



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Testing and Diagnostics Working Group

From: HHS Testing and Diagnostics Working Group
To: Pipette Tip Manufacturers and Distributors
Subject: Prioritized Distribution of Pipette Tips for Newborn Screening Laboratories
Reference: Supplies for Critical Newborn Screening
Date: April 28, 2021

Newborn screening identifies conditions that can affect a child's long-term health or survival. Early detection, diagnosis, and intervention can prevent death or disability. In 2018, more than 3.8 million newborns were screened for genetic, endocrine, and metabolic disorders in one of 34 different public health laboratories in the United States.

The COVID-19 pandemic has put a strain on laboratory consumables across the entire testing market, including pipette tips. As a result, the public health laboratories responsible for this critical screening program do not have access to a consistent supply of pipette tips. For the past 4 months, the Association of Public Health Laboratories (APHL) and their member laboratories, have asked for assistance in obtaining pipette tips from different suppliers to carry out this necessary screening.

The newborn screening program consumes less than 0.50% of the total pipette tip market in the United States or approximately 160,000,000 tips annually.

Due to the small market share by the newborn screening programs, ensuring their total supply is not likely to affect COVID testing programs. Based on the market share and the critical role this program plays in public health, distribution of U.S supply of pipette tips should be prioritized for state public health laboratories for use in newborn screening programs and related testing.

This market prioritization should remain in place until either the public health emergency is lifted or there are no longer supply concerns for pipette tips used in medical diagnostic testing or screening testing.

The federal government will continue to work with pipette tip manufacturers and state public health laboratories to ensure the continuation of the newborn screening program in the United States throughout this emergency.