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STATE OF MICHIGAN  
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS  
LANSING

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DIRECTOR

January 22, 2021

To Whom It May Concern:

The MRA has received an update regarding the AOAC Emergency Response Validation. The first round of testing in this project has been completed. A method must receive satisfactory results from the first round to move on to the second round. Three categories of test methods participated in this validation study:

- Molecular methods
  - This includes qPCR methods.
- Non-molecular automated systems methods
  - These are methods which rely on culture growth of microbes and use an automated system to estimate the total microbial load in a sample.
- Plating-based methods
  - These methods include both traditional plating methods as well as methods that utilize dehydrated plates.

According to the preliminary results of AOAC Emergency Response Validation, non-molecular automated systems methods and plating based methods passed the first round of testing. Therefore, the MRA finds it to be in the best interest of public health and safety to disallow the sole use of molecular methods such as qPCR for the quantification of total yeast and mold. This decision may be reevaluated as new information is gleaned from this study or any future studies by the AOAC.

Additionally, both non-molecular automated systems methods and plating based methods must include a 72-hour incubation period prior to quantification and all testing requires a duplicate for confirmation.



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All licensees who are currently using a qPCR method for total yeast and mold have 2 options:

1. The laboratory may switch to either a non-molecular automated systems method or a plating-based method.
2. The laboratory may opt to pair qPCR with either duplicate plating or a non-molecular automated system analysis as confirmation. If the results of the qPCR method and the plating method differ, the results of the plating method will be reported in Metrc.

The laboratories who previously opted to validate a qPCR method to [Appendix J](#) may continue to work on the validation internally but are not permitted to report the results of tests run using only the qPCR method.

Laboratories that are currently using qPCR methods must immediately cease reporting the results of total yeast and mold until they are able to perform internal verification of an alternative or confirmative method. The laboratory may opt to outsource testing for total yeast and mold during the verification period. Once verification is complete, the laboratory must submit the verification data, updated standard operating procedures, all relevant quality control procedures, and a passing proficiency test to [MRA-scf@michigan.gov](mailto:MRA-scf@michigan.gov). Once the method is approved, the laboratory may begin reporting results for total yeast and mold.

Laboratories that are currently using either non-molecular based automated methods or plating-based methods must immediately update their procedures to include a 72-hour incubation period. These laboratories must submit their updated method to [MRA-scf@michigan.gov](mailto:MRA-scf@michigan.gov) by January 27, 2021 for review. The method must be approved prior to use for reporting.

Sincerely,

MRA Scientific & Legal Section