enhanced risk assessment prior to implementation
- Regular random pack inspections will be conducted on finished goods held in the warehouse
- Continued liaison with NHS Supply Chain and provision of updates as required

8. Contact Information

If you require any further information regarding this report or the recall process, please do not hesitate to contact us.



Customer Services

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