

Manisha Juthani, MD Commissioner



Ned Lamont Governor Susan Bysiewicz Lt. Governor

Universal cCMV Screening Working Group Unapproved Meeting Minutes Thursday, March 14, 2024 12 – 1 PM

Working Group Members

Present: Jody Terranova, DO, MPA, FAAP (Chair), Nancy A. Louis, MD, FAAP, Ashley C. Howard, DO, FAAP, Carlos R. Oliveira, MD, PhD, Scott Schoem, MD, MBA, FAAP, Jafar H. Razeq, Ph.D., HCLD/PHLD (ABB), Debra Ellis, RN, BSN, Adrienne Manning, MPH, John Lamb, and Amaka Atuegbu

Others present: Charbel Khalil

Absent: Thomas Murray MD, PhD, FAAP and Marie Burlette, RN, BSN

- I. Call to Order
 - a. The meeting was held via Teams and Dr. Terranova called the meeting to order at 12:02 PM.
- II. Approval of Minutes
 - a. Dr. Oliveira moved to approve the minutes of February 28, 2023. Dr. Razeq seconded the motion. The motion passed unanimously.
- III. Public comment
 - a. None
- IV. New Business
 - a. Lab Methodology Subgroup presentation
 - i. Ms. Manning and Mr. Khalil presented on the validation of lab processes and proposed methodology for CMV detection.
 - Ms. Manning reviewed the verification procedure for the DNA extraction and amplification methods. Two distinct target genes of cCMV - UL83 and UL122 - were used to identify which target can reliably detect cCMV from the dried blood spots and two distinct thermocycling programs for cCMV detection were used to identify which conditions work best for cCMV detection.
 - iii. Ms. Manning noted that the lab also verified singlePlex (amplifying a single target gene per reaction) and multiPlex (amplifying multiple target

genes per reaction) qPCR with the UL83 and UL122 target genes using the CDC and University of Minnesota thermocycling methods.

- iv. Ms. Manning explained that the DBS CMV results are interpreted based on expected cycle threshold values indicating whether the newborn's result is within normal limits, cCMV positive, or inconclusive.
- v. Mr. Khalil provided an overview of the lab verification results
 - o Two dried blood spots are sufficient for DNA extraction.
 - o QuantaBio Extracta DBS is the DNA extraction method that produces the highest amount of DNA for screening cCMV.
 - o Multiplexing both UL83 and UL122 produce better sensitivity for detecting cCMV
 - The CDC method is the best thermocycling program for cCMV detection.
- vi. Ms. Manning noted the lab's next steps, including identifying and purchasing validation and testing supplies, methodology training for lab staff, developing a validation plan for approval, and validating other parameters before routine screenings begin in 2025.
- b. Working group discussion
 - i. Dr. Razeq asked if finding one of the two target genes through multiplexing would mean that an infant is CMV positive. Ms. Manning confirmed this to be the case. Dr. Razeq also asked if the lab can detect only one of the target genes during its experiment. Mr. Khalil agreed with Ms. Manning that the lab is not able to distinguish between the genes, noting that it may not be relevant as the goal is to detect CMV regardless of the gene.

V. Announcements

- a. April meeting (Monday, April 1, 11:45 AM 1 PM)
 - i. Dr. Terranova noted that Ms. Atuegbu will share the draft report with the Working Group before the April meeting. During the April meeting, CT DPH will present the comprehensive summary recommendations and the Working Group will review the draft report. Dr. Terranova noted that the report will be submitted to the Commissioner by Summer, 2024.
 - ii. Mr. Khalil thanked the Working Group for their time.

VI. Adjournment

a. Dr. Terranova adjourned the meeting at 12:39 PM.