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General Notice- Change Notification

November 28, 2018

This is to notify customers that Northeast Laboratory Services has initiated a change in the intended use for Mueller Hinton agars and broths. These products will now be labeled as “Not for in vitro diagnostic use”. These products should not be used in diagnostic procedures on humans.

This will be in effect by January 1st, 2019.

The products affected are as follows:

- P2000 Mueller Hinton Agar- 75mL
- P2050 Mueller Hinton Agar with Sheep’s Blood- 75mL
- P1470 Mueller Hinton Agar- 20mL
- P1460 Mueller Hinton Agar with Sheep’s Blood- 20mL
- T1544 Mueller Hinton Broth

These products are still manufactured to the highest quality standards. Testing will still be conducted to CLSI standards to ensure proper growth requirements are met. No changes have been made to the manufacturing process, and previous lots of media underwent quality testing to ensure they met all applicable guidelines.

Sincerely,

A handwritten signature in black ink, appearing to read 'Abby Tripp', with a stylized flourish at the end.

Abby Tripp
QA/QC Regulatory Supervisor